ILLINOIS EMERGENCY MANAGEMENT AGENCY
DIVISION OF NUCLEAR SAFETY

INSTRUCTIONAL SET NO. 52.2 **REVISION 4**
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Instructions for Preparing Applications for Radioactive Material Licenses Authorizing the

MEDICAL USE OF RADIOACTIVE MATERIAL

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I. INTRODUCTION

A. General

The Illinois Emergency Management Agency (herein referred to as IEMA or the Agency) regulates the possession and use of radioactive material. Certain uses of radioactive material require a radioactive materials license to be issued by the Agency pursuant to Part 330 of 32 Illinois Administrative Code Chapter II (herein referred to as 32 Ill. Adm. Code or the regulations).

The Agency issues a single radioactive material license to cover an entire radioactive material program. Separate licenses are not normally issued to different departments of a facility, nor are they issued to individuals associated with the facility. Facilities with more than one license may wish to combine those licenses when the storage and use of radioactive material are under the same administrative control.

B. Purpose of Instructions

This instructional set contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for materials licenses for the medical use of radioactive material. In particular, it describes the types of information needed to complete an, "Application Form for Medical Radioactive Material License," and the IEMA forms (similar to the U.S. NRC Form 313A series) for authorized users (AU), authorized medical physicists (AMP), Ophthalmic Physicists (OP), Radiation Safety Officers (RSO) and an Associate RSO (ARSO). This document describes both the methods acceptable to the IEMA in implementing the regulations and the techniques used by IEMA staff in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

NOTE: This instructional set does not address certain aspects of licensing and radiation safety for the medical use of radioactive materials. In particular, applicants and licensees should consider the following:

- NUREG–1556, Volume 15, Rev. 1, "Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses"

- NUREG–1556, Volume 11, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope," provides additional licensing guidance on medical use programs of broad scope.

- This instructional set does not address the commercial aspects of manufacturing, distribution, and service of sources containing byproduct material in devices. Applicants should review NUREG–1556, Volume 12, Rev. 1, "Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution," and NUREG–1556, Volume 18, Rev. 1, "Program-Specific Guidance About Service Provider Licenses."

- This instructional set does not address the accelerator production of radionuclides by the medical use applicant for either commercial or noncommercial distribution of radionuclides. Applicants should review NUREG–1556, Volume 13, Rev. 2, "Program-Specific Guidance About Commercial Radiopharmacy Licenses," and NUREG–1556, Volume 21, Rev. 1, "Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator," for additional guidance. "Consortium," as used here and in 32 Ill. Adm. Code Part 330, is defined as an association of medical use licensees and a Positron Emission Tomography (PET) radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distribution among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution, a Federal facility, or a medical facility.

Prior to applying for medical use, the applicant should carefully study these instructions and applicable regulations. IEMA staff may need to request additional information when necessary to ensure that the applicant has established an adequate radiation protection program (See 32 Ill. Adm. Code 330.240, 330.250 and 340.110). Such requests for additional information will delay approval of the application. This may be avoided by a thorough study of the regulations and instructions prior to completing and submitting the application.

This instructional set is not a substitute for IEMA regulations or the applicant's careful evaluation of the proposed use of radioactive material. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report may be acceptable, if they include a basis for the staff to make the determinations needed to issue or renew a license. **Applicants must assure the application correctly and adequately describes the procedures that will be followed day-to-day for radioactive material use and implementation of the radiation protection program.**

After a license is issued, the licensee must conduct its program in accordance with the following:

- Statements, representations, and procedures contained in the application and in correspondence with IEMA, when incorporated into a license by reference
- Terms and conditions of the license
- IEMA regulations

C. Purpose of Appendices

The document contains appendices that include a checklist for preparing an application; step-by-step instructions for adding authorized individuals; and examples of the types of

supporting documents, such as procedures, that may need to be prepared and submitted to IEMA by applicants. The development and implementation of these procedures are often explicitly required by regulation. The instructional set's appendices provide sample procedures, which the licensee may choose to use in their radiation protection program. Applicants should carefully read the applicable regulations and sample procedures to decide if they are appropriate for their specific radiation safety needs. While the appendices represent one means acceptable to IEMA staff of complying with applicable regulations; they are not intended to be the only means of satisfying requirements for a license.

Applicants may certify that they will commit to following the sample procedures or develop and submit an equivalent procedure for Agency review. If a sample procedure is followed, applicants must ensure that references to that procedure are clear and specific (e.g., references should include instructional set number, revision number, revision date, and appendix identification). If applicants choose to develop their own equivalent procedure(s), IEMA staff will evaluate the equivalent procedure against applicable regulations and the guidance in these instructions.

The U.S. Nuclear Regulatory Commission (U.S. NRC) maintains a Medical Uses Licensee Toolkit web page, which contains the following items and may serve as another source of guidance:

- Questions and answers on the implementation of 10 CFR Part 35 (U.S. NRC equivalent of 32 Ill. Adm. Code Part 335)
- specialty board certifications recognized by U.S. NRC and IEMA
- inspection procedures for inspections of medical use licensees
- applicable licensing guidance for other "emerging technology" medical uses, [e.g., Yttrium-90 Microsphere, Leksell Gamma Knife Perfexion®]
- list server subscription for automatic e-mail notifications of medical-related generic communications, Federal Register Notices, and U.S. NRC newsletters

D. Regulatory Jurisdiction

An Illinois radioactive materials license is required for applicants who request to possess or use licensed radioactive material within the State of Illinois in areas not under exclusive federal jurisdiction.

An Agreement State (such as Illinois) is a state that has entered into a formal agreement with the U.S. NRC that gives them the authority to license and inspect byproduct, source, and special nuclear materials, in quantities not sufficient to form a critical mass, that are used or possessed within their borders. Any applicant, other than a Federal entity, who wishes to possess or use licensed material in one of these Agreement States should contact the responsible officials in that State for guidance on preparing an application.

These applications should be filed with State officials, not with the U.S. NRC. In areas under exclusive Federal jurisdiction within an Agreement State, the U.S. NRC continues to be the regulatory authority. A list of Agreement States can be found at the U.S. NRC website along with additional information about their State and Tribal Programs.

For the special situation of performing work at Federally controlled sites in Agreement States, it is necessary to know the jurisdictional status of the land in order to determine whether U.S. NRC or the Agreement State has regulatory authority. U.S. NRC has regulatory authority over land determined to be, "exclusive Federal Jurisdiction," while Agreement States have jurisdiction over non-exclusive Federal jurisdiction land. Licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. IEMA recommends that licensees ask their local contact for the Federal Agency controlling the site to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with IEMA, Agreement State or U.S. NRC regulatory requirements.

Performing licensed activities in other jurisdictions is possible through reciprocal recognition of specific licenses (i.e., reciprocity). Agreement States and the U.S. NRC have reciprocity provisions that permit IEMA licensees to perform licensed activities under circumstances when another Agreement State or the U.S. NRC is the regulatory authority. U.S. NRC licensees and Agreement State licensees are subject to the regulations of the regulatory authority. To ensure compliance with reciprocity requirements, licensees are advised to request authorization from the appropriate Agreement State or U.S. NRC radiation control program office well in advance of the scheduled use of licensed material.

U.S. NRC and Agreement State licensees that wish to conduct licensed activities in areas under IEMA's jurisdiction must either obtain a specific IEMA license or file for reciprocity as detailed in 32 Ill. Adm. Code 330.900. Consult the IEMA website for FAQs and the appropriate form to file for reciprocity. Failure to file for reciprocity or obtain a specific IEMA license before working in areas under IEMA jurisdiction can result in IEMA enforcement action, which may include civil penalties. The reciprocity filing must be renewed annually.

E. Applicable Regulations

It is the applicant's or licensee's responsibility to obtain and have available up-to-date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation. The following parts of 32 Illinois Administrative Code contain regulations applicable to licensing medical use of radioactive material. Some of these parts are specific to one type of license, while others are general and will apply to many, if not all, licensees. Current regulations are publicly available at IEMA's website or the Illinois State Register.

- 32 Ill. Adm. Code 310 "General Provisions for Radiation Protection"

- 32 Ill. Adm. Code 326 "Financial Assurance Requirements"
- 32 Ill. Adm. Code 330 "Licensing of Radioactive Material"
- 32 Ill. Adm. Code 331 "Fees for Radioactive Material Licenses"
- 32 Ill. Adm. Code 335 "Medical Use of Radioactive Material"
- 32 Ill. Adm. Code 337 "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
- 32 Ill. Adm. Code 340 "Standards for Protection Against Radiation"
- 32 Ill. Adm. Code 341 "Radioactive Materials Transportation"
- 32 Ill. Adm. Code 400 "Notices, Instruction and Reports to Workers; Inspections"

The Agency may amend regulations periodically to remain compatible with current standards and federal regulations. IEMA (as well as all other State agencies) is required to publish notice of such amendments in the Illinois State Register.

Transportation Regulations

Licensees who will prepare for shipment, ship, or transport radioactive materials, including radioactive waste, must develop, implement, and maintain procedures to ensure compliance with the applicable requirements of the United States Department of Transportation (DOT) that are found in 49 CFR Parts 171-180. Copies of DOT regulations can be found on the DOT website or can be ordered from the Government Printing Office (GPO) Bookstore in Washington, DC. In accordance with 32 Ill. Adm. Code Part 337 (Subpart D), licensees must also preplan, coordinate, and provide advance notification of the shipment of Category 1 quantities of radioactive material and coordinate the shipment of Category 2 quantities of radioactive material.

Most packages of licensed material for medical use contain quantities of radioactive material that require the use of Type A packages. Many packages shipped by medical licensees (e.g., unused radiopharmaceutical dosages) frequently meet the "Limited Quantity" criteria described in 49 CFR 173.421, "Excepted Packages for Limited Quantities of Class 7 (Radioactive) Materials," and are, therefore, excepted from certain DOT requirements, provided certain other less restrictive requirements are met {e.g., activity in the package is less than the limited quantity and the radiation level on the surface of the package does not exceed 0.005 mSv/h [0.5 mrem/h]}. Notably, these shipments are not exempted from the hazardous material training requirements in 49 CFR Part 172, Subpart H (See 49 CFR 173.422).

Some medical use licensees that ship radioactive material have chosen to transfer possession of radioactive materials to a manufacturer or waste broker with an IEMA, U.S. NRC or Agreement State license, who then acts as the shipper. The manufacturer or

waste broker then becomes responsible for proper packaging of the radioactive materials and compliance with IEMA and DOT regulations. This is distinctly different from service licensees who will package, but not take possession of the radioactive material. Licensees who transfer ownership must ensure that the manufacturer or waste broker is authorized to possess the licensed material and actually takes possession of the licensed material under its license. Licensees should also ensure that the manufacturer or waste broker is authorized to possess the material at temporary jobsites (e.g., the licensee's facilities).

Additional information on applicable transportation regulations, exemptions and the application to medical licensees is contained in Section 8.10.22 of NUREG 1556 Volume 9, Rev. 3. Appendix Y of this instructional set lists major DOT regulations that apply to medical use licensees.

Medical use licensees are reminded of the following:

- The licensee must properly block and brace the transportation case when transporting byproduct material to ensure that the material does not shift during transport.

- The licensee must have emergency response information, including current emergency response telephone numbers that meet the requirements of 49 CFR Part 172, "Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans," Subpart G, "Emergency Response Information."

- Initial and recurrent training must be given to all employees who transport byproduct material per the requirements of Subpart H, "Training," of 49 CFR Part 172.

- The licensee shall maintain transportation shipping records in accordance with the requirements of Subpart C, "Shipping Papers," of 49 CFR Part 172, including the proper shipping name, hazard class (Class 7), United Nations identification number, the name of the shipper, and the name and activity of each radionuclide. While in transit on a public highway, transportation papers must be kept within the immediate reach of the driver, pursuant to 49 CFR 177.817(e)(2)(i)(A) and other applicable 49 CFR Part 177 requirements.

F. Radiation Protection Program (RPP)

As specified in 32 Ill. Adm. Code 340.110, the licensee must develop, document and implement a radiation protection program. In developing this program, the licensee should consider the size of the facility, potential hazards associated with radiation exposure, and the physical characteristics of the radionuclides. Specifically, the program should include provisions to ensure compliance with the regulations, the license and all commitments made therein. It should describe the procedures and engineering controls in place to keep occupational and public doses As Low As Reasonably Achievable (ALARA), and the auditing of the program at intervals not to exceed 12-months (see below). The commitments made to the Agency, which lead to the issuance of the

license, in conjunction with the regulations and the complete license document are considered the applicant's radiation protection program.

Active control over the radiation protection program should be exercised by management personnel in positions of authority. In addition, management should be aware that the assignment of duties to individuals (e.g., the Radiation Safety Officer (RSO) or associate radiation safety officers (ARSO)) does not relieve management of the responsibilities to review and control the licensed activities. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material.

Radiation Protection Program Review (Annual Audits)

Under 32 Ill. Adm. Code 340.110(c), all licensees must review the content and implementation of the radiation protection program at intervals not to exceed 12 months. The program reviews should ensure compliance with IEMA and applicable U.S. Department of Transportation (DOT) regulations and the terms and conditions of the license. Occupational doses and doses to members of the public should be reviewed for compliance with the applicable limits in 32 Ill. Adm. Code Part 340. IEMA encourages licensee management to conduct performance-based reviews by observing work in progress, interviewing staff, and spot-checking required records. As part of the review or audit programs, licensees should consider including unannounced audits of authorized and supervised users to observe whether radiation safety procedures are being followed.

It is essential that once problems are identified, comprehensive corrective actions are taken in a timely manner. Information Notice (IN) 96-28, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” dated May 1, 1996, provides guidance on this subject. IEMA routinely reviews licensee’s records to verify whether appropriate corrective actions were implemented in a timely manner to address recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them. IEMA can opt to exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented.

Appendix U of this instructional set contains a suggested annual audit program that is specific to medical licensees. Since all areas indicated in Appendix U may not be applicable to every licensee and all items may not need to be addressed during each audit, licensees may wish to develop a program-specific audit checklist. Records of audits and other reviews of program content and implementation are specified in 32 Ill. Adm. Code 340.1120 and must be maintained for 5 years after the record is made.

32 Ill. Adm. Code Part 337 Program Reviews

In accordance with 32 Ill. Adm. Code Part 337, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must, among other things,

- In accordance with 32 Ill. Adm. Code Part 337.1070, review its access authorization programs to confirm compliance with the requirements of Subpart B of 32 Ill. Adm.

Code Part 337 and ensure that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements and be performed at intervals not to exceed 12 months.

- In accordance with 32 Ill. Adm. Code Part 337.2080, review its security program at least annually to confirm compliance with the requirements of Subpart C of 32 Ill. Adm. Code Part 337 and ensure that comprehensive actions are taken to correct any noncompliance that is identified. The radioactive material security program review shall be performed at intervals not to exceed 12 months.

- Maintain records of reviews performed under 32 Ill. Adm. Code Part 337 for 3 years.

For additional guidance on implementing 32 Ill. Adm. Code Part 337 requirements, see NUREG–2155, Rev. 2, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

G. Record Retention

Licensees must maintain certain records to comply with IEMA regulations and the conditions of the license. The retention requirements have been established in order for inspection staff and other authorized entities to have access to these documents as required by the regulations. Operating procedures should identify which individuals in the organization are responsible for maintaining specific records. Appendix A of this instructional set contains a summary of the retention requirements for these records.

H. Management Responsibility

IEMA recognizes that effective radiation protection program management is vital to achieving safe, secure, and compliant operations. Consistent compliance with the regulations provides reasonable assurance that licensed activities will be conducted safely, and that effective management will result in increased safety, security, and compliance. See 32 Ill. Adm. Code 335.1040, "Authorities and Responsibilities for the Radiation Protection Program".

"Management" as used in this instructional set, pursuant to the definition in 32 Ill. Adm. Code 335.20, means the chief executive officer or other individual having the authority to manage or administer the licensee's activities, or those individuals' delegates. Any such individual or delegate must have authority and necessary resources to achieve regulatory compliance.

To ensure adequate management involvement in accordance with 32 Ill. Adm. Code 335.40, "License Amendments" and 32 Ill. Adm. Code 335.1040(a), a management representative (i.e., chief executive officer or delegate) must sign the submitted

application. If it is not clear whether the application was signed by someone duly authorized to act for and on behalf of the applicant or licensee, IEMA license reviewers may ask for additional assurances that the individual who signed the application is duly authorized to act for and on behalf of the applicant or licensee. The signature on an application acknowledges the applicant's or licensee's commitments and responsibility for the following:

- Radiation safety, security, and control of radioactive materials.
- Completeness and accuracy of records and all information provided to IEMA.
- Knowledge regarding the contents of the license and application.
- Compliance with current IEMA and U.S. Department of Transportation regulations.
- Compliance with the licensee's operating, emergency, and security procedures, and IEMA license commitments.
- Commitment to provide adequate financial and other resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that patients, 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), who agrees, in writing, to be responsible for implementing the radiation protection program. The RSO shall have independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities.
- Commitment to report defects, noncompliance, or reportable events, including medical events in accordance with regulations.
- Selection and assignment, if applicable, in writing, of one or more qualified associate radiation safety officers (ARSO) to support the RSO. The RSO, with written agreement of the licensee's management, will assign to each ARSO specific duties and tasks restricted to the types of use for which each ARSO is listed on the license.
- Commitment to ensure that radiation workers have adequate training.
- Prevention of discrimination of employees engaged in protected activities and commitment to provide information to employees about employee protection provisions (32 Ill. Adm. Code 400.160(c)).
- Commitment to provide information to employees about deliberate misconduct provisions (32 Ill. Adm. Code 310.78 "Deliberate Misconduct").

- Commitment to obtain IEMA's prior written consent before transferring control of the license (see Section IV.C, "Transfer of Control," of this Instructional Set.)

- Notification of IEMA, in writing, immediately following the filing of petition for voluntary or involuntary bankruptcy (32 Ill. Adm. Code 330.310(j), as discussed further in Section IV.C, "Notification of Bankruptcy Proceedings," of this Instructional Set.

- Approval of qualified individual(s) to serve as authorized medical physicists, ophthalmic physicists, and authorized users for licensed activities.

I. As Low As Reasonably Achievable (ALARA)

Persons engaged in activities authorized by radioactive material licenses issued by the Agency must to the extent practicable, make every reasonable effort to maintain the release of radioactive material and the total effective dose equivalent (TEDE), ALARA for both workers and members of the public. License applicants must consider the ALARA philosophy when designing facilities, procuring equipment and for developing procedures for work with radioactive material. The ALARA concept is a key element in establishing any radiation protection program as described above. The definition of ALARA may be found in 32 Ill. Adm. Code 310.20 and requirements for implementation in 32 Ill. Adm. Code 340.110. Section 1.3.1 of the U.S. NRC's NUREG 1556, Volume 9, Rev. 3 provides a listing of additional resources useful to those who are establishing radiation protection programs to maintain radiation exposures at ALARA levels in medical facilities.

A particularly important aspect of ALARA incorporation into a licensee's radiation protection program is the establishment of 'investigational levels' for both occupational and public doses. These investigational levels are not new dose limits but, as noted in ICRP Report No. 26, "Recommendations of the International Commission on Radiological Protection," which serve as check points above which the results are considered sufficiently important to justify investigations.

J. Security for Category 1 and Category 2 Radioactive Material

32 Ill. Adm. Code 340.810 requires that licensees secure licensed radioactive material from unauthorized access or removal. In addition, 32 Ill. Adm. Code 337 contains security requirements that must be implemented by licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material. Those requirements include the establishment, implementation, and maintenance of an access authorization program (Subpart B) and a security program (Subpart C) to ensure physical protection of the radioactive material. Table 1 of Appendix A, "Category 1 and Category 2 Radioactive Materials," to 32 Ill. Adm. Code 337 lists Category 1 and Category 2 threshold quantities of radioactive material. The applicant should refer to this table to determine whether its proposed activities would be subject to the 32 Ill. Adm. Code 337 requirements.

Before giving individuals unescorted access to Category 1 or Category 2 quantities of radioactive material (as defined in 32 Ill. Adm. Code 337.40), licensees must conduct background investigations of these individuals, to determine that they are trustworthy and reliable in accordance with 32 Ill. Adm. Code 337.1030.

In accordance with 32 Ill. Adm. Code 337.2010, licensees must establish a security program designed to monitor and, without delay, detect, assess, and respond to any actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material. Per 32 Ill. Adm. Code 337, Subpart D, licensees must provide for physical protection of Category 1 or Category 2 quantities of radioactive materials in transit. These requirements apply to licensees delivering such material to a carrier for transport, as well as cases in which licensees are transporting such material. Please note that the Subpart D requirements applicable to the transport of Category 1 quantities of radioactive material are more stringent than those applicable to Category 2 quantities. Applicants and licensees are required to implement the 32 Ill. Adm. Code 337 security requirements before they take possession of an aggregated Category 1 or Category 2 quantity of radioactive material. Any licensee that has not previously been made subject to the provisions of 32 Ill. Adm. Code 337, Subpart C, shall notify IEMA in writing at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold. Pursuant to 32 Ill. Adm. Code 337.2020, as part of the security program, the licensee must develop and maintain written procedures that document how the requirements of Subpart C will be met. These written procedures will be subject to IEMA review and inspection. However, these procedures should not be submitted to the Agency as part of an application or renewal.

For additional guidance on implementing 32 Ill. Adm. Code Part 337 requirements, see NUREG–2155, Rev. 2, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

K. Safety Culture

The Illinois Emergency Management Agency (IEMA) recognizes the importance of individuals at organizations performing or overseeing regulated activities establishing and maintaining a strong safety culture – a work environment where management and employees are dedicated to putting safety first. An active and positive safety culture within IEMA and at regulated facilities is a key element in IEMA's mission to protect public health and safety.

The safety culture policy statement defines nuclear safety culture as the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.

See the U.S. NRC's NUREG 1556 Vol. 9, Rev. 3; Section 3.2 for additional information on Safety Culture. Refer to Appendix A of U.S. NRC's NUREG 1556, Volume 9, Rev. 3 for their Safety Culture Policy Statement. More information on U.S. NRC activities relating to safety culture can be found on the U.S. NRC Safety Culture Web site.

L. Reporting

Licensees are required to report to IEMA via telephone, written report, or both, incidents in which the safety or security of radioactive material may be compromised. The specific events that require reporting are explained in 32 Ill. Adm. Code 335.45(b), 32 Ill. Adm. Code 335.1080, 32 Ill. Adm. Code Part 340 Subpart M, and in 32 Ill. Adm. Code Part 337.2090 and 337.3060. The timing and type of report are specified within these parts. The reporting timeline begins at discovery of the incident, not when the licensee confirms or completes an investigation. If the incident is found to be not reportable, it can be retracted. Licensees are also required in 32 Ill. Adm. Code 335.1080 and 32 Ill. Adm. Code 335.1100 to report information to referring physicians and certain individuals.

32 Ill. Adm. Code 335.4020 requires licensees to notify generator distributors that an eluate exceeded the permissible concentration at the time of generator elution.

IEMA requires licensees to report incidents that might compromise the health and safety of patients, health care providers, or the public. Therefore, 32 Ill. Adm. Code Parts 335 and 340 include provisions that describe reporting requirements associated with the medical use of radioactive material. A table of reporting requirements appears in Appendix X of this Instructional Set.

Other Required Notifications

32 Ill. Adm. Code 335.45 includes additional notification requirements for, among other items, changes in use, personnel and areas of use/storage. 32 Ill. Adm. Code 330.310(i) requires notification for the discontinuation of use.

II. HOW TO FILE

A. Application Preparation

Applicants wishing to possess or use licensed material for medical use should do the following:

- Use the **most recent guidance and current regulations** to prepare the application.
- Complete "Application Form for a Medical Radioactive Material License", in accordance with 32 Ill. Adm. Code 330.240(a).

- Complete forms as necessary to document training and experience of authorized users, authorized medical physicists, ophthalmic physicists, the radiation safety officer and associate radiation safety officers.

- Each item section on the application should provide sufficient detail for the Agency to determine that equipment, facilities, training, experience, and the radiation protection program are adequate to protect the health, safety, and minimize danger to life and property.

- Each appended sheet submitted with the application should be identified with the item number, page number, applicant's name, and application date in the lower right corner to which it refers.

- Avoid submitting proprietary information and personally identifiable information (PII). PII examples include personal home address, home telephone number, social security number, date of birth, and radiation dose information and should not be submitted unless specifically requested by the Agency. If submitted, proprietary information and other sensitive information (e.g., personal privacy and security-related) should be clearly identified as such by visibly marking, "Public inspections, exemptions, requests for withholding." Copies of security plans or other documents required under 32 Ill. Adm. Code Part 337 should not be submitted as a component of the application. Public inspection of applications and other documents submitted to the Agency pursuant to 32 Ill. Adm. Code 330.240, shall be handled in accordance with 2 Ill. Adm. Code 1800 and the requirements of the Freedom of Information Act (5 ILCS 140). As such, all license applications may be available for review by the general public. (see Section C of this Chapter, "Identifying and Protecting Sensitive Information.").

B. Where to File

Paper applications received by IEMA will be scanned and converted to an electronic format. To ensure a timely transfer to the electronic format, applicants should do the following:

- Ensure print is clear and sharp

- Ensure each page of the copy is legible

- Each application and each request for amendment is signed (physical or verifiable electronic) by the applicant, licensee, or a person duly authorized in writing to act for and on the licensee or applicant's behalf.

Paper copies need not be submitted in duplicate, but the licensee is responsible for maintaining a copy of all applications and correspondence related to the license.

The original may be mailed to:

Illinois Emergency Management Agency
Division of Nuclear Safety
Radioactive Materials Licensing
1035 Outer Park Drive
Springfield, Illinois 62704

The Agency will accept applications and requests for amendments electronically. These submittals may be directed to ema.speclic@illinois.gov.

NOTE: Licensees and applicants should never submit PII, security-sensitive or proprietary information via email as this is not an encrypted portal.

Electronic applications are accepted under the following conditions:

- Applicant must utilize an electronic signature that is secure and verifiable
- Identify yourself and intent to the Agency in the body of the email and attach forms and documents as necessary
- Forms submitted must be provided in common document formats (e.g. .pdf, .doc, .xls etc.); specialty software formats may not be accepted
- Use standard naming conventions for documents attached

Emails and attachments must NOT contain:

- Classified, proprietary information
- Payment information
- Financial assurance documents
- Personal Identifiable Information (PII)
- Embedded macros or hyperlinks
- Security related diagrams with explicit instructions to access materials such as access codes or key locations
- Documents that require an affirmation, oath, or notary
- Do NOT send initial reports or notifications required by regulations to this email

Applicants must retain a copy of their electronic application submission. As this is an official record, the applicant's copy, no matter the format, must be accessible for inspection purposes or for the applicant to reference as needed.

Send electronic applications to: ema.speclic@illinois.gov

C. Identifying and Protecting Sensitive Information

Public inspection of all licensing applications and other documents submitted to the Agency pursuant to 32 Ill. Adm. Code 330.240 shall be in accordance with 2 Ill. Adm.

Code 1800 and the requirements of the Freedom of Information Act [5 ILCS 140]. Due to the personal and security-sensitive nature of information submitted to and maintained by the Radioactive Materials Section, not all data is appropriate for public disclosure. Although there is no guarantee that the information will always be withheld, in order to assist the Agency in recognizing information identified as security-sensitive or containing personally identifiable information (PII), the applicant or licensee should identify and mark the information accordingly before it is submitted to IEMA. Key examples are as follows:

- Proprietary Information and Trade Secrets: It is the responsibility of the licensee to pre-identify proprietary information (clearly marked and identified as proprietary, privileged, trade secret, business confidential etc.). If it is necessary to submit proprietary information or trade secrets, the licensee or applicant should incorporate a stamp or marking prominently on the page(s) that reads "proprietary information" or similar. Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application.

- Personally Identifiable Information: Personally identifiable information (PII) about employees or other individuals should not be submitted unless specifically requested by IEMA. Examples of PII are social security number, home address, home telephone number, date of birth, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII, and the top of every page of a document that contains PII should be clearly marked as follows: "Personally Identifiable Information." For further information, see the U.S. NRC's Regulatory Issue Summary (RIS) 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, and Information Notice 2013-22, "Recent Licensing Submittals Containing Personally Identifiable Information," dated November 15, 2013, which can be found on the U.S. NRC's Generic Communications Web page.

- Security-Related Sensitive Information: Following the events of September 11, 2001, IEMA changed its procedures to avoid the release of information that terrorists could use to plan or execute an attack against facilities or citizens in the U.S. As a result, certain types of information are no longer routinely released and are treated as sensitive unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities, and associated security measures, are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain security-related sensitive information and the top of every page of a document that contains such information should be clearly marked: "Security-Related Information." For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see RIS 2005-31, Rev. 1, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to U.S. NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," December 26, 2017. Additional information on procedures and any updates are available in the U.S. NRC Library on the Withholding of Sensitive Information page.

D. Application and License Fees

Each application for which a fee is specified will be invoiced after initial processing at IEMA. Please do not submit your fee payment with the application. New applicants will be billed a prorated feed for the portion of the billing year remaining from the date the application is received. By regulation, the billing year means the period of time from October 1 of one year to September 30 of the following year. Refer to 32 Ill. Adm. Code 331, Appendix F, "Fee Schedule for Radioactive Materials Licensees" to determine the amount of the fee. Consult 32 Ill. Adm. Code 331.120 on payment of fees, remote site costs, recovery and remediation assessments and details pertaining to full cost recovery. In accordance with this part, the annual and remote site fees listed in Appendix F are nonrefundable and are assessed based on a 12-month period. Consult 32 Ill. Adm. Code 331.110, "Exemptions," for information on exemptions from these fees. Application fees will be charged regardless of IEMA's disposition of an application or the withdrawal of an application.

Most IEMA licensees are also subject to annual fees; which are addressed in the regulatory references above.

Direct all questions about IEMA's fees or completion of "License Fees" item of the application form to the Supervisor of Licensing, 217-785-9947. The e-mail address is ema.speclic@illinois.gov.

III. CONTENTS OF AN APPLICATION

The following paragraphs explain the information requested on the "Application Form for a Medical Radioactive Material License" and the "Expedited Renewal Application Form for a Medical Radioactive Material License".

Please review each item carefully and complete each section on the application in its entirety as to not impede the Agency licensing staff review process. Agency staff are available to answer questions regarding application content requirements and new applicants are encouraged to contact the Agency to discuss their licensing needs.

All items in the application should be completed in enough detail for IEMA to determine whether the proposed equipment, facilities, training and experience, and the radiation safety program satisfy regulatory requirements and are adequate to protect public health and safety and minimize danger to life and property. Consideration should be given, when developing the application, to the concepts of keeping exposure as low as is reasonably achievable (ALARA), minimizing contamination, and maintaining control of radioactive materials.

32 Ill. Adm. Code 340.110 states: "The licensee or registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA)." Regulatory Guide (RG) 8.10, "Operating Philosophy for

Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," discusses the ALARA concept and philosophy. The application should document ALARA considerations, including establishing administrative action levels and monitoring programs.

The application should include information on how the licensee will implement the security requirements in 32 Ill. Adm. Code 340.810, "Security and Control of Licensed or Registered Sources of Radiation."

All supplemental information should be provided as an attachment to the applicant's signed and dated application. Several appendices in this instructional set present sample procedures that applicants may use in developing their procedures. Suggested responses for each block on the application appear under "Response from Applicant" in this guide.

All information submitted to IEMA during the licensing process may be incorporated as part of the license and will be subject to review during inspection.

Item 1. Type of Application

Indicate by checking the appropriate box, if the application is for a new license, an amendment to an existing license, or a renewal. A shortened form exists for expedited renewals. Expedited renewals are typically only offered to a licensee whose previous renewal was not expedited, has no significant noncompliance or enforcement history, the management and scope of operations have not substantively changed, and the procedures and facilities utilized by the licensee are expected to remain the same. If the application is for amendment, renewal or expedited renewal of an existing license, specify the license number in the space provided.

Item 2. Applicant's Name and Mailing Address

List the legal entity name of the applicant's corporation or other legal entity with day-to-day control over use of the radioactive material. A division or department within a legal entity may not be a licensee. In order to validate the legal entity, the applicant/licensee may provide documentation of current registration with the Illinois Secretary of State to conduct business within Illinois, *or a similar registration in another state.* An individual may be designated as the applicant only if the individual is acting in the private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Each applicant must submit their federal tax identification number (FEIN). Applicants that are individuals must provide their social security number.

Provide the mailing address where correspondence should be sent. The applicant's mailing address may or may not be the same as the address where radioactive material will be used. Enter the name, mailing address, telephone number and email address of the applicant in the space provided.

NOTE: In accordance with 32 Ill. Adm. Code 330.400, if a change of ownership occurs, IEMA must be notified of and licensees must have prior written consent of the change of ownership or control **prior to** transferring ownership or control of licensed material. If personnel and procedures are changing with the new ownership, the new owners must apply for and obtain a new license. If the personnel and procedures remain the same, the license may be transferable. Additional information required for a Transfer of Control Application is discussed in Section IV and an example form which provides the information required by the Agency is on the Agency's website.

IEMA must be notified in the event of bankruptcy proceedings in accordance with 32 Ill. Adm. Code 330.310(j). Even though a licensee may have filed for bankruptcy, the licensee remains responsible for all regulatory requirements. IEMA needs to know when licenses 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, etc.). Any health and safety issues must be resolved before bankruptcy actions are completed.

Item 3. Person(s) Authorized to Act on Behalf of Licensee

The applicant should name a qualified individual who is authorized by the applicant's management to answer questions and make commitments regarding this application and the radiation protection program. This individual, usually the Radiation Safety Officer (RSO) or a principal radioactive material user, will serve as the point of contact during the application review. In the space provided, enter the name, address, telephone number, telefacsimile number and email address of the individual to be contacted regarding this application. Email addresses are important as the Agency distributes numerous items of interest to affected licensees via email, including notices of proposed rules that could affect the licensee's operations or fees.

If this individual is not a full-time employee of the licensed entity, his or her position and relationship to the licensee should be specified. IEMA should be notified if the person assigned to this function changes or if his or her telephone number, cell phone number, or e-mail address changes. Notification of a contact change is only provided for informational purposes and would not be considered an application for license amendment, unless the notification involves a change in the contact person who is also the RSO.

IEMA recognizes that licensees may contract with a consultant or consultant group to help prepare the license application and provide support to the radiation protection program. However, IEMA reminds licensees that regardless of the role of the consultant in radiation protection program management, the licensee remains responsible for all aspects of the licensed program, including the services performed by the consultant.

NOTE: If the individual(s) listed in Item 3 are unknown to the Agency and/or have never been associated with a radioactive materials license, the Agency may seek additional information on an individual's background to ensure that radioactive materials

will be used as intended. In order to expedite the review process, the applicant or licensee may wish to submit the "Release and Authorization Full Due Diligence Investigation" form with the application. A fillable form is available on the Agency's website and is included as Exhibit A. The form is also available here: https://www2.illinois.gov/iema/NRS/RadSafety/documents/RAM_Documents/BackgroundCheck.pdf

Item 4. Address(es) Where Radioactive Material will be Used and/or Stored

Specify all the addresses and physical locations where licensed radioactive material will be used and/or stored. Each location description should include the street address, city and other descriptive information (e.g., building name/number, suite, room or floor number) to allow specific facility identification. If multiple facilities will be used, specify the extent of use, storage or both at each location. Do not specify a post office box number as a use location. Locations where radioactive material is received and eventually redistributed or taken to other sites for use are typically included as permanent jobsites on specific licenses. If more than one permanent facility is used, specify where records will be maintained for each facility. Indicate if the licensee anticipates intermittently declaring any area of use as an unrestricted area. A license amendment is required before receiving, using, or storing licensed material at an address or location not already listed on the license.

If an applicant submits documents that identify the exact location of use and storage for any amount of radioactive material, the applicant should mark these documents as "Security-Related Information". See Chapter II.C, "Identifying and Protecting Sensitive Information," for more details.

Illinois law [420 ILCS 40/10(11)] requires IEMA to notify a local government of each listed location of storage or use of radioactive material. This allows local officials, fire and police the opportunity to review local ordinances and prepare for emergencies. An IEMA license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements).

If the applicant does not own the use/storage locations(s), submit confirmation that the owner of the property/facility has been notified in writing of the use/storage of radioactive material on this property in accordance with 32 Ill. Adm. Code 330.240(a)(9). This can be a letter from the facility/property owner acknowledging radioactive materials will be used and/or stored at this location.

NOTE: Personal residences are generally not considered ideal locations for storage of radioactive material because of local ordinances and access restrictions for public dose and security.

Temporary Jobsites

Permanent facilities are address locations where radioactive material can be used or stored for more than 180 days in a 12-month period. If the applicant is proposing to use

or store radioactive material authorized under the license at other temporary locations for periods less than 180 days per year, than 'Use of radioactive material at temporary job sites' should be requested by checking off the box provided under Item 4 on the application. Use of licensed material at temporary job sites will become part of the license conditions and each separate address does not need to be specified so long as the licensee does not use, receive or store radioactive material at any one site for more than 180 days during any 12-month period.

Intermittent Areas of Use – Declaring an Unrestricted Area

In accordance with 32 Ill. Adm. Code 330.310(e), licensees are to ensure all areas where licensed radioactive material will be used or stored are confined to locations identified in the license. Combined with the definition of an '*area of use*' in 32 Ill. Adm. Code 335.20, this means the licensee shall identify all portions of a physical structure dedicated for the purpose of receiving, using or storing radioactive material. The licensee should indicate if additional areas, outside of those identified in facility diagrams but still within the same physical structure, could be reasonably anticipated for intermittent use of radioactive material administrations. These typically include patient rooms and surgery suites. Describe, in general terms, the location of these facilities and the building(s) in which they reside. Due to the fact these areas of use are typically released and utilized for activities not covered under the scope of the license, the licensee must acknowledge the regulatory requirements for declaring an 'unrestricted area' within an 'area of use'. The licensee may commit to the following procedures identified in this instructional set or submit equivalent procedures for Agency evaluation.

See definitions below for of an "*area of use*", "*unrestricted area*" and "*restricted area*".

- *"Area of use"* is defined in 32 Ill. Adm. Code 335.20 as a portion of a physical structure that has been set aside for the purpose of receiving, using or storing radioactive material.

- *"Restricted area"* is defined in 32 Ill. Adm. Code 310.20 as any area access to which is limited by the licensee or registrant for purposes of protecting individuals against undue risks from exposure to sources of radiation. Restricted area shall not include areas used for residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

- *"Unrestricted area"* is defined in 32 Ill. Adm. Code 310.20 as any area access to which is not controlled by the licensee or registrant for purposes of protection of individuals from exposure to radiation and radioactive material, and any area used for residential quarters. AGENCY NOTE: Licensees or registrants may control access to certain areas for purposes other than radiation protection, but such action does not affect whether the areas are unrestricted areas as defined in this Part.

Discussion

The Agency recognizes that emerging patient conditions and certain facility requirements may dictate that radioactive material be administered in patient rooms, surgery suites, or

other intermittent areas of use. These locations may not have been anticipated as an area of use at the time of application. Additionally, licensees often wish to return these areas to unrestricted use after the use of radioactive materials has ceased. Licensees must be aware that there are distinct regulatory requirements for declaring these locations as an 'unrestricted area'. Therefore, the purpose of identifying these intermittent areas of use, in addition to complying with 32 Ill. Adm. Code 330.310(e), is to ensure the licensee is aware and has appropriately implemented procedures for converting an '*area of use*' to an '*unrestricted area*' until such time that it is again needed. The most common scenario associated with this process is the administration of radiopharmaceuticals in patient rooms or the use of operating or surgery suites for certain procedures involving radioactive materials.

The licensee should develop procedures which ensure compliance with applicable regulations when allowing an '*area of use*' to be used as an '*unrestricted area*'. At a minimum, the following provisions should be addressed:

- All radioactive material should be removed from the area and unauthorized access to radioactive material must be controlled in accordance with 32 Ill. Adm. Code 340.810.

- If the licensee asserts an '*area of use*' is an '*unrestricted area*', then they must demonstrate that dose to the public will be less than the limits specified in 32 Ill. Adm. Code 340.310.

- In accordance with 32 Ill. Adm. Code 340.320, radiation surveys need to be performed in '*unrestricted areas*' that demonstrate compliance with the public dose limits specified in 32 Ill. Adm. Code 340.310. These surveys must satisfy the provisions of 32 Ill. Adm. Code 340.510 and 32 Ill. Adm. Code 335.2080. The values in Appendix A of 32 Ill. Adm. Code Part 340 are appropriate for this purpose. However, see the Agency note in 32 Ill. Adm. Code 335.2080 regarding additional radiation survey considerations.

- Records of surveys need to contain the information specified in 32 Ill. Adm. Code 340.1130 and be retained for five years.

- Radiation worker training: As outlined in 32 Ill. Adm. Code 400.120, radiation safety training is required for workers any time they are working in, or the performance of whose duties requires access to, any portion of a '*restricted area*' or who frequent areas where radioactive material is used or stored (i.e., '*areas of use*'). Therefore, radiation safety training is required for workers in all '*areas of use*', regardless of '*restricted*' or '*unrestricted*' status. "Worker" is defined in 32 Ill. Adm. Code 310.20.

- Public instruction: In accordance with 32 Ill. Adm. Code 340.310(c), the licensee shall provide members of the public with instructions on radiation safety hazards prior to allowing entrance to a '*restricted area*'. Training and/or instructions are not required for members of the public entering an '*unrestricted area*'.

- If changes are being made to an '*area of use*' identified in the license, regardless of the '*restricted*' or '*unrestricted*' status, an amendment may be required. Review 32 Ill. Adm. Code 335.40 for amendment requirements.

- In accordance with 32 Ill. Adm. Code 335.40, request and obtain a license amendment before the intermittent use of licensed radioactive materials in a building or location not identified in the license.

32 Ill. Adm. Code Part 337 Facilities and Equipment

In accordance with 32 Ill. Adm. Code Part 337, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must, among other requirements;

- implement the physical protection requirements in 32 Ill. Adm. Code Part 337 for material in use and storage, at both permanent and temporary jobsites; and

- in accordance with 32 Ill. Adm. Code 337.2050, be able to monitor, detect without delay, assess, and respond to any unauthorized entries into security zones, including those surrounding mobile devices, and immediately detect any unauthorized removal of Category 1 quantities of radioactive material from the security zone. (Monitoring and detection systems may include, among other methods, monitored video surveillance systems and electronic devices for intrusion detection alarms.)

- for mobile devices containing Category 1 or Category 2 quantities of radioactive material, have two independent physical controls to secure the material from unauthorized removal when the device is not under direct control and constant surveillance in accordance with 32 Ill. Adm. Code 337.2070. "Mobile device" is defined in 32 Ill. Adm. Code 337.40.

For additional guidance on implementing 32 Ill. Adm. Code Part 337 requirements, see NUREG–2155, Rev. 2, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

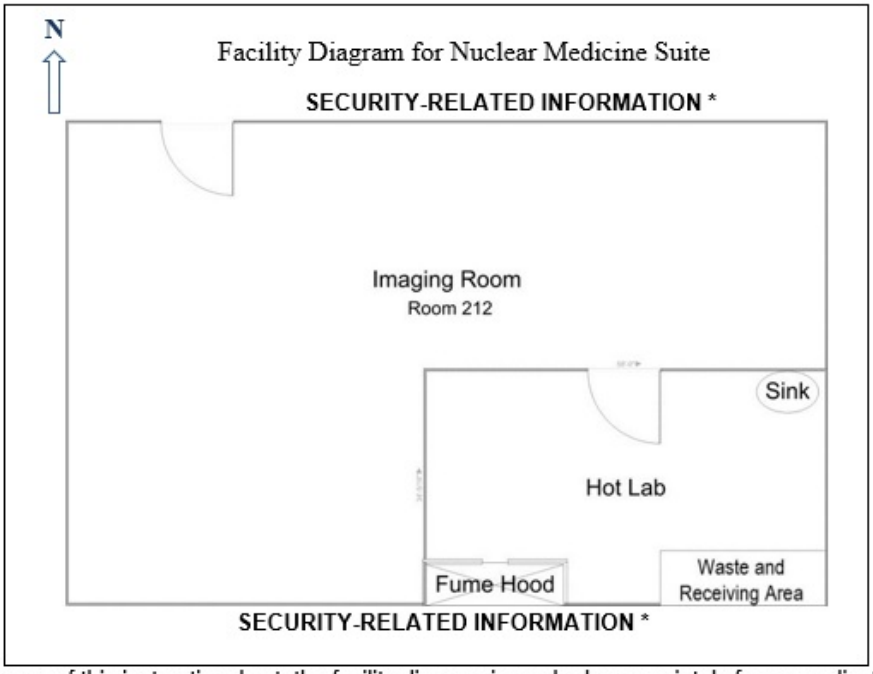
Please note, under 32 Ill. Adm. Code Part 337, security plans are not submitted to IEMA, but are required to be available for review and inspection during both pre-licensing site visits and routine inspections.

Facility Diagrams

To issue a license, IEMA must find that facilities and equipment are adequate to protect health and minimize danger to life or property, as required under 32 Ill. Adm. Code 330.250(a) and 32 Ill. Adm. Code 330.250(a)(3). In accordance with 32 Ill. Adm. Code

340.110, the licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

Applicants must describe the proposed facilities and equipment, as required by 32 Ill. Adm. Code 330.250(a) and 32 Ill. Adm. Code 335.40(f). The facility diagram should identify the floor and the room or rooms where byproduct material is prepared, used, administered, and stored, at a level of detail that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property. Because of the low energy of radionuclides used in nuclear medicine departments for diagnostic studies, a description of adjacent areas is unnecessary.



*For the purpose of this instructional set, the facility diagram is marked appropriately for an application.

If PET radionuclides are used, then a description of the specialized PET facilities should be provided. The description should include facility diagrams, the shielding installed, specialized handling equipment, and survey results to ensure that the regulatory limits in 32 Ill. Adm. Code 340.210, "Occupational dose limits for adults," and 32 Ill. Adm. Code 340.310, "Dose limits for individual members of the public," are not exceeded. The applicant should demonstrate that the limits specified in 32 Ill. Adm. Code 340.310(a) will not be exceeded and how access will be controlled in accordance with 32 Ill. Adm. Code 340.610 and 32 Ill. Adm. Code 340.620. If the facility descriptions or calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant may consider adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.

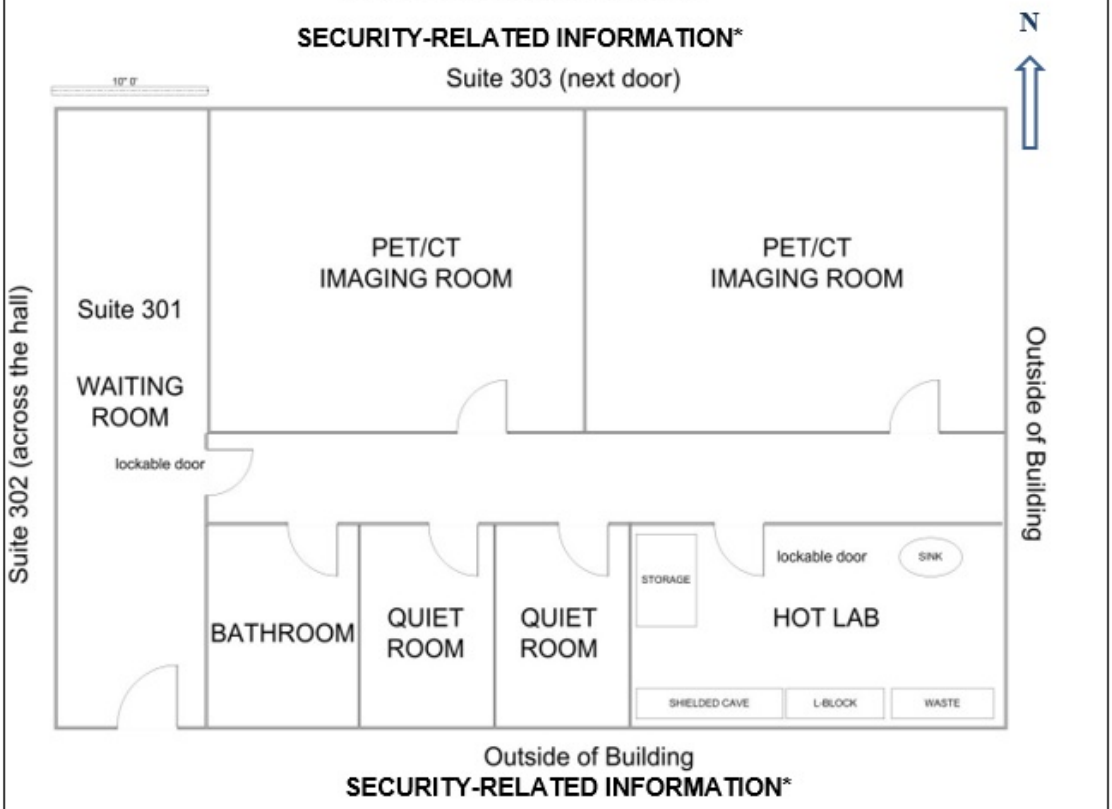
Drawings and diagrams that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "Security-Related Information" See Section II.C, "Identifying and Protecting Sensitive Information."

For types of use permitted by 32 Ill. Adm. Code Parts 335.3010 and 335.4010, applicants should provide room numbers for areas in which radioactive materials are used or prepared for use (i.e., "hot labs"). (see Nuclear Medicine Suite diagram below.)

If the applicant uses PET radionuclides under 32 Ill. Adm. Code Parts 335.3010 or 335.4010, the applicant should provide a description of the imaging rooms, quiet rooms, hot cells (if applicable), and location of the PET delivery line (if applicable).

Facility Diagram for PET Suite

SECURITY-RELATED INFORMATION*



SECURITY-RELATED INFORMATION*

Suite 301 is on the top floor in the corner of the building. Suite 302 is occupied by an oncology practice. Suite 303 is occupied by an obstetrics and gynecology practice. Directly below Suite 301 is a dental practice.

XX centimeters (cm) of lead† or *XX* cm of poured concrete† will be in doors, walls, ceiling, andfloors of hot lab, quiet rooms, and imaging rooms.

†AAPM task group report 108 provides guidance on determining appropriate thicknesses based on workload and distances to meet the regulatory requirements in 32 Ill. Adm. Code 340.310. Applicants should provide assumptions used in their calculations to determine this thickness.

*For the purpose of this instructional set, the facility diagram is marked appropriately for an application.

PET Shielding Calculations

Licensees will be required to submit shielding calculations to demonstrate compliance with the public dose limits in 32 Ill. Adm. Code 340.310. The following is an excerpt from the AAPM Task Force Group 108 "PET and PET/CT Shielding requirements" abstract,

"The shielding of positron emission tomography (PET) and PET/CT (computed tomography) facilities presents special challenges. The 0.511 MeV annihilation photons associated with positron decay are much higher energy than other diagnostic radiations. As a result, barrier shielding may be required in floors and ceilings as well as adjacent walls. Since the patient becomes the radioactive source after the radiopharmaceutical has been administered, one has to consider the entire time that the subject remains in the clinic."

The AAPM Task Force Group 108 report discusses shielding associated with a PET facility, including shielding calculations, that an applicant may elect to utilize to demonstrate compliance with public dose limits. Specifically, the applicant will need to provide site-specific patient throughput, distance to publicly occupied areas, occupancy factors, and the shielding to be installed. The exposures in uncontrolled areas can then be assessed against the limits in 32 Ill. Adm. Code 340.310 and those in controlled areas against the applicant's ALARA goals.

As applicable, the applicant will also need to calculate exposures in uncontrolled areas above, below and adjacent to the PET facility. Mobile PET facilities will need to detail how controlled areas will be maintained and the applicable dose limits maintained. The same report discusses appropriate design considerations to limit exposure to radiation workers as well as avoiding impacts from the PET annihilation radiation on nearby nuclear medicine equipment (gamma cameras, uptake probes, scintillation counters, etc.).

Additional Facility Considerations

For types of use permitted by 32 Ill. Adm. Code Parts 335.5010 or 335.7010, applicants should provide the locations where sources are stored (e.g., fume hood or shielded cave). The most widely used source of radiopharmaceutical therapy is I-131 sodium iodide. Since this radionuclide is volatile in either liquid or capsule form, applicants should detail appropriate radiological controls put in place. In general, though, the amount of I-131 sodium iodide that may become volatile is greatly reduced when encapsulated and is a fraction of a percent of the capsule activity; and therefore, fume hoods may not be necessary for storage. In addition, in accordance with 32 Ill. Adm. Code Parts 335.50309a) and 335.7030(a), the applicant should describe the rooms where patients will be housed, if they cannot be released under 32 Ill. Adm. Code 335.2110. When patients are treated with I-131 sodium iodide, sources of contamination include airborne I-131, urine, perspiration, saliva, and other secretions.

The discussion should include a description of shielding to ensure that the dose rates in adjacent areas are in accordance with the regulations. Regulatory requirements, the

principle of ALARA, and access control should be considered when determining the location of the therapy patient's room.

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

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

For types of use permitted by 32 Ill. Adm. Code Parts 335.6010, the applicant should provide the room numbers of use.

For types of use permitted by 32 Ill. Adm. Code Parts 335.8010 and as required by 32 Ill. Adm. Code Parts 335.8050, the applicant should provide a diagram and the shielding calculations for the facility. See the HDR Suite facility diagram below for an example. The applicant's diagram should be based on proposed room layout and shielding. The HDR storage location should also be indicated if different from the use room. Detail how the unit will be secured.

When preparing applications for use under 32 Ill. Adm. Code 335.2140, applicants should review the guidance on the IEMA website and the U.S. NRC's Medical Uses Licensee Toolkit Web page to determine the type of information appropriate to evaluate the adequacy of the facilities.

All limited, specific medical use licensees are required by 32 Ill Adm. Code 335.40, "License amendments," to obtain a license amendment before adding to or changing an area of use identified in the application or on the license. This includes areas used in accordance with Section 335.3010 or 335.4010 if the change includes addition or relocation of an area where PET radionuclides are used, administered, produced, or stored. However, changes and additions to other areas of use within the same address, where radioactive material is used only in accordance with either Section 335.3010 or 335.4010 do not require a license amendment and can be made, provided IEMA is notified, as required by 32 Ill. Adm. Code 335.45, within 30 days following the changes. The broad scope medical use licensee does not have to notify IEMA of changes that do not require a license amendment.

Facility Diagram for HDR Suite

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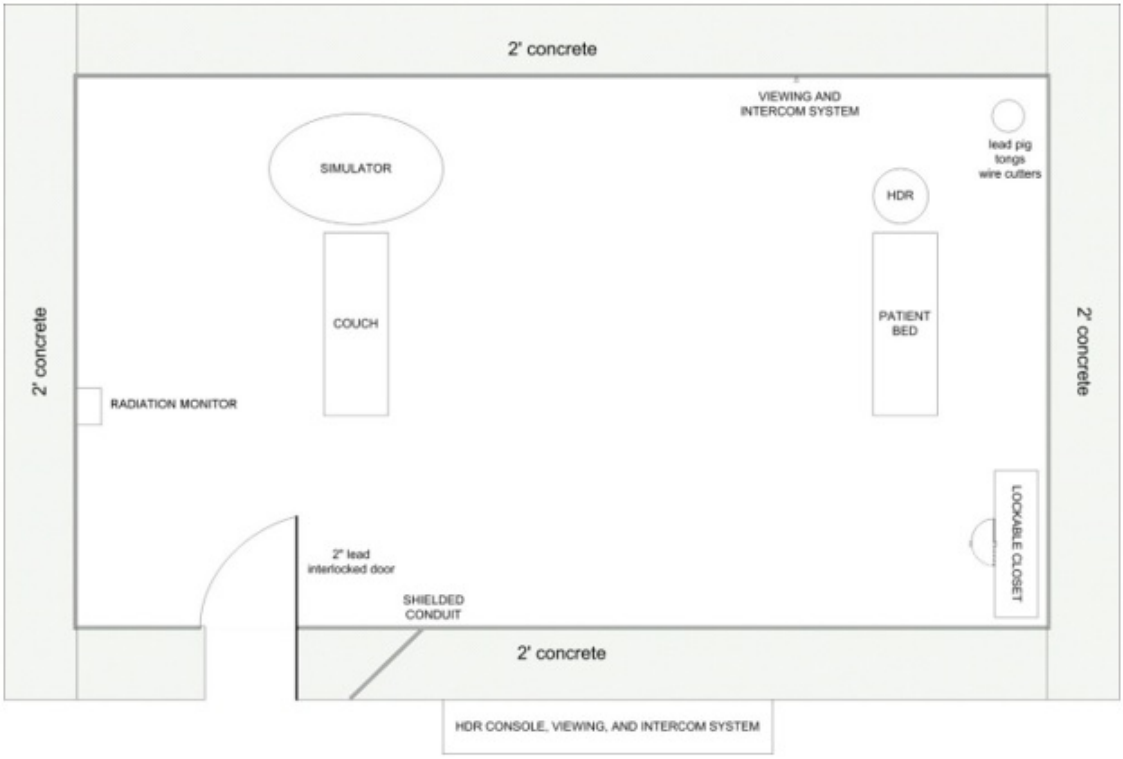
SECURITY-RELATED INFORMATION *



SECURITY-RELATED INFORMATION *

Iridium (Ir)-192 gamma constant from NCRP Report No. 49: 4.8 roentgen-$cm^2 h^{-1} mCi^{-1}$
Ir-192 Tenth Value Layer from NCRP Report No. 49: 2 cm lead, 14.7 cm poured concrete.
XX centimeters (cm) of lead† or *XX* cm of poured concrete† will be in doors, walls, ceiling,and floor.

*For the purpose of this instructional set, the facility diagram is marked appropriately for an application.

†NCRP report Numbers 49 and 151 provide guidance on determining appropriate thicknesses based on the assumed beam on-time, distances, and maximum loading to meet the regulatory requirements in 32 Ill. Adm. Code 340.310. Applicants should provide assumptions used in their calculations to determine these thicknesses.

Applicant Response

Provide the following:

- All medical use applicants, including broad scope medical use applicants, are required to provide facility diagrams of locations where radioactive material will be used and/or stored.

- Facility diagrams should be to scale with the scale indicated, or the dimensions provided. The direction of north must be indicated.

- Specify the location, building, floor, room number and principal use of each room, including patient treatment rooms or areas where radioactive material is prepared, used, and stored.

- Clearly mark or identify all areas adjacent, including above and below, to radioactive material storage/use rooms or areas (e.g., offices, hallways, outside walls, etc.). Specify the distance of the closest occupied workstation to the radioactive material storage/use area.

- Doors should be indicated, and specify which doors are access controlled (i.e., locked).

- Indicate all cabinets, lockers and storage containers which will be used for the storage or use of radioactive material. Include a description of the storage containers (e.g., manufacturer's shipping container, etc.).

  NOTE: Devices should be stored away from occupied areas and secured against unauthorized removal.

- Provide a description of the security measures implemented to limit access to the storage/use areas to authorized personnel only (e.g., areas locked when not in use and only accessible by authorized users).

- For each permanent storage or use location, if the applicant does not own the use/storage facility/property, submit a letter from the owner of the facility/property verifying the owner is aware of the use/storage of radioactive material on this property or verify the owner has been informed in writing of the use/storage of radioactive material within their facility. If the facility/property is owned by the applicant, so indicate.

- If the applicant will periodically release areas of use as unrestricted areas, commit to the procedures in the instructional set or submit equivalent procedures for Agency evaluation.

- Submit shielding calculations for PET facilities, in-patient rooms for 32 Ill. Adm. Code 335.5010 and 335.7010 use, high dose-rate/pulsed dose rate and low-dose rate remote afterloaders, teletherapy, and gamma stereotactic radiosurgery (GSR). Include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations should include the workload assumptions used.

- For PET, radiopharmaceutical and sealed-source therapies, provide a description of surrounding areas, including the occupancy factors, and indicate whether the areas

are restricted or unrestricted, as defined in 32 Ill. Adm. Code 310.20. For calculations of the maximum exposure in any given hour, an occupancy factor will not be used. Licensees can determine the radiation levels adjacent to the storage and use locations either by calculations or a combination of direct measurements and calculations using some or all of the following: typical known radiation levels provided by the manufacturer, the "inverse square" law to evaluate the effect of distance on radiation levels, and occupancy factors to account for the actual presence of the member of the public and of the device(s).

- For teletherapy facilities, applicants should provide the directions of primary beam use and, in the case of an isocentric unit, the plane of beam rotation is identified in the shielding calculations.

- For 32 Ill. Adm. Code 335.2140 (e.g., Perfexion®, View-Ray), applicants should provide information described in the guidance on the Medical Uses Licensee Toolkit Web page or, if available, specific guidance posted on the IEMA website.

  Note: The applicant should follow the guidance in Section II.C, "Identifying and Protecting Sensitive Information," to determine if the response includes security-related sensitive information and needs to be marked accordingly.

References and Resources:

- National Council on Radiation Protection and Measurements (NCRP) Report No. 40, "Protection Against Radiation from Brachytherapy Sources," 1972.

- NCRP Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies up to 10 MeV," 1976.

- NCRP Report No. 102, "Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use)," 1989.

- NCRP Report No. 151 "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities," 2005.

- AAPM Task Group 108, "PET and PET/CT Shielding Requirements," 2005.

Item 5A. Individuals Who Will Use Radioactive Material - Authorized Users (AUs)

Applicants are to utilize the applicable IEMA "Training and Experience" form to provide the name of each person who will use or directly supervise the use of radioactive material. Existing licensees should identify any changes to authorized users currently listed on the license. Specify the amendment number in which no changes are being requested. The full names of each authorized user no longer need to be listed on the application itself. That information and the categories of radioactive material for which the users wish to be authorized, are specified in the IEMA Training and Experience

forms. Categories of use are found in 32 Ill. Adm. Code 335 Subparts D, E, F, G, H, I, and 32 Ill. Adm. Code 335.2140 (Emerging Technologies). An "Training and Experience Documentation Worksheet" is provided in Appendix B which may be used by licensees to summarize authorized users, identify the associated forms to submit and request needed license amendments. This form may also be utilized (with the required attachments) to notify the Agency of authorized user changes required under 32 Ill. Adm. Code 335.45.

Physicians who will use or directly supervise the human use of radioactive material must be licensed to practice medicine in accordance with the laws of Illinois and must have clinical radionuclide training and experience commensurate with the proposed radioactive material use.

32 Ill. Adm. Code 335.20 defines "Authorized user" or "AU" for medical use. The responsibilities of AUs involved in medical use include the following:

- radiation safety commensurate with use of radioactive material
- administration of a radiation dose or dosage and how it is prescribed
- direction of individuals under the AU's supervision in the preparation of radioactive material for medical use and in the medical use of radioactive material
- preparation of a written directive (WD), if required

Applicants must meet recentness of training requirements described in 32 Ill. Adm. Code 335.9180. The AU applicants must have successfully completed the applicable training and experience criteria described in 32 Ill. Adm. Code 335 within 7 years preceding the date of the application. Alternatively, applicants must submit documentation of related continuing education and experience since completing the required training and experience. This time provision applies to the board certification as well as to other training pathways. Acceptable continuing education and experience for physicians include the following, to be reviewed on a case-by-case basis:

- successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use (this review may include various types of instruction, including online training, as long as the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested)
- practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization
- practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization

- for therapy devices, experience with the therapy unit and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant

Regulations in 32 Ill. Adm. Code 335.9160, "Training for Experienced Radiation Safety Officer, Authorized Medical Physicist or Authorized User," provide that experienced AUs who are named on a license or permit are not required to comply with the training requirements in Subpart J to continue performing those medical uses for which they were authorized before the effective date of changes to the regulations in 32 Ill. Adm. Code 335.9160 (January 2022).

Effective January 2022, 32 Ill. Adm. Code 335.9160 provides that a physician, dentist, or podiatrist that has never been identified as an AU and was board certified by any of the boards listed in 32 Ill. Adm. Code 335.9160(b)(2) on or before October 24, 2007, satisfies the requirements to be an AU for the use of those materials. The applicant must provide documentation that the individual used the materials and performed the medical uses before October 24, 2007, to meet the requirements to be an AU for those materials and uses. This documentation will be reviewed on a case-by-case basis to see if the time period of use, the materials used, and the types of medical use meet the criteria in the regulation. This provision of the rule "grandfathers" these board-certified individuals that were never named as an AU but perform medical uses with the same materials prior to October 24, 2007.

Technologists, therapists, or other personnel may use radioactive material for medical use under an AU's supervision, in accordance with 32 Ill. Adm. Code 335.1050, "Supervision." As stated in 32 Ill. Adm. Code 310.70, nothing in 32 Ill. Adm. Code: Chapter II, Subchapters b and d relieves the licensee or registrant from complying with other applicable Federal, State or local requirements.

Effective January 2022, the requirement in 32 Ill. Adm. Code 335.1060 that an AU must render an interpretation of a diagnostic image or results of a therapeutic procedure was repealed. IEMA recognizes that the AU may or may not be the physician who interprets such studies. Additionally, IEMA regulations do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of radioactive material to individuals.

An individual who is qualified to be an AU but has not been named as an AU on a medical use license or permit may apply for and be authorized simultaneously as the RSO and the AU on the same new medical use license. The individual must have experience with radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous authorization and training specified in 32 Ill. Adm. Code 335.9010(e).

Instructions for documenting training and experience can be found in Appendix B to this Instructional Set. IEMA Training and Experience Forms "Authorized User Diagnostic (AUD)", "Authorized User Therapy (AUT)", and "Authorized User Sealed Source (AUS)" can be found on the IEMA web page, https://www2.illinois.gov/iema/NRS/RadSafety/pages/medical.aspx. Information in 32

Ill. Adm. Code 335.2140, "Other medical uses of radioactive material or radiation from radioactive material," regarding training and experience for emerging technologies (e.g., microspheres) can be found on the Agency website as well as the U.S. NRC's Medical Uses Licensee Toolkit Web page.

Applicant Response

Provide the following:

- full name of each proposed AU and uses requested

AND

- Illinois medical, podiatry, or dental license number

AND

For an individual currently or previously listed as an AU on an IEMA, U.S. NRC or Agreement State license or permit for the same type of use(s) requested

- provide the license number, or a copy of the license (if issued by another Agreement State or the U.S. NRC) or a copy of a permit issued by an U.S. NRC master materials licensee (MML), a permit issued by an U.S. NRC or Agreement State broad scope licensee, or a permit issued by an U.S. NRC MML permittee of broad scope on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested

AND

- if applicable, attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180.

For an individual listed as an AU on an IEMA, U.S. NRC or Agreement State license or permit but seeking an additional authorization under 32 Ill. Adm. Code 335

- provide an IEMA license number or a copy of the license (if issued by an Agreement State or the U.S. NRC) or a copy of a permit issued by an U.S. NRC master materials licensee, a permit issued by an U.S. NRC or Agreement State broad scope licensee, or a permit issued by an U.S. NRC MML permittee of broad scope on which the individual was specifically named as an AU

AND

- attach additional documentation of training and experience necessary to demonstrate the AU is qualified for the new medical uses requested:

- To add 32 Ill. Adm. Code 335.3010 authorization for an AU qualified under 32 Ill. Adm. Code 335.9040, no additional documentation is needed.

- To add 32 Ill. Adm. Code 335.4010 authorization for an AU qualified under 32 Ill. Adm. Code 335.9050, attach documentation of the supervised work experience eluting generator systems as required in 32 Ill. Adm. Code 335.9040(c)(1)(B)(vii).

- To add an additional authorization under 32 Ill. Adm. Code 335.5010 (for uses listed in 32 Ill. Adm. Code 9060 or 335.9070), for an AU qualified under 32 Ill. Adm. Code 335.9060, 32 Ill. Adm. Code 335.9070, and/or 32 Ill. Adm. Code 335.9080; attach documentation of casework experience for uses listed under the desired subpart, as applicable.

- To add an authorization under 32 Ill. Adm. Code 335.5010 (for uses listed in 32 Ill. Adm. Code 335.9080), for an AU qualified under 32 Ill. Adm. Code 335.9100 or 32 Ill. Adm. Code 335.9140, attach documentation of the classroom and laboratory training and supervised work experience required in 32 Ill. Adm. Code 335.9080(d)(1) and 32 Ill. Adm. Code 335.9080(d)(2),

OR

- To add an additional authorization under 32 Ill. Adm. Code 335.8010 (for an authorized user already qualified for one type of device under 32 Ill. Adm. Code 335.8010), attach documentation of training needed to meet the requirements in 32 Ill. Adm. Code 335.9140(c).

AND

- attach a preceptor attestation, if required (e.g., attestation is required for all individuals to meet the requirements in 32 Ill. Adm. Code 335.9080 and for individuals seeking authorization under the alternate training and experience pathway for 32 Ill. Adm. Code 335.9050 and 32 Ill. Adm. Code 335.9140)

AND

- if applicable, attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180.

For an individual who was certified before October 24, 2007, by a board listed in 32 Ill. Adm. Code 335.9160(b)(2)

- attach a copy of the board certification issued before October 24, 2007, by a specialty board whose certification is listed in 32 Ill. Adm. Code 335.9160(b)(2)

AND

- attach documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2007

AND

- attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180

For an individual qualifying under 32 Ill. Adm. Code Part 335, Subpart J because of a recognized board certification

- attach a copy of the board certification(s) issued by a specialty board whose certification process has been recognized by IEMA, the U.S. NRC or an Agreement State under 32 Ill. Adm. Code Part 335, Subpart J, as applicable to the use requested

AND

- attach additional documentation of training and experience necessary to demonstrate the AU is qualified for the medical uses requested:

    - To add 32 Ill. Adm. Code 335.4010 authorization with a board certification recognized under 32 Ill. Adm. Code 335.9050, attach documentation of the supervised work experience eluting generator systems required in 335.9040(c)(1)(B)(vii).

    - To add authorization for uses listed under 32 Ill. Adm. Code 335.9080 with a board certification recognized under 32 Ill. Adm. Code 335.9100 or 32 Ill. Adm. Code 335.9140, attach documentation of the classroom and laboratory training and supervised work experience required in 32 Ill. Adm. Code 335.9080(d)(1) and 32 Ill. Adm. Code 335.9080(d)(2) and a copy of the attestation required in 32 Ill. Adm. Code 335.9080(d)(3).

NOTE: Physicians seeking medical uses described in 32 Ill. Adm. Code 335.9060 or 32 Ill. Adm. Code 335.9070 with a board certification recognized under 32 Ill. Adm. Code 335.9060 and 32 Ill. Adm. Code 335.9070 do not need to provide a description of supervised work experience administering dosages of radioactive drugs.

To add 32 Ill. Adm. Code 335.8010 authorization with a board certification recognized under 32 Ill. Adm. Code 335.9140, attach documentation of the training specified in 32 Ill. Adm. Code 335.9140(c).

AND

- if applicable, attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180

For an individual qualifying under 32 Ill. Adm. Code Part 335, Subpart J by classroom and laboratory training, supervised work experience, and supervised clinical experience

- attach documentation of the classroom and laboratory training, supervised work experience, and supervised clinical experience identified in 32 Ill. Adm. Code Part 335, Subpart J, demonstrating that the proposed AU is qualified by training and experience for the use(s) requested

NOTE: IEMA "Documentation of Training and Experience" series of forms may be helpful in documenting the above information.

AND

- for an individual seeking authorization under 32 Ill. Adm. Code Part 335, Subpart G or I, attach documentation of the training specified in 32 Ill. Adm. Code 335.9130(d) or 32 Ill. Adm. Code 335.9130(c), as applicable, demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought

AND

- attach a written attestation, signed by a preceptor physician AU or, if applicable, the residency program director, that the above training and experience have been satisfactorily completed and the individual is able to independently fulfill the radiation safety-related duties as an AU for the requested medical uses

AND

- if applicable, attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180

For an individual qualifying for medical use of specific emerging technologies under Subpart C, 32 Ill. Adm. Code 335.2140

- attach documentation of training and experience, as described for the technology in the applicable guidance found on either the IEMA Website or the U.S. NRC's Medical Uses Licensee Toolkit Web page

NOTES*:*

- Under 32 Ill. Adm. Code 335.45(b)(1), licensees must notify IEMA within 30 days if an AU permanently discontinues his or her duties under the license or has a name change.

- Descriptions of training and experience will be reviewed using the criteria listed above. IEMA will review the documentation to determine if the applicable criteria in 32 Ill. Adm. Code Part 335 are met. If the training and experience do not appear to meet the 32 Ill. Adm. Code Part 335 criteria, IEMA may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience. The documentation should include the terminal degree designation(s) (e.g., D.O., M.D.), if those designations are relevant to the authorized use requested.

- Issued licenses will reflect any limitations on use for listed AUs (e.g., whether administrations in excess of 33 mCi [1.22 GBq] of I-131 are allowed and specific uses under 32 Ill. Adm. Code 335.8010).

Item 5B. Authorized Medical Physicist (AMP)

Authorized Medical Physicists (AMP) who will use or directly supervise the use of radioactive material for uses identified in 32 Ill. Adm. Code 335 Subpart I or select emerging technologies, must meet the training and experience requirements identified in 32 Ill. Adm. Code 335.9150. Additionally, the recentness of training requirements in 32 Ill. Adm. Code 335.9180 will apply. An AMP specifically listed on an existing radioactive material license may submit a complete copy of that license (or reference an Illinois Radioactive Material License number) as evidence of training and experience or may submit a complete description of their training and experience using the appropriate IEMA Training and Experience Form.

NOTE: Individuals who transport licensed radioactive material or who may offer such material to a carrier for transport must comply with the applicable requirements of the United States Department of Transportation (DOT) as described in 49 CFR 172, Subpart H, which is 172.700 – 172.704. Currently, the DOT training is required within 90 days after employment or change in job duties and at least once every three years.

NOTE: If the applicant is unknown to the Agency (not identified in another license), additional information on an individual's background and training may be requested to ensure that radioactive materials will be used as intended. See Exhibit A for a Release and Authorization Full Due Diligence Investigation form. Submitting this form in advance may help to expedite the application process.

Discussion: While the AMP may not administer the dose, at licensed medical facilities conducting radiation therapy treatments, an AMP is directly involved with the calculation and other tasks associated with the administration of the radiation dose. A licensee performing ophthalmic radiation therapy treatments under 32 Ill. Adm. Code 335.7010 must ensure that certain tasks described in 32 Ill. Adm. Code 335.7100(c) are performed by either an AMP or an ophthalmic physicist. The American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit their involvement in radiation therapy to areas for which they have established competency.

Applicants are reminded of recentness of training requirements described in 32 Ill. Adm. Code 335.9180. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria described in 32 Ill. Adm. Code Part 335 within 7 years preceding the date of the application. Alternatively, medical physicist applicants must submit documentation of related continuing education and experience since completing the required training and experience. This time provision applies to the board certification as well as to other training pathways for meeting requirements for training and experience.

The regulation in 32 Ill. Adm. Code 335.9160 provides that experienced AMPs who were named on a license or permit are not required to comply with the training requirements in 10 CFR 35.51 to continue performing those uses for which they were authorized on or before January 2022. 32 Ill. Adm. Code 335.9160 also provides that physicists holding certain board certifications on or before October 24, 2007, are not required to comply with the training requirements in 32 Ill. Adm. Code 335.9150 for those materials and uses that they performed on or before October 24, 2007. All AMPs are required to meet the requirements of 32 Ill. Adm. Code 335.9150(d) after January 2022, if they are seeking authorizations for new materials and medical uses.

If the medical physicist has never been identified as an AMP and was board certified by any of the boards listed in 32 Ill. Adm. Code 335.9160(a)(3) on or before October 24, 2007, the applicant must provide documentation that the individual used the materials and performed the medical uses before October 24, 2007, to meet the requirements to be an AMP for those materials and uses.

This documentation will be reviewed on a case-by-case basis to see if the time period of use, the materials used, and the types of medical use meet the criteria in the regulation. This provision of the rule "grandfathers" these board-certified individuals that were never named as an AMP but perform medical uses with the same materials prior to October 24, 2007.

Applicant Response

Provide the following:

- name of the proposed AMP

AND

For an individual currently or previously identified as an AMP on an IEMA, U.S. NRC or Agreement State license or permit for the same type of use(s) requested

- provide an IEMA license number or a copy of the license (if issued by the U.S. NRC or another Agreement State) or a copy of a permit issued by an U.S. NRC MML, a permit issued by an IEMA, U.S. NRC or Agreement State broad scope licensee, or a permit issued by an U.S. NRC MML permittee of broad scope on which the individual was specifically named an AMP for the uses requested

AND

- If applicable, attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180

For an individual listed on a license or permit but seeking authorization for a new medical use under 32 Ill. Adm. Code 335.9150(d)

- provide an IEMA license number or a copy of the license (if issued by the U.S. NRC or another Agreement State) or a copy of a permit issued by an U.S. NRC MML, a permit issued by an IEMA, U.S. NRC or Agreement State broad scope licensee, or a permit issued by an U.S. NRC MML permittee of broad scope on which the individual was specifically named an AMP for the uses requested

AND

- attach documentation of the additional training and experience specified in 32 Ill. Adm. Code 335.9150(d) demonstrating that the individual is also qualified by training in the new types of use for which the applicant seeks approval of the individual as the AMP, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system

AND

- if not board certified by a board recognized under 32 Ill. Adm. Code 335.9150(a) or listed in 32 Ill. Adm. Code 335.9160(a)(3), attach a written attestation, signed by a preceptor AMP, that the required training and experience in 32 Ill. Adm. Code 335.9150(d) has been satisfactorily completed and that the individual is able to independently fulfill the radiation safety-related duties as an AMP for the type of therapeutic medical unit for which the individual is requesting authorized medical physicist status

For an individual qualifying under 32 Ill. Adm. Code 335.9150(a)

- attach a copy of the board certification issued by a specialty board whose certification process has been recognized by IEMA, the U.S. NRC or an Agreement State under 32 Ill. Adm. Code 335.9150(a)

AND

- attach documentation of the training and experience specified in 32 Ill. Adm. Code 335.9150(d) demonstrating that the proposed AMP is qualified by training in the types of use for which the applicant seeks approval of the individual as the AMP, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system

AND

- if applicable, attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180

For an individual qualifying by board certification under 32 Ill. Adm. Code 335.9160(a)(3):

- attach a copy of the board certification for the same medical uses requested

AND

- if applicable, attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180

For an individual qualifying because of a degree, medical physics training, and medical physics work experience under 32 Ill. Adm. Code 335.9150(b)

- attach documentation of the training and experience specified in 32 Ill. Adm. Code 335.9150(b), demonstrating that the proposed AMP is qualified by training and experience for the use(s) requested

AND

- attach documentation of the training and experience specified in 32 Ill. Adm. Code 335.9150(d) demonstrating that the proposed AMP is qualified by training in the types of use for which the licensee seeks approval of an individual as AMP, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system

AND

- attach a written attestation, signed by a preceptor AMP, that the proposed AMP has satisfactorily completed the training and experience required in 32 Ill. Adm. Code 335.9150(b), as well as the training in 32 Ill. Adm. Code 335.9150(d) for the types of use specified, and that the individual is able to independently fulfill the radiation safety-related duties as an AMP for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status

AND

- if applicable, attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180

For an individual qualifying for radiation safety-related duties with specific emerging technologies under Subpart C, 32 Ill. Adm. Code 335.2140

- attach documentation of training and experience as described for the technology in the applicable guidance found either on the IEMA website or on the U.S. NRC's Medical Uses Licensee Toolkit Web page

NOTES*:*

- Under 32 Ill. Adm. Code 335.45(b)(1), licensees must notify IEMA within 30 days if an AMP permanently discontinues his or her duties under the license or has a name change.

- Descriptions of training and experience will be reviewed using the criteria listed above. IEMA will review the documentation to determine if the applicable criteria in 32 Ill. Adm. Code Part 335, Subpart J, are met. If the training and experience do not appear to meet the criteria in Subpart J, IEMA may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience. The documentation should include the terminal degree designation(s) (e.g., M.S., Ph.D.), if those designations are relevant to the requested authorization.

Item 5C. Ophthalmic Physicist (OP)

Training and experience requirements for ophthalmic physicists are described in 32 Ill. Adm. Code 335.9120. A licensee performing ophthalmic radiation therapy treatments under 32 Ill. Adm. Code 335.7010 must ensure that either an AMP or an ophthalmic physicist performs certain tasks described in 32 Ill. Adm. Code 335.7100(c). These individuals perform the same tasks but have different training and experience requirements.

While the ophthalmic physicist may not administer the dose at licensed medical facilities conducting ophthalmic radiation therapy treatments, this individual is responsible for calculating the activity of each strontium-90 source that is used to determine treatment times. This individual will further assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive.

Applicants are reminded of recentness of training requirements described in 32 Ill. Adm. Code 335.9180. Specifically, ophthalmic physicist applicants must have successfully completed the applicable training and experience criteria described in 32 Ill. Adm. Code Part 335 within 7 years preceding the date of the application. Alternatively, ophthalmic physicist applicants must have had related continuing education and experience since completing the required training and experience.

Applicant Response

Provide the following:

- name of the proposed Ophthalmic Physicist

For an individual currently or previously identified as an authorized Ophthalmic Physicist *on an IEMA, U.S. NRC or Agreement State license or permit*

- provide an IEMA license number or a copy of the license (if issued by the U.S. NRC or another Agreement State) or a copy of a permit issued by an U.S. NRC MML, a permit issued by an IEMA, U.S. NRC or Agreement State broad scope licensee, or a permit issued by an U.S. NRC MML permittee of broad scope on which the individual was specifically named an authorized Ophthalmic Physicist

AND

- if applicable, attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180

For an individual qualifying as an Ophthalmic Physicist based on education and supervised work experience under 32 Ill. Adm. Code 335.9120(b)

- attach documentation of the training and experience specified in 32 Ill. Adm. Code 335.9120, demonstrating that the proposed ophthalmic physicist is qualified by training and experience for ophthalmic treatments using Strontium-90 sources

AND

- if applicable, attach a description of recent related continuing education and experience as required by 32 Ill. Adm. Code 335.9180

Notes*:*

- Under 32 Ill. Adm. Code 335.45(b)(1), licensees must notify IEMA within 30 days if an ophthalmic physicist permanently discontinues his or her duties under the license or has a name change.

- Descriptions of training and experience will be reviewed using the criteria listed above. IEMA will review the documentation to determine if the applicable criteria in 32 Ill. Adm. Code Part 335, Subpart J, are met. If the training and experience do not appear to meet the criteria in Subpart J, IEMA may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

Item 5D. Individuals Authorized for Nonmedical Use

Individuals authorized for nonmedical use must have adequate training and experience with the types and quantities of licensed material they propose to use in accordance with 32 Ill. Adm. Code 330.250(a)(1).

For in vitro studies, animal research, calibration of survey instruments, and other uses that do not involve human use, the list of proposed individuals authorized for non-medical use or uses should include the individuals who will actually be responsible for the safe use of the radioactive material for the requested use.

An applicant should note which user will be involved with a particular use by referring to Items 5 and 7 of the application and providing information about the user's training and experience. Authorized nonmedical use or uses that do not involve human use (e.g., in vitro and animal research, calibration, dosimetry, research) will be reviewed on a case-by-case basis.

Applicant Response

- name of the proposed nonmedical use AU

AND

- description of types, quantities, and proposed nonmedical uses for each individual requested

AND

- documentation of individual's education and radiation safety training and experience with the types of materials and uses requested. This may include the IEMA license number or a copy of the U.S. NRC or Agreement State license, permit issued by an U.S. NRC master materials licensee, permit issued by an IEMA, U.S. NRC or Agreement State broad scope licensee, or permit issued by an U.S. NRC Master Materials License broad scope permittee on which the individual was specifically named

AND

- detailed radiation training and experience applicable to the use requested

Note: Authorized nonmedical use or uses that do not involve the intentional exposure of humans (e.g., in vitro and animal research, calibration, dosimetry, research) will be reviewed on a case-by-case basis. Refer to the applicable U.S. NRC NUREG volume for additional guidance

(e.g., NUREG–1556, Volume 7, Rev. 1, "Consolidated Guidance About Materials Licenses: Program- Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers").

Item 6. Radiation Safety Officer (RSO), Associate Radiation Safety Officer (ARSO), Off-Site Personnel and Consultant Roles

Item 6A Radiation Safety Officer

The applicant's management must appoint a Radiation Safety Officer (RSO) who agrees, in writing, to be responsible for implementing and maintaining the radiation protection program. The RSO is designated by, and responsible to, the applicant's management for the coordination of the applicant's radiation protection program (RPP) and for ensuring compliance with the applicable regulations and license provisions. The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO, as required by 32 Ill. Adm. Code 335.1040(b). The RSO must have adequate training to

understand the hazards associated with radioactive material and be familiar with all applicable regulatory requirements. The RSO should have independent authority to stop operations that he or she considers unsafe. In accordance with 32 Ill. Adm. Code 335.1040, "Authority and responsibilities of the radiation protection program," the licensee must provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to perform his or her duties.

The RSO must meet the minimum training and experience requirements of 32 Ill. Adm. Code 335.9010 and recentness of training requirements of 32 Ill. Adm. Code 335.9180. The RSO qualifications must be commensurate to the authorized uses of the license.

Submit the name, contact information, supporting training and experience documentation, and job title of the RSO when appointing or changing a RSO. In addition, the duties and responsibilities of the RSO must be submitted. Typical RSO duties are described in Appendix C of this instructional set. IEMA requires the name of the RSO to be listed on the license to ensure that licensee management always has a responsible, qualified person identified and that the named individual knows of his or her designation as RSO. Appendix C of this instructional set also provides a model Delegation of Authority, which should be used to further emphasize the agreement on duties and responsibilities of the RSO by management and the designated RSO. Indicate that the RSO will commit to these duties and responsibilities or submit an alternate document for Agency review. The Delegation of Authority document must be countersigned by an individual who has active management over the radiation protection program, submitted with the application and maintained for the duration of the license. A completed template from Appendix C or equivalent may be used when submitting this information to the Agency.

Item 6B Associate Radiation Safety Officer

The licensee may appoint one or more associate radiation safety officers (ARSOs) to support the RSO. The RSO, with written agreement from licensee management, may then assign duties and tasks to each ARSO that are limited to the types of use for which the ARSO is listed on the license. These duties and tasks are also commensurate with his or her training and experience. The ARSOs are required, per 32 Ill. Adm. Code 335.9010, to complete the same training and experience requirements as the named RSO for their assigned sections of the radiation protection program. The ARSOs may be assigned duties and tasks in the oversight of the radiation safety operations of designated sections of the licensed program, but the RSO retains responsibility for all sections of the program. ARSO(s) do not replace the need for a qualified RSO. The RSO retains full responsibility for the Radiation Protection Program including responsibility for any delegated duties. The ARSO is not equivalent to the temporary RSO described in 32 Ill. Adm. Code 1040(c).

The ARSO must be identified on the license. The licensee must amend the license, through a request to the Agency, and provide documentation that the individual meets the

appropriate training and experience requirements and submit the duties and tasks for which the ARSO is assigned. A template document for naming an ARSO is provided in Appendix C. A completed Appendix C, or equivalent, may be used when requesting to name an ARSO.

NOTE: The regulatory changes in 32 Ill. Adm. Code Part 335 implementing the ARSO formalize IEMA past policy where individuals were delegated duties where there was a demonstrated lack of training and experience of the named RSO in a specific modality. Going forward all individuals fulfilling this role should be named on the license.

Off-site Personnel and Consultant

The RSO should be a full-time employee of the licensed facility. However, IEMA has authorized individuals who are not directly employed by the licensee, such as consultants, to fulfill the role of RSO or to provide support to the facility RSO. The Agency generally does not recommend utilizing off-site personnel and consultants in the position of RSO unless there is a significant lack of experience for on-site staff that could otherwise assume RSO duties. To fulfill the duties and responsibilities, an on-site RSO is more suitable to address incidents, emergencies, and to accommodate unannounced inspections.

If the RSO is not an on-site individual, then in addition to RSO training and experience requirements, information as to the availability of the RSO and the means of contacting the RSO when they are not on-site, including response time for emergencies, must be submitted. The licensee may also name ARSOs in order to support off-site personnel in the RSO position.

Consultants may be useful in an oversight role for the RPP if the facility has persistent enforcement concerns. If the applicant employs a consultant to support the RSO, the licensee is still responsible for assuring the RPP is in accordance with licensee-approved procedures and regulatory requirements. Routine duties such as training, leak testing, calibrations, close-out surveys, and RPP reviews or audits may continue to be performed by consultants as RSO designees, with periodic review of this work by the RSO.

Applicant Response

- name of the proposed RSO (RSO is required for all licenses)

AND

- name(s) of each proposed ARSO, if desired (A licensee may choose to identify one or more individuals as ARSOs to support the RSO), and a signed appointment by management

AND

- for each proposed ARSO, identify the types of use (e.g., 32 Ill. Adm. Code 335.4010, 32 Ill. Adm. Code 335.5010) of radioactive material for which the individual may be assigned duties and tasks under the licensee's program in oversight of the radiation protection program

AND

- for each proposed RSO, submit the duties and responsibilities, along with a signed delegation of authority as required in 32 Ill. Adm. Code 335.1040.

AND

For an individual who is currently or was previously identified as an RSO or ARSO on an IEMA, U.S. NRC or Agreement State license for the same materials and use

- provide an IEMA license number or a copy of the license (if issued by the U.S. NRC or another Agreement State) on which the individual was named as the RSO or ARSO

AND

- if applicable, attach documentation of recent, related continuing education and experience as required by 32 Ill. Adm. Code 335.9180

For an individual who is a current RSO or ARSO seeking authorization to be recognized as an RSO or ARSO for additional medical uses

- attach documentation of completion of the supervised training and experience specified in 32 Ill. Adm. Code 335.9010(e) for any new materials or new medical uses requested

AND

- if not qualified under 32 Ill. Adm. Code 335.9160(a)(1) or board certified by an IEMA-recognized board, attach a written attestation as prescribed in 32 Ill. Adm. Code 335.9010(b)(3), signed by a preceptor RSO or ARSO, that the individual has successfully completed the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and is able to independently fulfill the radiation safety-related duties as an RSO or as an ARSO for a medical use licensee. Provide documentation of the board certification, if applicable.

For an individual who is board certified by an IEMA-recognized board qualifying under 32 Ill. Adm. Code 335.9010(a)

- attach a copy of the board certification issued by a specialty board whose certification process has been recognized by IEMA, the U.S. NRC or an Agreement State under 32 Ill. Adm. Code 335.9010(a)

AND

- attach documentation of supervised training and experience specified in 32 Ill. Adm. Code 335.9010(e) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the applicant seeks approval of the individual as the RSO or ARSO

AND

- if applicable, attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180

For an individual who is board certified as a medical physicist by an IEMA-recognized board qualifying under 32 Ill. Adm. Code 335.9010(c)

- attach a copy of the board certification issued by a specialty board whose certification process has been recognized by IEMA, the U.S. NRC or an Agreement State under 32 Ill. Adm. Code 335.9150(a) and documentation of the experience specified in 32 Ill. Adm. Code 335.9010(c) demonstrating that the proposed RSO or ARSO is qualified by experience with the radiation safety aspects of similar types of use of byproduct material for which the applicant seeks approval of the individual as the RSO or ARSO

AND

- attach documentation of supervised training and experience specified in 32 Ill. Adm. Code 335.9010(e) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the applicant seeks approval of the individual as the RSO or ARSO

AND

- if applicable, attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180

For an individual who is board certified by an IEMA-recognized board qualifying under 32 Ill. Adm. Code 335.9160(a)(2):

- attach a copy of the board certification issued on or before October 24, 2007, by a specialty board whose certification is listed in 335.9160(a)(2)

AND

- attach documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2007

AND

- attach documentation of recent related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180

For an individual who *is an AU or AMP qualifying under 32 Ill. Adm. Code 335.9010(d)):*

- attach a copy of the IEMA, U.S. NRC or Agreement State license, permit issued by an U.S. NRC master material licensee, permit issued by an IEMA, U.S. NRC or Agreement State licensee of broad scope, or permit issued by an U.S. NRC master material license permittee of broad scope indicating that the individual is an AU, AMP, or ANP identified on the license or permit and has experience with the radiation safety aspects of similar types of use of byproduct material for which the applicant seeks approval of an individual to serve as RSO or ARSO

AND

- attach documentation of the training and experience specified in 32 Ill. Adm. Code 335.9010(e) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO

AND

- if applicable, attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180

For an individual who is applying simultaneously to be the RSO and AU on a new license qualifying under 32 Ill. Adm. Code 335.9010

- attach documentation of the training and experience of the new AU

AND

- attach documentation of supervised training and experience specified in 32 Ill. Adm. Code 335.9010(e), demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures, as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO

For an individual who is qualifying b*y classroom/laboratory training and supervised radiation safety experience under 32 Ill. Adm. Code 335.9010(b)*

- attach documentation of the training and experience specified in 32 Ill. Adm. Code 335.9010(b) in completed IEMA Training and Experience Form (RSO) or equivalent documentation demonstrating that the proposed RSO or ARSO is qualified by training and experience, as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO

AND

- attach documentation of supervised training and experience specified in 32 Ill. Adm. Code 335.9010(e) in attached IEMA Training and Experience Form (RSO) or equivalent documentation demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures, as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO or ARSO

AND

- attach a written attestation, as prescribed in 32 Ill. Adm. Code 335.9010(b)(3), signed by a preceptor RSO or ARSO, that the individual has satisfactorily completed the requirements in 32 Ill. Adm. Code 335.9010(b), as well as the required training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and is able to independently fulfill the radiation safety-related duties as an RSO or as an ARSO for the medical use licensee

AND

- if applicable, attach documentation of recent, related continuing education and experience, as required by 32 Ill. Adm. Code 335.9180

If the proposed RSO is an outside consultant or contractor, address the following in the application or amendment:

- An outside consultant or contractor must qualify as an RSO in accordance with 32 Ill. Adm. Code 335.9010 or 32 Ill. Adm. Code 335.9160 and 32 Ill. Adm. Code 335.9180 criteria specified above.

- Identify other commitments of the consultant-RSO for other IEMA, U.S. NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO, as described in the regulations. State the consultant-RSO's minimum amount of onsite time (hours per week or days per quarter, as appropriate for the size of the program).

- Identify an in-house representative who will serve as the point of contact during the RSO's absence. Additionally, detail the capacity that person will serve (ARSO or simply an administrative contact).

***Note**:* This person may be allowed to assist the consultant RSO in his or her duties. Any such duties should be clearly defined.

- Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.

- Specify the maximum amount of time it will take the consultant RSO to arrive at the facility, in the event of an emergency that requires his or her presence.

***Notes**:*

- The licensee must notify IEMA within 30 days if, under 32 Ill. Adm. Code 335.45, "Notifications," an RSO or ARSO permanently discontinues performance of duties under the license or has a name change; licensees must also request an amendment to change an RSO or ARSO under 32 Ill. Adm. Code 335.45.

- An AU for medical uses or AMP may be designated as the RSO or ARSO on the license if the individual has experience with the radiation safety aspects of similar types of radioactive material use for which he or she will have RSO responsibilities or ARSO duties and tasks [see 32 Ill. Adm. Code 335.9010(d)] and, as required by 32 Ill. Adm. Code 335.1040(g), the RSO has sufficient time, authority, organizational freedom, resources, and management prerogative to perform the duties.

- Descriptions of training and experience will be reviewed using the criteria listed above. IEMA will review the documentation to determine if the applicable criteria in 32 Ill. Adm. Code Part 335, Subpart J, are met. If the training and experience do not appear to meet the criteria in Subpart J, IEMA may request additional information from the applicant or may request the assistance of the U.S. NRC in evaluating such training and experience.

- The training and experience for the RSO of a medical use broad scope license will be reviewed using the above criteria and NUREG–1556, Volume 11, Rev. 1.

<u>Item 6C. Radiation Safety Committee (RSC)</u>

Licensees that are authorized for two or more different types of use of radioactive material under Subparts F, H and I or Section 335.2140 for emerging technologies, or two or more types of units under Subpart I, shall establish a Radiation Safety Committee (RSC) to oversee all uses of radioactive material permitted by the license. Note that this is a change with the revisions to 32 Ill. Adm. Code Part 335 in 2022, and licensees authorized for use under Subparts D, E and F (combined or separately) do not require an

RSC. The Committee shall include an authorized user of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. The Committee may include other members the licensee considers appropriate. Please note that the RSC requirements and duties that were previously outlined in 32 Ill. Adm. Code 335.1030 have been repealed and references to the former regulatory citation should be replaced with a written program.

U.S. NRC NUREG 1516, "Management of Radioactive Material Safety Programs at Medical Facilities", May 1997, describes a systematic approach for effectively managing radiation safety programs at medical facilities. Various aspects of program management are discussed, and guidance is offered on selecting the radiation safety officer, determining adequate resources for the program, using such contractual services as consultants and service companies, conducting audits, and establishing the roles of authorized users and supervised individuals. Although some of the referenced material has been superseded, Chapter 1 and 2, as well as appendices B – D provided relevant information licensees may wish to utilize in the construct of RSC procedures. Model RSC procedures are contained in Appendix W. A licensee may elect to use these procedures or submit alternate procedures for Agency evaluation.

Applicant Response

If applicable, submit procedures for a Radiation Safety Committee for Agency review. Procedures shall address, at a minimum:

- A written commitment by the applicant's management to the establishment of an RSC which will oversee all uses of radioactive material permitted by the license,
- A list of duties and responsibilities of the radiation safety committee which includes both the requirements in 32 Ill. Adm. Code 335.1040 and 32 Ill. Adm. Code 340.110,
- The specified minimum frequency with which the RSC will meet,
- The required quorum to meet,
- Confirmation that the RSC membership will meet the requirements specified in 32 Ill. Adm. Code 335.1040(f),
- Verification that the member of management on the RSC is able to effect change or allocate resources for the Radiation Protection Program,
- Specification on how many RSC meetings must a member attend annually to retain membership on the RSC.
- A written commitment to maintain RSC meeting minutes and a record of actions taken by the licensee's management for 5 years as specified in 32 Ill. Adm. Code 335.1040.

Item 7A. Radioactive Material

32 Ill. Adm. Code 335 is divided into nine categories of use. For routine medical use, the applicant should indicate on IEMA's Medical Application or Expedited Renewal form, the type and quantity of radioactive material requested for each category of use. Depleted uranium is used in shielding and collimation in medical devices. Licensees must also protect aggregated Category 1 and Category 2 quantities of radioactive material, as defined in 32 Ill. Adm. Code 337.40, from theft, diversion, and sabotage. The following describes the types of radioactive material uses authorized by the different sections in 32 Ill. Adm. Code 335 and indicates information that needs to be submitted to obtain approval for the use of that material.

For licensees conducting sentinel lymph node biopsy, the biopsied tissue may be transferred to a non-licensed facility for pathology analysis as long as the tissue does not contain more than 100 μCi [3.7 megabecquerels (MBq)] of Tc-99m, which is based on the exemption criteria in Appendix B to 32 Ill. Adm. Code Part 330, "Exempt Quantities." See RIS 2008-31, "Licensing Requirements for Sentinel Lymph Node Biopsy," December 1, 2008, for additional information.

If an applicant's request is limited to one radionuclide under a particular use, the license will be limited to that radionuclide. In addition, the radionuclide and purpose may be limited, if the AU's training or experience is limited.

When determining both individual radionuclide and total quantities, all materials to be possessed at any one time under the license should be included [i.e., materials received awaiting use (e.g., new teletherapy or brachytherapy sources for exchange), materials in use or possessed, materials used for shielding, and materials classified as waste awaiting disposal or held for decay-in-storage].

<u>32 Ill. Adm. Code 335.2040 – Authorization for Calibration, Transmission, Attenuation Correction and Reference Sources</u>

This section refers to sealed and unsealed radioactive material used for check, calibration, transmission, attenuation correction and reference use. For all calibration, transmission, and reference sources covered under 32 Ill. Adm. Code 335.2040, the specific sources do not need to be listed on the license as long as the licensee is authorized pursuant to 32 Ill. Adm. Code 335.30 for the medical use of radioactive material. However, if the quantity specified in 32 Ill. Adm. Code 335.2040 is exceeded, the specific sources need to be listed on the license.

Reference sources containing radioactive material authorized under this Part shall not be used for medical use except in accordance with the requirements in Section 335.6010. Sealed sources shall not be combined (i.e. bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this Section.

32 Ill. Adm. Code 335.3010 (Subpart D) – Unsealed Radioactive Material for Uptake, Dilution and Excretion Studies – Written Directive Not Required

This section refers to the diagnostic use of radiopharmaceuticals involving measurements of uptake, dilution and excretion. Radiopharmaceuticals authorized for use under this section are those for which the Food and Drug Administration (FDA) has granted approval. Radiopharmaceuticals in this section can be requested in quantities expressed "as needed". The chemical/physical form requested may be "Any" unsealed radioactive material permitted by 32 Ill. Adm. Code 335.3010.

32 Ill. Adm. Code 335.4010 (Subpart E) – Unsealed Radioactive Material for Imaging and Localization for Which a Written Directive Is Not Required

This section refers to the use of radiopharmaceuticals, generators and reagent kits for imaging and localization studies. Radiopharmaceuticals, generators or reagent kits used for the preparation and diagnostic use of radiopharmaceuticals authorized for use under this section are those for which the FDA has granted approval. Radiopharmaceuticals that require a written directive are authorized under 32 Ill. Adm. Code 335.5010. Radiopharmaceuticals in this section can be requested in quantities expressed "as needed".

Applicants planning to use Positron Emission Tomography (PET) radionuclides for imaging must include information detailing special safety precautions to be taken when handling high-energy, short-lived radionuclides. Diagrams of proposed use areas should include shielding calculations to verify members of the public, at the frequency of use specified by the applicant, will remain beneath the limits listed in 32 Ill. Adm. Code 340.310. Applicants must indicate whether or not they intend to acquire radiopharmaceuticals prepared and distributed in accordance with a specific license. If they intend to acquire radionuclides distributed in accordance with a specific license and perform the pharmaceutical labeling at the licensee's facility, then the labeling and radiopharmaceutical testing procedures must be submitted to the Agency. In addition, licensees wishing to install a self-shielded cyclotron for production of radionuclides should contact the Agency regarding information to be submitted.

NOTE Regarding Gases/Volatile Material: The Agency will not authorize the use of radioactive gas/volatile material in this subsection unless the applicant also submits the information required in Item 22 of the application. If the applicant's facilities are not equipped for use of radioactive gas/volatile material, "*Excluding Gases and Volatiles*" should be selected. IEMA license reviewers should note that restrictions on gases/volatile material are applicable to the authorized facility/site and do not necessarily apply to any authorized users approved under this license.

NOTE Regarding Generators: Some generators require manufacturer training and/or shielding considerations. There are also specific regulatory requirements that apply to the use of generators and breakthrough assessment. These additional requirements will be assessed at the time of application based on the equipment to be used by the applicant. If no generators are to be used, the applicant should select, "Excluding Generators". IEMA license reviewers should note that restrictions on the use of generators are

applicable to the authorized facility/site and do not necessarily apply to any authorized users approved under this license. Some generators are licensed under 32 Ill. Adm. Code 335.2140, “Emerging Technologies”. Consult the U.S. NRC website for specific guidance on these generators.

32 Ill. Adm. Code 335.5010 (Subpart F) - Use of Unsealed Radioactive Material for Which a Written Directive is Required

This section refers to the use of radiopharmaceuticals for which a written directive is required. This includes both diagnostic and therapeutic materials. This subpart also includes radiopharmaceuticals where the FDA has accepted an "Investigational New Drug Application" (IND) or approved a "New Drug Application" (NDA). The chemical/physical form may be “Any” unsealed radioactive material permitted by 32 Ill. Adm. Code 335.5010. The applicant must specify a maximum possession limit for radiopharmaceuticals requested in this section.

This section can be limited to only those uses that are available at your facility. These limitations can include diagnostic procedures for which a written directive is required, the use of NaI in quantities less than 33 mCi, the use of NaI in quantities greater than 33 mCi or the use of parenteral materials only.
The application and expedited renewal forms provide an option for applicants that wish to restrict their 32 Ill. Adm. Code 335.5010 authorization to diagnostic studies only. This is typically I-131 sodium iodide administrations for diagnostic use that exceed 1.11 MBq (30 μCi).

32 Ill. Adm. Code 335.6010 (Subpart G) – Use of Sealed Sources for Diagnosis

This section historically referred to the use of iodine-125 (I-125), americium-241 (Am-241) and gadolinium-153 (Gd-153) as sealed sources for use in either bone mineral analyzers or diagnostic imaging devices. However, applicants should select this category if they intend to utilize any sealed source for diagnostic medical use. NOTE: The sealed source and/or medical device containing a sealed source must be explicitly listed in the Sealed Source and Device Registry as approved for diagnostic medical use. In addition, sealed sources used in devices, as authorized by this section, must be sources that have been evaluated for use in the specific device they will be used. Such evaluations must be listed in an Agency-accepted publication such as the U.S. NRC's "Registry of Radioactive Sealed Sources and Devices" (SS&D).

In accordance with 32 Ill. Adm. Code 335.6010(d), sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Section 335.35 are met.

The radionuclide; the chemical/physical form (e.g., sealed source or device identified by manufacturer and model number); the activity per source and the total activity in becquerels (Bq), microcuries (μCi), millicuries (mCi), or curies (Ci), including replacement sources; and the maximum number of sources or activity possessed at any one time must be specified. Applicants should include all possible alternate source

models they might use to minimize the need for license amendments if they change model or vendor.

32 Ill. Adm. Code 335.7010 (Subpart H) - Use of Sealed Sources for Brachytherapy

This section refers to the use of sealed sources for brachytherapy. The radionuclide; the chemical/physical form (e.g., sealed source or device identified by manufacturer and model number); the activity per source and the total activity in becquerels (Bq), microcuries (μCi), millicuries (mCi), or curies (Ci), including replacement sources; and the maximum number of sources or activity possessed at any one time must be specified. Applicants should include all possible alternate source models they might use to minimize the need for license amendments if they change model or vendor.

Such sources must be used in accordance with the manufacturer's radiation safety and handling instructions and the sealed sources must be evaluated for use and listed in the U.S. NRC's "Registry of Radioactive Sealed Sources and Devices" (SS&D).

In accordance with 32 Ill. Adm. Code 335.7010(b), a licensee may also use brachytherapy sources in research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of Section 335.35 are met.

32 Ill. Adm. Code 335.8010 (Subpart I) - Use of a Sealed Source in Remote Afterloader Units, Teletherapy Units or Gamma Stereotactic Radiosurgery Units

This section refers to the use of remote afterloader units, intravascular brachytherapy units, teletherapy units and some gamma stereotactic radiosurgery (GSR) units Developments in GSR technology may require some devices (such as the Elekta, Inc. Leksell Gamma Knife ® Perfexion®) to be authorized under 32 Ill. Adm. Code 335.2140, “Emerging Technologies”. The radionuclide; the chemical/physical form (e.g., sealed source or device identified by manufacturer and model number); the activity per source and the total activity in becquerels (Bq), microcuries (μCi), millicuries (mCi), or curies (Ci), including replacement sources; and the maximum number of sources or activity possessed at any one time must be specified. Applicants should include all possible alternate source models they might use to minimize the need for license amendments if they change model or vendor.

The applicant must consider the shipped, installed, and medical use limitations on activity. Limitations are described in the Sealed Source and Device (SSD) registration certificates and U.S. Food and Drug Administration (FDA) 510k certificates.

GSR and teletherapy sources are usually above Category 1 quantities, and aggregated high dose-rate (HDR) brachytherapy sources may be at or above Category 2 quantities. The applicant should also review NUREG–2155, Rev. 2, “Implementation Guidance for 10 CFR Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,”” and NUREG–2166, “Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material,” for additional guidance

implementing 32 Ill. Adm. Code Part 337 (Illinois-equivalent of 10 CFR Part 37) requirements for these therapy devices. Applicant information on manufacturers, model numbers, and possession limits is sensitive and should be marked accordingly. See Section II.C, "Identifying and Protecting Sensitive Information." Category 1 and Category 2 sources regulated by the U.S. NRC and Agreement States must be tracked in the National Source Tracking System (NSTS).

32 Ill. Adm. Code 335.2140 - Emerging Technologies

This section authorizes the use of emerging technologies that are not specifically addressed in Subparts D through I above, or if the use is inconsistent with those Subparts. For 32 Ill. Adm. Code 335.2140 use: The radionuclide, the chemical/physical form, and the total amount must be specified.

This Section currently includes the use of Y-90 microspheres, radioactive seed localization of non-palpable lesions and lymph nodes, intravascular brachytherapy (IVB), Ge-68/Ga-68 pharmacy grade generators, the ViewRay® System and the Elekta, Inc. Leksell Gamma Knife ® Perfexion®. However, applicants should refer to the U.S. NRC Medical Uses Licensee Toolkit Web page for current information, the medical section of the IEMA website (https://www2.illinois.gov/iema/NRS/RadSafety/pages/medical.aspx) or contact the IEMA Licensing unit for these and any other medical applications under emerging technologies.

Applicants wishing to add IVB should reference the additional regulatory requirements specified in 32 Ill. Adm. Code 335.2150 and contact the IEMA Licensing Unit to discuss the contents of the application.

Item 7B. Radioactive Material for Uses Not Listed in Item 7A

For uses not listed in Item 7a and for possession of materials for non-human use, list, for each radionuclide to be used, the chemical and physical form, the maximum activity you wish to possess at any one time and the intended use of the material. This would include authorization for *in vitro* material in amounts greater than allowed by 32 Ill. Adm. Code 330.220(f), depleted uranium for shielding, instrument calibration sources, etc. In addition, if you wish to be licensed to possess and use sealed sources, specify the manufacturer's name, nuclide, source model, the maximum activity per source and the total number of sources you wish to possess.

Instrument Calibration Sources

For licensees who request to perform instrument calibration, not as a customer service, as described in Item 8B of this instructional set, specify the isotope (s), activity, make and model number(s)of the calibration sources and the make and model number of the calibration instrument (s) requested for performing radiation monitoring instrument calibration.

Leak Test Analysis Sources

For licensees who request authorization to perform in-house leak test analysis as described in Item 16 of this instructional set, specify the isotope (s), activity, make and model number(s) of the source (s) requested if they exceed the limits specified in 32 Ill. Adm. Code 335.2040.

Shielding Material/Depleted Uranium

Some high-activity radionuclide generators used to produce byproduct materials for 32 Ill. Adm. Code 335.3010 and 335.4010 uses [e.g., technetium-99m (Tc-99m) generators] may include depleted uranium [i.e., uranium depleted in uranium-235 (U-235), as defined in 32 Ill. Adm. Code 310.20] as shielding material. If a generator has depleted uranium shielding, an applicant should request authorization to possess depleted uranium as shielding material. Applicants receiving large therapy sources and devices also should determine if depleted uranium is used to shield or collimate the therapy sources and devices. This includes identifying depleted uranium used as shielding in linear accelerators because, even though IEMA does not license the accelerator, it does license the depleted uranium in the accelerator.

If applicable, the applicant should request authorization to possess depleted uranium (i.e., uranium depleted in U-235) in quantities sufficient to include shielding material in both the device(s) and source containers used for source exchange and shielding for other devices. The applicant should review the manufacturer's specifications for each device specified in the license request to determine (i) if depleted uranium is used to shield the source(s) within the device and (ii) the total quantity of depleted uranium present in the device in kilograms. The applicant should also consult the manufacturer's specifications or the source supplier to determine if depleted uranium is contained in shielding source containers used during source exchange, as well as the total quantity of depleted uranium in such containers in kilograms.

Note: Most depleted uranium used for shielding or beam collimation in therapy devices is covered under a general license in accordance with 32 Ill. Adm. Code 330.210(g). Applicants or licensees may either request to include the depleted uranium on the specific medical license or, as applicable, submit IEMA Form, "Registration Certificate– Use of Depleted Uranium Under General License," to register within 30 days after the first receipt or acquisition of depleted uranium. The information required on this report is detailed in 32 Ill. Adm. Code 330.210(g)(3)(A).

Sealed Sources and Devices

For medical use, licensees may only use sealed sources meeting requirements specified in 32 Ill. Adm. Code 335.35. In accordance with 32 Ill. Adm. Code 330.240(a)(8), applicants must provide the manufacturer's (or distributor's) name and model number for each requested sealed source and device (except for calibration, transmission, and reference sources authorized by 32 Ill. Adm. Code 335.2140 for either medical uses under 32 Ill. Adm. Code 335.6010 or nonmedical uses under 32 Ill. Adm. Code 335.2140, and certain Naturally-Occurring and Accelerator-Produced Radioactive Material (NARM) sources for which this information is not available). Licensees will be

authorized to possess and use only those sealed sources and devices specifically approved or registered by IEMA, the U.S. NRC or an Agreement State or when information required in 32 Ill. Adm. Code 330.240(a)(8)(D) is provided.

Applicants will need to request authorization for possession of these sealed source(s) or device(s). Background on this process is provided on under Section 8.5.1 of the U.S. NRC's NUREG 1556, Volume 9, Rev. 3. Please contact the IEMA licensing unit for questions regarding the content of this application.

Blood Irradiators

If the use of a device to irradiate blood is anticipated, the applicant should review NUREG–1556, Volume 5, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses," and submit information as applicable. The applicant should also review NUREG–2155, Rev.2, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,"" and NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material," for additional guidance implementing 10 CFR Part 37 requirements for blood irradiators. NOTE: 32 Ill. Adm. Code Part 337 is the Illinois-equivalent of 10 CFR Part 37. Applicant information on manufacturers, model numbers, and possession limits is sensitive and should be marked accordingly. See Section II.C, "Identifying and Protecting Sensitive Information." Category 1 and Category 2 sources regulated by the U.S. NRC and Agreement States must be tracked in the NSTS.

The regulations in 32 Ill. Adm. Code Part 337 apply to licensees that possess an aggregated "Category 1 quantity of radioactive material" or "Category 2 quantity of radioactive material." These terms are defined in 32 Ill. Adm. Code 337.40, and the radionuclides referenced in these 32 Ill. Adm. Code 337.40 definitions are listed in Appendix A to 32 Ill. Adm. Code Part 337. See Section I.J, "Security Program for Category 1 and Category 2 Radioactive Material," of this instructional set for more information on the applicability and requirements of 32 Ill. Adm. Code Part 337.

Production of Radionuclides by Accelerators

If the applicant will use an accelerator to produce radionuclides, a separate license application will be needed for the production of the radionuclides. The applicant should review NUREG–1556, Volume 21, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator."

Production of PET Radioactive Drugs for Noncommercial Distribution to Medical Use Licensees Within a Consortium

If the applicant will produce Positron Emission Tomography (PET) radioactive drugs for its own medical use and noncommercial distribution to other members of its consortium, the applicant should review NUREG–1556, Volume 13, Rev. 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial

Radiopharmacy Licenses," for production guidance and NUREG–1556, Volume 21, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator." Contact the IEMA licensing unit for Illinois-specific regulatory references and application contents.

When applying for this authorization, the applicant should also consider applying for authorization to take back potentially contaminated transport shields from other consortium members. Each consortium member should dispose of unused dosages and used syringes and vials at its own facility.

Item 8A. Instrumentation

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

The radiation protection program that licensees are required to develop, document, and implement, in accordance with 32 Ill. Adm. Code 340.110, must include provisions for survey instrument calibration (32 Ill. Adm. Code 340.510). Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated at intervals not to exceed 12 months for the radiation measured or at alternative intervals specified in regulations of the Agency, the U.S. NRC, or an Agreement State. The instruments should always be available for use when radioactive material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low-energy or low-activity seeds [e.g., iodine-125, palladium-103] if they become dislodged in the operating room or patient's room (e.g., NaI instruments).

For the purposes of this instructional set, 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
- area monitors
- single or multichannel analyzers
- liquid scintillation counters
- gamma counters
- proportional counters
- solid-state detectors
- hand- and foot-contamination monitors

Radiation Detection and Measurement Instruments

Amendments to 32 Ill. Adm. Code 335.2080 were made in 2021 to improve compatibility with equivalent U.S. NRC and Agreement State regulations. Those changes included removal of specified detection ranges for an applicant's instrumentation. However, the requirements in 32 Ill. Adm. Code 330.510 and 330.540 relative to instrumentation remains applicable. The licensee must maintain and calibrate instrumentation that is appropriate for the radiation being assessed and sufficiently sensitive to demonstrate compliance with the applicable provisions of 32 Ill. Adm. Code Parts 335 and 340.

The required sensitivity will vary based on an applicant's use but generally requires detection capability of both low-level dose rates (1 μSv/hr to 500 μSv/hr [0.1 millirem per hour (mrem/hr) to 50 mrem/hr]) as well as the ability to assess removable contamination in counts per minute (cpm). Additional considerations must be given for the types of radiation emitted by the radioactive material in use (e.g., low energy gamma, beta and alpha radiation). Licensees are required to assess removable contamination under 32 Ill. Adm. Code 335.2080. As indicated by the Agency Note in 32 Ill. Adm. Code 335.2080, 2000 dpm (disintegrations per minute) per 100 square centimeters of surface area may be utilized as a sufficiently sensitive detection limit for removable contamination unless the licensee has developed alternate removable contamination limits which take into consideration the unsealed radionuclides in use, their respective contribution to the dose limits in 32 Ill. Adm. Code 340.210 and 340.310, and the detection capability of the radiation detection survey instruments in use. Measurement of removable contamination shall only be performed with a survey instrument, in lieu of wipes, if the instrument is sufficiently sensitive to detect the contamination at the limits specified in this Section. Licensees that wish to be able to release a restricted area for unrestricted use may require further detection sensitivity to adequately demonstrate compliance with Appendix A to 32 Ill. Adm. Code Part 340. Whichever release limit is sought by the applicant, calculations must be submitted that show the instrumentation used to analyze wipe test samples is sufficiently sensitive. Appendix D contains information regarding minimum detectable activity (MDA) calculations.

Applicants requesting authorization to use radioactive material for radiopharmaceutical therapy, brachytherapy, low and high dose rate afterloader therapy, gamma stereotactic radiosurgery or imaging and localization studies originating from an in-house Mo 99/Tc 99m generator program will require an instrument capable of measuring higher exposure rates. An instrument such as an ionization chamber should be available of measuring over the range of 10 μSv/hr to 10 mSv/hr (1 mrem/hr to 1000 mrem/hr) to meet the regulatory requirements in the applicable Subparts.

If the licensee requests authorization to analyze samples for leakage and/or contamination (leak/wipe tests) required under 32 Ill. Adm. Code 340.410, a radiation measurement instrument that is sufficiently sensitive to detect 185 Bq (0.005 uCi) is also required. The applicant must submit the MDA calculations, for each instrument used for leak/wipe test analysis. Appendix D contains information regarding minimum detectable activity (MDA) calculations.

NOTE: An instrument that has sufficient sensitivity and range, such as a compensated G-M, may meet the requirements for both measurement and detection instruments. Please also note that when a required monitoring instrument is sent for repair, calibration or maintenance, the licensee must ensure that an equivalent, operable, calibrated monitoring instrument is available. The licensee must maintain copies of calibration records for loaner equipment.

Applicant Response:

Provide the following:

- Complete and attach Exhibit B to describe the applicant's instrumentation.

OR

- If Exhibit B is not used, then submit equivalent information including a description of the instrumentation (e.g., gamma counter, solid-state detector, portable or stationary count-rate meter, portable or stationary dose-rate or exposure-rate meter, single or multichannel analyzer, liquid scintillation counter (LSC), proportional counter) that will be used to perform required surveys. Gamma Cameras should not be noted unless they are being used to analyze area wipe samples.

NOTE: A licensee reserves the right to upgrade survey instruments as necessary, as long as they are adequate to measure the type and level of radiation for which they are used.

Item 8B. Instrument Calibration and Operability Checks

Radiation survey meter calibrations must be performed by persons, including licensed personnel, who are qualified to perform calibrations. A licensee should determine if the service vendor is qualified to perform these activities by requesting and maintaining a copy of their IEMA, U.S. NRC or equivalent Agreement State license. Alternatively, an applicant may choose to develop, implement, and maintain procedures to calibrate their own instruments. Appendix E of this Instructional Set provides guidance regarding appropriate instrumentation and model survey instrument calibration procedures, if the licensee requests to perform in-house calibration of their own radiation survey meters to meet the requirements detailed in 32 Ill. Adm. Code 340.540, “Calibration of survey instruments.”

Additionally, if electing to perform calibrations, the applicant should include the manufacturer, model, radionuclide and activity of the sources and the manufacturer and model of the devices used for performing instrument calibrations.

NOTE: At the time of publishing this instructional set, 32 Ill. Adm. Code 340.510 is more limiting in terms of calibration intervals than 32 Ill. Adm. Code 340.540. Specifically, the requirement in 32 Ill. Adm. Code 340.510 to calibrate “at intervals not

to exceed 12 months" is more specific than the "annual" term used in 32 Ill. Adm. Code 340.540.

Regardless of whether an applicant is authorized to calibrate radiation survey meters or contracts an authorized vendor to perform calibrations, the licensee must retain records of the calibration of instruments and equipment used for quantitative radiation measurements for 5 years after the record is made in accordance with 32 Ill. Adm. Code 340.1130(b). If any reading varies greater than 20% from the reading measured immediately after calibration, the licensee shall require that the instrument be repaired or recalibrated before use for monitoring required to maintain compliance with 32 Ill. Adm. Code 340.540(b).

Reference NUREG 1556 Vol. 7, Rev. 1, for the minimum source strength required to achieve an adequate calibration field. The sources should be strong enough to give an exposure rate of at least 7.7 microcoulomb per kilogram per hour [30 milliroentgen per hour] at 100 centimeters {e.g., 3.1 gigabecquerels [85 millicuries] of cesium-137 or 780 megabecquerels [21 millicuries] of cobalt-60}.

Operability Checks

In accordance with 32 Ill. Adm. Code 340.510(c), the Agency requires the licensee to check instrument operability by using a source of radiation. These instrument operability checks are required to be performed on each day that the instrument is used; however, a record of these checks is required only after repair, battery change or instrument calibration.

Applicant Response

Provide either of the following in Item 8B:

- Radiation survey/monitoring instruments will be calibrated by a service company authorized to perform such services. We will maintain a copy of a company's license authorizing such services.

OR

- We will calibrate radiation survey/monitoring instruments in accordance with the attached procedures, which contain all information requested in Appendix E of Instructional Set 52.2 (Rev. 4, 2022), or equivalent.

Item 8C. Dose calibrator calibration and operability checks

In 32 Ill. Adm. Code 335.2010, "Possession, use, and calibration of instruments used to measure the activity of unsealed radioactive material," and 32 Ill. Adm. Code 335.2030, "Assay of Radiopharmaceutical Dosages," IEMA describes requirements for the use, possession, calibration, and check of instruments (e.g., dose calibrators) used to measure

patient dosages. As described in 32 Ill. Adm. Code 335.2030, dosage measurement is required for licensees who prepare patient dosages.

If the licensee uses only unit dosages made by a manufacturer or preparer licensed under 32 Ill. Adm. Code 330.280(i), "Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Specific Licenses," or a PET radioactive drug producer authorized under 32 Ill. Adm. Code 330.260(c)(23) (and does not split, combine, or otherwise modify unit dosages), the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.

If the licensee performs direct measurements of dosages in accordance with 32 Ill. Adm. Code 335.2030 (e.g., prepares its own dosages, breaks up unit dosages for patient administration, or decides to measure unit dosages), the licensee is required to possess and calibrate all instruments used for measuring patient dosages. See Appendix F of this Instructional Set for model procedures that may assist licensees in dose calibrator calibration. Please note that a licensee need not commit to the use of Appendix F for the calibration of dose calibrators. 32 Illinois Administrative Code 335.2010(b) requires these procedures be performed in accordance with nationally approved standards or the manufacturer's instructions. Although Appendix F is still acceptable and considered a national standard, a licensee may wish to use one of the other two approved methods. Submittal of the actual procedure is not required; the procedure must be maintained for inspection staff to review.

Equipment used to measure dosages must be calibrated in accordance with nationally recognized standards [e.g., American National Standards Institute (ANSI)] or the manufacturer's instructions. The measurement equipment may be a well-type ionization chamber, an LSC, etc., as long as the instrument can be calibrated appropriately for the type and energy of radiation emitted and is both accurate and reliable.

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

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

The inherent technical difficulties in measuring alpha emitting radionuclides are even greater than those of measuring beta emissions. In the absence of an additional photon, gamma, or beta particle emission that can be measured with traditional instrumentation used in nuclear medicine (e.g., ion chambers) and quantified in relation to the alpha-particle emissions, most alpha-measuring instruments (e.g., gas-proportional counters and LSC) will require preparation and measurement of an aliquot of the unsealed byproduct material. Measurement of aliquots introduces additional uncertainties associated with removing precise and reproducible volumes from homogeneous samples. For example, U.S. NRC issued Information Notice (IN) 2016-03, "Revision to the National Institute of Standards and Technology Standard for Radium-223 and Impact on Dose Calibration for the Medical Use of Radium-223 Dichloride," January 12, 2016, to notify licensees of a correction in measuring radium-223, which is primarily an alpha emitter. To avoid these difficulties, the best method is to use unit dosages and the manufacturer's or commercial nuclear pharmacy's dose label for measurement of the dosage and decay-correct the dosage to the time of administration. These difficulties can also be avoided when not using unit dosages by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation.

Licensees who use rubidium (Rb)-82/strontium (Sr)-82 generators should refer to the following for further guidance on the measurement of dosages:

- RIS 2013-12, "Notice of Issuance of Enforcement Guidance Memorandum—Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages," August 23, 2013

- EGM-13-003, "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages," April 18, 2013

Applicant Response

(Select One on Item 8C):

For the administration of alpha, gamma, and beta emitting unsealed byproduct materials, provide the following:

- Not applicable, the applicant will use unit doses only

OR

- Licensee will calibrate the dose calibrator in accordance with the manufacturer's instructions and/or a National Standard in accordance with 335.2010(b).

AND

- For measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, identify specialized measurement equipment and the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer's instructions to calibrate the instrument.

Item 9. Procedures for Use of Radioactive Gas / Volatile Material

The use of radioactive gas or volatile material (e.g., Xe-133 gas or I-131) requires attention not only to the standard radiation safety considerations but also to an evaluation of expected air concentrations of the radioactive effluent in restricted and unrestricted areas, including effluent released to the atmosphere. Each applicant who wishes to use radioactive gas or volatile material and does not capture or monitor effluent must submit unrestricted area concentration calculations to the Agency in support of that request as well as document personnel exposures as a result of restricted area releases in accordance with 32 Ill. Adm. Code 340.230 and 340.240. If ventilation systems are used in conjunction with radioactive gas/volatile material, procedures for use and maintenance are detailed in 32 Ill. Adm. Code 340.820 and 830. Compliance with these requirements will be evaluated during routine inspections.

Appendix G contains model procedures that address the use of monitored traps and sample calculations for those applicants releasing effluents. As applicable, the applicant should refer to the sample calculations in Appendix G to compile information in support of a request to use radioactive gas/volatile material such as Xe-133/I-131.

Item 10. Personnel Training Program

All individuals working with or around licensed materials should receive safety instructions commensurate with their assigned duties and as specified by 32 Ill. Adm. Code 400.120. For example, housekeeping staff, should be informed of the nature of the licensed material and the meaning of the radiation symbol and instructed not to touch the licensed material and to remain out of the room if the door to the licensed material storage location is open. Providing minimal instruction to ancillary staff (e.g.,

housekeeping, security) may assist in controlling abnormal events, such as loss of radioactive material. In addition, licensees should ensure that contractor staff receives safety instructions.

32 Ill. Adm. Code 400.120 requires all individuals working in, or the performance of whose duties requires access to, any portion of a restricted area to receive radiation safety training. Additionally, any workers who frequent areas where radioactive material is used or stored shall be provided radiation safety training. The radiation safety training must be provided initially before the individuals perform assigned duties and refresher training conducted at intervals not to exceed 12 months. The minimum topics to be covered are detailed in 32 Ill. Adm. Code 400.120.

NOTE: Additional information regarding radiation, its effects on humans, protection against radiation and how these items apply to individuals working in a medical facility can be found in NCRP Report Number 105.

Supervision by an Authorized User

Under 32 Ill. Adm. Code 335.1050, the licensee's AUs are required to provide safety instruction to all personnel using radioactive material under their supervision.

Therapeutic Treatment Training

Additional requirements for training in radiation safety for individuals involved with therapeutic treatment of patients are described in 32 Ill. Adm. Code 335.5020, 335.7020, and 335.8040. This safety instruction should be commensurate with the duties of the personnel and include safe handling of radioactive material, patient control, visitor control, contamination control, waste control, and notification of the RSO and the AU, if the patient has a medical emergency or dies. If applicable, a licensee shall ensure that operators, authorized medical physicists and authorized users participate in drills of the emergency procedures required under 32 Ill. Adm. Code 335.8040, initially and at least annually.

Security Training

Any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material (as defined in 32 Ill. Adm. Code 337.40) must conduct a training program for those individuals implementing the security program as outlined in 32 Ill. Adm. Code 337.2020(c). The training should ensure that those individuals who may have a responsibility to implement portions of the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. Additionally, in accordance with 32 Ill. Adm. Code 337.2020(c)(3), refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program.

Hazardous Materials Training

If applicable, the licensee is required under 32 Ill. Adm. Code 341.10, to provide hazardous material employee training that meets the requirements of 49 CFR 172, Subpart H. In accordance with 49 CFR Part 172.702(b), and except as provided in 49 CFR 172.704(c)(1), an employee may not perform any hazmat function unless instructed in the requirements of this subchapter that apply to that function. 'Hazmat functions', or more formally, the duties that would require hazmat training, are detailed in 49 CFR Part 171.1(b).

For instance, 49 CFR Part 172.702(b) applies to any person who packages or prepares a package for pickup. The Agency would interpret this as including the placement of spent unit doses into packaging, placing UN markings, and offering the package for shipment. These functions are outlined in 49 CFR 171.1(b) and may include actions taken by nuclear medicine technologists. Note that 49 CFR 173.422 states shipment of even excepted packages are still subject to the training requirements of subpart H of part 172. Initial and recurrent training shall be provided consistent with 49 CFR 172.704.

Training Members of the Public

32 Ill. Adm. Code 340.310(c) requires that prior to allowing a member of the public to enter a restricted area (as defined in 32 Ill. Adm. Code 310.20), the licensee shall give instructions on radiation hazards and protective measures to that individual.

Training Record Retention

A licensee must retain a record of individuals receiving instruction under 32 Ill. Adm. Code Parts 335.1050, 335.5020, 335.7020 and 335.8040 for 5 years. Records of training conducted under 32 Ill. Adm. Code Part 337 and 49 CFR Part 172 must be maintained for 3 years. Note that each of these Parts contain specifics on the record content that must be reviewed by the applicant.

Applicant Response

- Submit a description of the training that will be provided to all personnel who work with, or in the vicinity of, radioactive material.

- Identify additional training areas (therapeutic, security, hazardous materials, etc.) required for the applicant's proposed use.

- This training description should include the format of training (e.g., formal course work, lectures, online modules), a commitment to meet the specified training frequencies and record retention, the name(s) of the individual providing the training, and the manner in which the licensee will document completion and understanding of the material as outlined in 32 Ill. Adm. Code 400.120(b).

  Note: Each topical training area above has specific recordkeeping requirements that should be reviewed by the licensee.

Appendix H provides a model training program that provides one way to satisfy the requirements referenced above. In addition, the Medical Uses Licensee Toolkit Web page provides guidance for training suggested for emerging technologies [e.g., yttrium(Y) -90 microsphere], regulated under 32 Ill. Adm. Code 335.2140. The applicant should either commit to the use of Appendix H, or submit an alternate training program for Agency review.

Item 11. Procedures for Ordering and Receiving Radioactive Material

Licensed materials must be tracked from "cradle to grave," from receipt (from another licensee or from its own radionuclide production facility) to its eventual transfer/disposal. This is done to ensure accountability at all times; identify when licensed material may be lost or stolen; and ensure that the possession limits listed on the license are not exceeded.

The requirements for receiving packages containing licensed material are found in 32 Ill. Adm. Code 340.960, "Procedures for Receiving and Opening Packages." Additionally, the security of licensed material, required by 32 Ill. Adm. Code 340.810 and 32 Ill. Adm. Code Part 337 (if applicable), must be considered for all receiving areas. This section also discusses the licensees' responsibilities to maintain accountability and document receipt of radioactive material.

For aggregated Category 1 and Category 2 quantities of radioactive material listed in Appendix A to 32 Ill. Adm. Code Part 337, licensees must fully implement the requirements of 32 Ill. Adm. Code Part 337 before receipt of the radioactive material.

Licensees are required under 32 Ill. Adm. Code 340.810 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.

Receipt, inventory, transfer, and disposal records must be maintained for the times specified in Appendix A. Typically, these records contain the following types of information:

Licensees must ensure that the type and quantity of licensed material possessed is in accordance with the license. Additionally, licensees must ensure that packages are secured and radiation exposure from packages is minimized. To maintain accountability of licensed material, licensees must do the following:

- Secure licensed material. (32 Ill. Adm. Code 340.810)

- Maintain records of receipt, transfer, and disposal of licensed material to indicate the current inventory of sources at the licensee's facility. (32 Ill. Adm. Code 310.40, 32 Ill. Adm. Code 340.810, and 32 Ill. Adm. Code 340.1180)

- Ensure that material received does not exceed license possession limits. (32 Ill. Adm. Code 330.310(e))

- Update transactions in the NSTS, including an annual inventory reconciliation. (32 Ill. Adm. Code 330.950)

- Conduct physical inventories at required frequencies to account for all sealed sources containing radioactive material and retain records for 5 years. (32 Ill. Adm. Code 340.810)

- Maintain accountability for brachytherapy sources in storage or use and retain records for 5 years. (32 Ill. Adm. Code 335.7040)

- Maintain access control and surveillance to Category 1 and Category 2 quantities of radioactive material in accordance with 32 Ill. Adm. Code 337.2050.

- Before transferring aggregated Category 1 or Category 2 quantities of radioactive material listed in Appendix A to 32 Ill. Adm. Code 337, use U.S. NRC's license verification system to verify that the recipient licensee is authorized to possess the radioactive material. (32 Ill. Adm. Code 337.3010)

- Preplan, coordinate, and provide advance notification of shipment of Category 1 quantities of radioactive material and coordinate shipment of Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37. (32 Ill. Adm. Code 337.3030 and 337.3040)

Applicant Response

Submit a description of procedures for ordering, receiving radioactive material and safely opening radioactive material packages, including receipt during off-duty hours and for notification of responsible persons upon receipt of radioactive material. This procedure should be adequate to meet the requirements of 32 Ill. Adm. Code 340.960, to ensure that possession limits are not exceeded, radioactive material is secured at all times against unauthorized access or removal, accountability is maintained for licensed material, radiation levels in unrestricted areas do not exceed the limits specified in 32 Ill. Adm. Code 340.310, all receipts/transfers/disposals are properly documented, and damaged packages are promptly evaluated. If applicable, include a commitment that the licensee will comply with the NSTS reporting requirements, as described in 32 Ill. Adm. Code 330.950.

If packages are only received during normal working hours, so indicate. Security personnel or any other individuals who receive packages of radioactive material during off-duty hours should be issued written procedures, which detail receipt, examination and required security of packages. Radiation safety training provided under 32 Ill. Adm. Code 400.120 to these staff should include training on these procedures. Procedures required under this section should include:

- Notification procedures to be followed for packages that are missing, found or suspected to be damaged, contaminated or leaking. Indicate the immediate steps to be taken to prevent the spread of contamination.

- Procedures or methods for verifying the contents of packages of radioactive material, not only against the packing slip, but also against the amount, type and form of material ordered and against the license to ensure that possession limits are not exceeded.

- Procedures or methods to ensure that radioactive material is secured at all times against unauthorized removal.

- Procedures or methods to ensure that receipt of radioactive material is properly documented.

Appendix I contains model procedures that represent one acceptable method for ordering and receiving licensed material. The applicant should either commit to the use of Appendix I or submit an alternate procedure for Agency review.

Item 12. Procedure for Opening Radioactive Material Packages

Licensees must establish, maintain, and retain written procedures for safely opening packages, to ensure that the monitoring requirements of 32 Ill. Adm. Code 340.960 are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA.

Applicant Response

Appendix J of this instructional set contains model procedures that represent one acceptable method for safely opening packages containing radioactive materials. Applicants are reminded that 32 Ill. Adm. Code 340.960(b) requires, in part, that licensees monitor the external surfaces of a labeled package for radioactive contamination within 3 hours of receipt if it is received during normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours. The applicant should either commit to the use of Appendix J or submit an alternate procedure for Agency review.

Item 13. General Rules for the Safe Use of Radioactive Material

In accordance with 32 Ill. Adm. Code 340.110, licensees are responsible for developing, documenting, and implementing procedures to ensure the security and safe use of all licensed material, from the time it arrives at their facilities until it is used, transferred, and disposed of. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to themselves, other workers, or members of the public. In addition, these procedures should contain protective measures for occupational workers to maintain their

doses as low as reasonably achievable (ALARA). These procedures should include general safety instructions to be followed by all personnel while working with radioactive material and may include the following:

- Required safety apparel to be worn, including items such as laboratory coats, eye protection, disposable gloves, sleeves, and booties.

- Type(s) of personnel monitoring device to be used, as well as how they should be worn, when handling radioactive material,

- Instrumentation and techniques to be used to perform radiation monitoring of hands, clothing, shoes, etc. after working with radioactive material.

- Limitations and conditions for handling liquid or unsealed sources of radioactive material.

- Shielding, handling tools, or other safety equipment to be used when handling beta and/or gamma emitting radioactive materials. (e.g., PET shields should be used when handling high-energy fluorine-18)

- Procedures to secure radioactive material from unauthorized access.

- Procedures for the movement of radioactive material between rooms, in hallways, or through corridors.

- Facility design and procedures for operation that will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste

- Contamination control procedures including prohibitions against smoking, eating, drinking or the application of cosmetics and prohibiting the storage of personal items (food, drink, cosmetics, etc.) in areas where radioactive material is used or stored.

Appendix K of this instructional set contains a sample set of general rules for safe radioactive materials use that may be acceptable for most programs. Complex radiation protection programs may require more elaborate procedures to ensure safe use of radioactive material. The applicant should either commit to the use of Appendix K or submit an alternate procedure for Agency review.

Item 14. Emergency Procedures

This section summarizes required emergency procedures. Many of these procedures are covered in greater detail in other sections of this document. Emergency procedures

regarding security and surveillance should be sufficient to limit the exposure to the public ALARA during use or storage and after accidents. Applicants should develop emergency procedures that address a spectrum of incidents (e.g., major spills, leaking sources, medical events, interlock failures, stuck sources). After its occurrence becomes known to the licensee, IEMA must be notified when an incident involving licensed material occurs. Refer to the regulations (32 Ill. Adm. Code Part 340, Subpart M, 32 Ill. Adm. Code 335.1080, and 32 Ill. Adm. Code 337.2090 and 337.3060) for a description of when notifications are required.

Items 17 and 18 of this instructional set also detail the need for emergency procedures in the event a therapy patient treated with unsealed radionuclides or permanent implant brachytherapy undergoes emergency surgery or dies as it is necessary to ensure the safety of others attending the patient. As long as the patient's body remains intact, the radiation received by anyone near it is due almost entirely to gamma rays. When an operation or autopsy is to be performed, there should be an increased awareness of the possible exposure of the hands and face to relatively intense beta radiation. Additional care for patients recently treated with medium- to high-energy gamma emitters, such as I-131, and high-energy beta emitters, such as Y-90, should be observed. Procedures for emergency surgery or autopsy can be found in NCRP Report No. 155, "Management of Radionuclide Therapy Patients," December 2006.

Item 14A. General Emergency Procedures

Submit a copy of the procedure to be implemented during an emergency involving radioactive materials. A copy of this procedure should be posted in all areas where radioactive material is used/stored and should be available to authorized users at each temporary job site. The procedure should:

- Describe immediate action to be taken after an incident in order to prevent contamination of personnel and work areas (e.g., turning off the ventilation, area evacuation and spill containment). Actions to be taken for handling injured personnel who may be contaminated should also be addressed.

- For spills, describe what constitutes a major vs. a minor spill and the appropriate actions for each.

- List the names and telephone numbers of the responsible persons (e.g., RSO) to be notified in case of an emergency, including an off-hour contact. An alternate contact is also recommended. The Agency's 24-hour telephone number is to be included in this section (217-782-7860).

- Instruct personnel on appropriate methods of re-entering and decontaminating contaminated areas.

- Describe what action is to be taken in the event of fire, theft or loss involving radioactive material. This response must include notification to IEMA in accordance with 32 Ill. Adm. Code 340.1210 and 340.1220.

- Describe what actions are to be taken regarding suspicious activity, inquiries, or attempted theft/diversion of a Category 1 or 2 source of radioactive material. This response must include notification to IEMA in accordance with 32 Ill. Adm. Code 337.2090.

- Be posted or readily accessible to all authorized users.

- For authorized uses under 32 Ill. Adm. Code Part 335 Subparts F and H, detail procedures to be followed in the case of emergency surgery or patient death.

Appendix L of this instructional set contains a sample set of emergency procedures for general radioactive materials use that may be acceptable for most programs. Complex radiation protection programs may require more elaborate procedures to ensure safe use of radioactive material. The applicant should either commit to the use of Appendix L or submit alternate procedures for Agency review.

Item 14B. Emergency Procedures for Therapy Devices Containing Sealed Sources

In addition to general emergency procedures for the use of radioactive material, regulations in 32 Ill. Adm. Code 335.8040, "Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units," require, in part, that written procedures be developed, implemented, and maintained for responding to an abnormal situation involving a remote afterloader unit, a teletherapy unit, or a GSR unit. The procedures needed to meet 32 Ill. Adm. Code 335.8040 must include

- instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions

- the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure

- the names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally

The applicant must establish and follow written procedures for emergencies that may occur (e.g., a therapy source fails to retract or return to the shielded position, or a GSR couch fails). A copy of the manufacturer's recommendations and instructions should be given to each individual performing therapy treatments or operating the therapy device. A copy of these procedures must be physically located at the therapy unit console. The instructions must inform the operator of procedures to be followed if the operator is unable to place the source(s) in the shielded position or remove the patient from the radiation field with controls from outside the treatment room.

The licensee must provide instructions, initially and annually, to include responding to an abnormal situation described in 32 Ill. Adm. Code 335.8040(a)(4). Practice drills, using

nonradioactive (dummy) sources when possible, must be practiced at least annually and may be conducted more frequently, as needed. Team practice is important for adequate emergency coordination. The drills should include dry runs of emergency procedures that cover stuck or dislodged sources and applicators, if applicable, and emergency procedures for removing the patient from the radiation field. These procedures, designed to minimize radiation exposure to patients, workers, and the general public, should address the following points, as applicable to the type of medical use:

- When the procedures are to be implemented, such as any circumstance in which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation.

- The actions specified for emergency source recovery or shielding that primarily consider minimizing exposure to the patient and health care personnel while maximizing the safety of the patient.

- The step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios. The procedure should specify situations in which surgical intervention may be necessary and the steps that should be taken in that event.

- Location of emergency source recovery equipment, specifying what equipment may be necessary for various scenarios. Emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient and tools necessary for removal of the patient from the device.

- Radiation safety priorities, such as giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position).

- Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation.

- Specifying who is to be notified.

- Requirements to restrict (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

32 Ill. Adm. Code 335.2140 Emerging Technologies

Before using materials under certain 32 Ill. Adm. Code 335.2140 medical uses, the applicant must develop, document, submit, and implement written safety procedures for emergency responses. If appropriate, review the guidance on the IEMA website for uses

authorized under 32 Ill. Adm. Code 335.2140 (Emerging Technologies), as well as the 10 CFR 35.1000 medical use licensing guidance on U.S. NRC's Web site Medical Uses Licensee Toolkit Web page, and provide safety and emergency procedures requested for the particular 32 Ill. Adm. Code 335.2140 medical use.

Response from Applicant:

Appendix L contains a sample emergency procedure for the general use of radioactive material. If the applicant is requesting authorization for emerging technologies under 32 Ill. Adm. Code 335.2140 or therapy devices containing sealed sources, additional emergency procedures will be required. Indicate that you will follow the procedure contained in Appendix L or submit alternate procedures for Agency review.
If applicable, provide procedures required by 32 Ill. Adm. Code 335.8040(a)(4).

Item 15. Waste Disposal

The radiation protection program that licensees are required to develop, document, and implement in accordance with 32 Ill. Adm. Code 340.110 must include provisions for waste disposal of licensed material. Appendix R of this instructional set contains model procedures that represent one acceptable method to provide for decay-in-storage, generator or other licensed material return and disposal of liquids into sanitary sewerage.

All radioactive waste must be stored in appropriate containers until its disposal, and the integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal. IEMA requires medical licensees to dispose of radioactive waste generated at their facilities in accordance with regulations in 32 Ill. Adm. Code 340.1010-1070. Generally, medical licensees dispose of radioactive waste by one or both of the following methods:

- decay-in-storage (DIS)
- transfer to an authorized recipient

Licensees may choose any one or both of these methods to dispose of their radioactive waste.

Decay-in-Storage (DIS)

Radioactive materials with half-lives of less than or equal to 120 days have been deemed appropriate for DIS and interim storage. The holding time of the waste should be based on the radionuclide(s), half-life, and the activity present when the waste was placed into storage. Such waste may be disposed of as in-house trash if radiation surveys of the waste indicate that radiation levels are indistinguishable from background. The surveys should be performed with an appropriate radiation detection meter set on its most sensitive scale in a low background area and without any interposed shielding. In accordance with 32 Ill. Adm. Code 340.940(b), all radiation labels must be defaced or

removed from containers and packages prior to disposal as ordinary trash, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released in accordance with 32 Ill. Adm. Code 340.1045. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed. Applicants must maintain accurate records of monitoring and disposals that include the following information:

- Manufacturer, model and serial number of the survey instrument used,
- Background radiation levels and measured radiation levels,
- Identify of the individual performing the radiation surveys,
- Date the radioactive material was placed in storage for decay, and
- Date of disposal.

When setting up a program for decay-in-storage, consider short-term and long-term storage. Consider designing long-term storage to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers) and use of containers with shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location and appropriately posted in accordance with 32 Ill. Adm. Code 340.920. In addition, all storage containers must be appropriately labeled in accordance with 32 Ill. Adm. Code 340.940. Weekly monitoring of radioactive waste storage areas is required under 32 Ill. Adm. Code 335.2080 with a record retention of 5 years.

Note: Some short half-life radionuclide products (e.g., samarium-153, Tc-99m/Mo-99 generator columns and Y-90 microspheres) may contain long half-life contaminants that may preclude disposal by decay-in-storage. Long-lived contaminants need not be listed on an IEMA license; however, licensees need to perform surveys and dispose of the material in accordance with 32 Ill. Adm. Code Parts 340 and 335 requirements. Licensees using Y-90 microspheres should review IN 2007-10, "Yttrium-90 Theraspheres® and Sirspheres® Impurities," for guidance. Note that licensees utilizing the IEMA microsphere guidance need to perform sealed source inventories on Y-90 microspheres every six months (which may become applicable if long lived contaminants warrant the storage of waste for a prolonged period).

Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. Check and calibration sources with half-lives greater than 120 days (e.g., cobalt-57, germanium-68, gadolinium-153) may not be held for DIS and must be disposed of in accordance with 32 Ill. Adm. Code Part 340. Generally, medical licensees only dispose of radioactive waste with half-lives greater than 120 days by transfer to authorized recipients (e.g., low-level radioactive waste disposal facilities or manufacturers). Follow the packaging instructions received from the transfer agent and the burial site operator.

Before transferring radioactive material, a licensee must verify that the recipient is properly licensed to receive it. In addition, all leak test analysis must be up to date for

sealed sources and all packages containing radioactive material must be prepared and shipped in accordance with 32 Ill. Adm. Code 341 and DOT regulations.

Records pertaining to transfer or disposal are required to be maintained and will be required to be submitted when the licensee requests to remove the radioactive material from the license, to delete an authorized site location, or to terminate the license. Keep any consignment sheets or other documents from transfer agents as the record of disposal. A waste manifest alone will likely not be sufficient in memorializing the transfer. Typically, both the regulator and the transferring party want a letter or other document, countersigned by the receiving entity, that indicates the radioactive material was transferred into the other party's inventory. Include serial numbers if sources were transferred.

Other Waste Management Issues

Consider the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements regarding the release of material into air and water under 32 Ill. Adm. Code 340.320, "Compliance with dose limits for individual members of the public," and 32 Ill. Adm. Code 340.1030, "Disposal by Release into Sanitary Sewerage," respectively.

- Regulations for disposal in sanitary sewerage appear in 32 Ill. Adm. Code 340.1030. Material must be readily soluble or dispersible in water. There are also monthly and annual limits, based on the total sanitary sewerage release of the facility. [Excreta from patients undergoing medical diagnosis or therapy are not subject to these limitations. See 32 Ill. Adm. Code 340.1030(b).] See Appendix R for more information. Calculations detailing the proposed concentrations of radioactive material to be released under 32 Ill. Adm. Code 340.1030 must be submitted for Agency review.

- Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area and shall be used to demonstrate compliance with the annual dose limits in 32 Ill. Adm. Code 340.310 [32 Ill. Adm. Code 340.320(b)(2)]. Calculations demonstrating compliance with the annual dose limits in 32 Ill. Adm. Code 340.310 must be submitted for Agency review.

- Liquid scintillation-counting media containing 1.85 kBq [0.05 μCi] or less per gram of tritium (H-3) or carbon-14 may be disposed of without regard to its radioactivity [32 Ill. Adm. Code 340.1050(a)(1)].

Waste from in vitro kits (except mock I-125) that are generally licensed under 32 Ill. Adm. Code 330.220(e) is exempt from waste disposal regulations in 32 Ill. Adm. Code Part 340, as set forth in 32 Ill. Adm. Code 330.220(e)(6). Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

If applicants/licensees propose to treat or dispose of licensed material by incineration, they must comply with 32 Ill. Adm. Code 340.1040. Contact the IEMA Radioactive Materials branch for guidance on treatment or disposal of material by incineration.

Applicants who wish to use waste volume reduction operations (e.g., compactors) should provide a detailed description (as outlined below), along with their response to Section III. Item 4:

- Describe the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations.

- Provide manufacturer's specifications, annotated sketches or photographs, and other information about the compactor design.

- Describe the type, quantities, and concentrations of waste to be compacted.

- Provide an analysis of the potential for airborne release of radioactive material during compaction activities.

- Provide the location of the compactor(s) within the waste processing area(s), as well as a description of the ventilation and filtration systems used in conjunction with the compactors. Include a description of the procedures for monitoring filter blockage and exchange.

- Discuss the methods used to monitor worker breathing zones and/or exhaust systems.

- Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area.

- Discuss the instruction provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and examining containers for defects.

Note: Before licensed activities are transferred or assigned in accordance with 32 Ill. Adm. Code 330.310(c), the licensees must, in accordance with 32 Ill. Adm. Code 330.310(d), transfer the following records to the new licensee:

- records of disposal of licensed material made under 32 Ill. Adm. Code 340.1020, 340.1030, 340.1040 and 340.1050

- records required by 32 Ill. Adm. Code 340.1130(b)(4) of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment

<u>Nuclear pacemakers</u>

Medical facilities are often the first to come into contact with plutonium-powered pacemakers or the first to be contacted by nursing homes and funeral homes when a patient with an implanted pacemaker dies. In such cases, and when the medical facility is not responsible for control or disposal of the pacemaker, notify IEMA and attempt to contact the hospital (licensee) where the pacemaker was implanted to address any removal or disposal concerns. The licensee that implanted the device is responsible for the follow-up, removal, and return of the pacemaker to the manufacturer for proper disposal. IN 98-12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers," April 3, 1998, provides additional information.

Waste Return from Landfills or Medical Incinerators

Medical licensees are periodically contacted by the waste broker after receipt of potentially contaminated medical waste. As described in IN 99-33, "Management of Wastes Contaminated with Radioactive Materials," December 21, 1999, licensees must evaluate waste in accordance with 32 Ill. Adm. Code Part 340, Subpart F, "Surveys and Monitoring," and manage the storage and disposal of the waste in accordance with applicable regulations and license conditions. If contaminated waste is identified at a local landfill and determined to not have been appropriately disposed of by a licensed facility, IEMA may return the waste or may assess all or a portion of the costs incurred to abate violations to responsible persons in accordance with 32 Ill. Adm. Code 310.74.

32 Ill. Adm. Code Part 337 Category 1 or 2 Wastes

In accordance with 32 Ill. Adm. Code 337.50, a licensee that possesses radioactive waste that contains Category 1 or Category 2 quantities of radioactive material as defined in 32 Ill. Adm. Code 337.40 is exempt from the requirements of 32 Ill. Adm. Code Part 337, Subparts B, C, and D. However, any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg [4,409 lbs] is not exempt from the requirements of 32 Ill. Adm. Code Part 337. For additional guidance on implementing 32 Ill. Adm. Code Part 337 requirements, see NUREG–2155, "Implementation Guidance for 10 CFR Part 37, Rev. 2, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

A licensee possessing radioactive waste that is exempt under 32 Ill. Adm. Code 337.50 from the requirements of 32 Ill. Adm. Code Part 337, Subparts B, C, and D must implement the following requirements to secure the radioactive waste:

- use continuous physical barriers that allow access to the radioactive waste only through established access control points;

- use a locked door or gate with monitored alarm at the access control point;

- assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

- immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains Category 1 or Category 2 quantities of radioactive material.

Note: 32 Ill. Adm. Code Part 337 security plans are not submitted to IEMA but will be subject to review and inspection.

Applicant Response

Appendix R of this instructional set contains model procedures that represent one acceptable method to provide for decay-in-storage, generator or other licensed material return and disposal of liquids into sanitary sewerage. Indicate that you will follow the procedure contained in Appendix R or submit alternate procedures for Agency review.

If applicable, provide procedures for waste volume reduction (compactors), incineration or alternate disposal requests under 32 Ill. Adm. Code 340.1020. Contact the IEMA Radioactive Materials branch for guidance on treatment or disposal of waste by incineration or compaction.

If applicable, include calculations of proposed discharges to the sanitary sewer.

If applicable, include calculations demonstrating compliance with the annual dose limits for gaseous or liquid discharges of radioactive material to unrestricted areas.

Item 16. Testing Sealed Sources for Leakage and/or Contamination

32 Ill. Adm. Code 340.410 requires testing to determine whether there is any radioactive leakage from sealed sources. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 microcurie) of radioactivity. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Testing of sealed sources for leakage and/or contamination (leak/wipe tests) shall be performed only by persons who are specifically licensed by either the Agency, the U.S. NRC, another Agreement State to perform such services. Leak test records shall be retained for 5 years after they are made or until the source in storage is removed. The requirements for records pertaining to leak tests are detailed in 32 Ill. Adm. Code 340.1135.

Under 32 Ill. Adm. Code 340.410, licensees are required to perform leak tests at 6-month intervals or at other intervals approved by the Agency, the U.S. NRC or an Agreement State and specified in the SSD registration certificate and before first use, unless accompanied by a certificate indicating that the test was performed within the past 6 months.

The licensee or contractor does not need to leak test sources if:

- Sources contain only byproduct material with a half-life of less than 30 days.
- Sources contain only byproduct material as a gas.
- Sources contain 3.7 MBq [100 μCi] or less of beta emitting or gamma-emitting material, or 0.37 MBq [10 μCi] or less of alpha emitting material.
- Sources contain iridium-192 seeds in nylon ribbon.
- Sources are stored and not being used. The licensee, shall, however, test each such source for leakage before any use or transfer, unless it has been leak-tested within 6 months before the date of use or transfer.

The services of a licensed consultant or commercial organization may be used to obtain test samples, analyze the samples and report the results back to the applicant. In addition, a commercially available test kit may be used to obtain a test sample for subsequent analysis by a licensed service company. When using a licensed service, please note the licensee is required to maintain a copy of that company's license, which authorizes them to perform leak tests as a customer service. Collectively, the wipe and the analysis make up the complete "leak test". The date complete should be used for regulatory purposes.

Applicant Response

Leak test sample collection and analysis will be performed by an organization authorized by the Agency, the U.S. NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the Agency, the U.S. NRC or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit.

OR

The applicant requests authorization to perform leak tests, including sampling and analysis. Appendix M of this instructional set provides model procedures that represent one acceptable method to perform leak testing for sealed sources. Either commit to the use of Appendix M or submit alternate procedures with all required calculations for Agency evaluation.

Item 17. Unsealed Radioactive Material – Written Directive Required

Authorization for use under 32 Ill. Adm. Code 335 Subpart F requires that the licensee develop, implement and maintain additional procedures for administrations requiring a

written directive, handling therapeutic radiopharmaceuticals and patients treated with therapeutic radiopharmaceuticals, and patient release. These procedures should describe:

- Procedures for all administrations requiring a written directive, which address all applicable requirements in 32 Ill. Adm. Code 335.1120.

- Procedures for providing radiation safety instruction to nursing staff, patients and visitors. See Section III. Item 10 of this instructional set for additional information.

- Bioassay procedures. As applicable, criteria and procedures for bioassay of personnel in accordance with 32 Ill. Adm. Code 335.5030(a)(11), including the performance of baseline bioassays prior to administering therapeutic doses of I-131. See Item 21 of this instructional set for additional information.

- Procedures for opening containers of therapeutic doses of I-131 in an operating fume hood.

- Procedures for controlling contamination, such as using disposable items (e.g., dishes, utensils, etc.) and disposal/storage of items contaminated with radioactive material from the patient.

- Procedures to be followed in case of emergency surgery or patient death.

Procedures for Administrations When a Written Directive Is Required

The requirements for written directives (WD) are set forth in 32 Ill. Adm. Code 335.1110, "Written directives." If a written directive is generated or stored in a computerized system, the licensee must have a method of authenticating the AU's signature (*see "Supplementary Information," Section III, "Summary of Public Comments and Responses to Comments", as published in the Federal Register on April 24, 2002*).

Under 32 Ill. Adm. Code 335.1120, "Procedures for administrations requiring a written directive," medical use licensees are required to develop, maintain, and implement written procedures to provide high confidence that, among other items, each administration is in accordance with the WD and the patient's identity is verified. Therefore, licensees should have checks in place to ensure that the correct patient is treated and each component of the WD is met.

Licensees are reminded that procedures should correctly document the program currently in place. Licensees are required to determine if a medical event, as defined in 32 Ill. Adm. Code 335.20, has occurred. For purposes of determining whether medical event reporting is required, licensees should also provide definitive criteria for evaluating the adequacy of the dose delivered or activity implanted to the intended treatment site, compared to the prescribed dose, and the acceptability of the dose delivered to any other organ or tissue, compared to the dose expected from the administration defined in the written directive. At a minimum, these procedures shall address the following items:

- Verifying the identity of the patient or human research subject;

- Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

- Checking both manual and computer-generated dose calculations; and

- Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Section 335.2140 or 335.8010 of this Part;.

- Determining if a medical event, as described in Section 335.1080, has occurred;

- Determining, for administrations of I-131 in quantities greater than 1.11 megabecquerel (30 microcuries), the criteria to be used to identify patients required to be tested for pregnancy in accordance with subsection 335.5010(b), including type of pregnancy testing permitted, time in advance of I-131 administration in which the tests shall be conducted, age range of patients to be tested, and criteria a physician may use to determine that a patient is not capable of childbirth.

The procedures do not need to be submitted to IEMA but must be retained by the licensee for the duration of the license. This gives licensees the flexibility to revise the procedures to enhance effectiveness without obtaining IEMA approval. Appendix S of this instructional set provides guidance on developing the procedures.

Licensees may find the list of informational notices on the U.S. NRC's Medical Uses Licensee Toolkit Web page useful in developing written directive procedures.

Safety Procedures for Treatment When Patients are Hospitalized

Although some therapy procedures are performed on an outpatient basis, these patients sometimes require hospitalization; therefore, the applicant's procedure should address the hospitalization, release and care of all radiopharmaceutical therapy patients. Patients or human research subjects that are administered radioactive materials under this Subpart and cannot be immediately released under 32 Ill. Adm. Code 335.2110 require specialized staff training, dedicated facilities and operational controls that are specified in 32 Ill. Adm. Code 335.5020 and 335.5030. Applicants are required to specify if they intend to administer radioactive materials which may require the patient or human research subject to be hospitalized in order to meet the patient release criteria in 32 Ill. Adm. Code 335.2110. Diagrams of use areas submitted under Item 4 should identify any areas which will be used to meet the requirements of 32 Ill. Adm. Code 335.5030. The applicant should focus on facilities to be used for radioactive drug therapy administration and patient accommodations (e.g., patient rooms). The most widely used source of radiopharmaceutical therapy is I-131 sodium iodide. If the radionuclide is administered in volatile liquid form, it is important to place the patient dosage in a closed environment (e.g., a fume hood) and consider the hazards from airborne I-131. Additionally, for both liquid and capsule form of I-131, applicants should recognize the source of potential

contamination from I-131 found in the patient's urine, perspiration, saliva, and other secretions. An assessment of potential public dose to adjacent rooms should also accompany the application. The description of training provided under Item 11 should include a commitment to include radiation safety instruction, prior to beginning work and at least annually, to personnel caring for patients or human research subjects who have been administered radioactive materials requiring a written directive as described in 32 Ill. Adm. Code 335.5020.

Release of Patients or Human Research Subjects

The following pertains to applicants that indicate they will administer radiopharmaceuticals identified in 32 Ill. Adm. Code 335.5010 and anticipate all patients/human research subjects will be able to be released in accordance with 32 Ill. Adm. Code 335.2110. A contingency plan is still required in the event an administration results in a patient/human research subject condition which does not allow patient release under 32 Ill. Adm. Code 335.2110 (e.g., an exposure rate exceeding the release rate specified in U.S. NRC Reg Guide 8.39, Rev. 1). This may be a written arrangement with another facility or alternate procedures. Submitting this information with the application will expedite IEMA's evaluation.

As referenced above, the U.S. NRC Regulatory Guide 8.39, Rev. 1, "Release of Patients Administered Radioactive Material" Rev. 1 provides additional guidance on release criteria. In addition, the guide includes a section on "Death of a Patient Following Radiopharmaceutical or Implants Administrations," as well as "Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child". A copy is available from the U.S. NRC here, https://www.nrc.gov/docs/ML1923/ML19232A081.pdf

Licensees may wish to review the medical section of the IEMA website (https://www2.illinois.gov/iema/NRS/RadSafety/pages/medical.aspx) for additional guidance on specific administrations.

Applicant Response

For all administrations requiring a written directive, commit to the establishment of procedures that meet all applicable requirements in 32 Ill. Adm. Code 335.1120. Appendix S of this instructional set provides guidance on developing these procedures.

Indicate if I-131 will be utilized only in capsule form or attach procedures for handling/storage of liquid I-131 in fume hoods as well as bioassay of personnel (See Section III, Items 9 and 22, respectively).

Indicate if the licensee intends to admit patients pending release under 32 Ill. Adm. Code 335.2110 or submit procedures for contingencies in which patients must be admitted for reasons other than 32 Ill. Adm. Code 335.2110 (e.g., emergency surgeries, admittance for other health complications. This may be a commitment that radiopharmaceuticals will not be administered if the patient is not a candidate for release, or the licensee will

send the patient who cannot be released to another facility that is properly equipped. An MOU to that effect should be attached.)

Appendix N contains a sample procedure to be followed using therapeutic radiopharmaceuticals. Either indicate that you will follow the procedure contained in Appendix N or submit an alternate procedure for Agency review.

Item 18. Brachytherapy

Authorization for use under 32 Ill. Adm. Code 335 Subpart H requires that the licensee develop, implement and maintain additional procedures for administrations requiring a written directive, handling brachytherapy sources and patients implanted with brachytherapy sources, calibration of source activity and patient release. These procedures should describe:

- Procedures for all administrations requiring a written directive, which address all applicable requirements in 32 Ill. Adm. Code 335.1120.

- Procedures for providing radiation safety instruction to nursing staff, patients and visitors. See Section III. Item 10 of this instructional set for additional information.

- Procedures detailing precautions to be used while handling sealed sources and preventing inadvertent disposal

- Procedures to be followed for the transport of sources from storage to the site of administration, including a description of the transport container

- Procedures to be followed in case of emergency surgery or patient death.

- In accordance with 32 Ill. Adm. Code 335.7100, the licensee's AMP or ophthalmic physicist must calculate the activity of each Sr-90 source that is used to determine the treatment times for ophthalmic therapy. The calibration procedures for therapy sources should address, in part, the method used to determine the exposure rate (or activity) under specific criteria (e.g., distances used for the measurement, whether the measurement is an "in air" measurement or done using a phantom configuration of the chamber with respect to the source(s) and device, scatter factors used to compute the exposure rate).

<u>Procedures for Administrations When a Written Directive Is Required</u>

The requirements for written directives (WD) are set forth in 32 Ill. Adm. Code 335.1110, "Written directives." If a written directive is generated or stored in a computerized system, the licensee must have a method of authenticating the AU's signature (*see "Supplementary Information," Section III, "Summary of Public Comments and Responses to Comments", as published in the Federal Register on April 24, 2002*).

Under 32 Ill. Adm. Code 335.1120, "Procedures for administrations requiring a written directive," medical use licensees are required to develop, maintain, and implement written procedures to provide high confidence that, among other items, each administration is in accordance with the WD and the patient's identity is verified. Therefore, licensees should have checks in place to ensure that the correct patient is treated and each component of the WD is met.

Licensees are reminded that procedures should correctly document the program currently in place. Licensees are required to determine if a medical event, as defined in 32 Ill. Adm. Code 335.20, has occurred. For purposes of determining whether medical event reporting is required, licensees should also provide definitive criteria for evaluating the adequacy of the dose delivered or activity implanted to the intended treatment site, compared to the prescribed dose, and the acceptability of the dose delivered to any other organ or tissue, compared to the dose expected from the administration defined in the written directive. Licensees are required for permanent implant brachytherapy, to determine, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

Additionally, under 32 Ill. Adm. Code 335.7090, the licensee must perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies.

At a minimum, written directive procedures for brachytherapy shall address the following items:

- Verifying the identity of the patient or human research subject;

- Verifying that the administration is in accordance with the treatment plan and the written directive;

- Checking both manual and computer-generated dose calculations; and

- Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Section 335.2140 or 335.8010;

- Determining if a medical event, as described in Section 335.1080, has occurred;

  NOTE: 32 Ill. Adm. Code 335.1080 lists the medical event criteria for permanent implant brachytherapy for administrations involving sealed sources implanted into a location "discontiguous" from the treatment site as documented in the post-implantation portion of the written directive. Discontiguous in general terms is used to describe things that are not contiguous in space, things that are not adjacent or touching, and things that have a gap in between or are disconnected or separate. As it

relates to the medical event criteria for permanent implant brachytherapy, discontiguous means a location that is not physically adjacent to or touching the treatment site.

- Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented;

- As required by 32 Ill. Adm. Code 335.7100 for sources used for ophthalmic treatments, specify the frequencies that licensee's authorized medical physicist or ophthalmic physicist will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

The procedures do not need to be submitted to IEMA but must be retained by the licensee for the duration of the license. This gives licensees the flexibility to revise the procedures to enhance effectiveness without obtaining IEMA approval. Appendix S of this instructional set provides guidance on developing the procedures.

Licensees may find the list of informational notices on the U.S. NRC's Medical Uses Licensee Toolkit Web page useful in developing written directive procedures.

Safety Procedures for Treatment When Patients are Hospitalized

Patients or human research subjects who are receiving brachytherapy under this Subpart and cannot be immediately released under 32 Ill. Adm. Code 335.2110 require specialized staff training, dedicated facilities and operational controls that are specified in 32 Ill. Adm. Code 335.7020 and 335.7030. Diagrams of use areas submitted under Item 4 should identify any areas which will be used to meet the requirements of 32 Ill. Adm. Code 335.7030. An assessment of potential public dose to adjacent rooms should also accompany the application. The description of training provided under Item 11 should include a commitment to include radiation safety instruction, prior to beginning work and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under Section 335.2110 as described in 32 Ill. Adm. Code 335.7020.

Applicant Response

- Commit to the development, implementation and maintenance of procedures for all administrations requiring a written directive, which address applicable requirements in 32 Ill. Adm. Code 335.1120 and, as applicable 32 Ill. Adm. Code 335.7100.

- Submit procedures detailing radiation safety instruction specified in 32 Ill. Adm. Code 335.7020 to nursing staff, patients and visitors. See Section III. Item 10 of this instructional set for additional information.

- Submit a procedure for handling brachytherapy sources and patients treated with brachytherapy sources as described in 32 Ill. Adm. Code 335 Subpart H.

- Submit procedures addressing the requirements of 32 Ill. Adm. Code 335 Subpart H, including accountability, handling and transport of brachytherapy sources.

- Submit procedures to prevent the inadvertent disposal of brachytherapy sources and meeting the requirements in 32 Ill. Adm. Code 335.7040.

- Submit procedures to be followed in the case of emergency surgery or patient death.

- Describe the emergency response equipment and its availability in accordance with 32 Ill. Adm. Code 335.7030(b).

- Appendix P contains a sample procedure which may be utilized when treating patients with brachytherapy sources. Either indicate that you will follow the procedure contained in Appendix P or submit an alternate procedure for Agency review.

Item 19. Remote Afterloaders, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Authorization for use under 32 Ill. Adm. Code 335 Subpart I requires that the licensee develop, implement and maintain additional procedures for administrations requiring a written directive, performing full calibrations of sealed sources, performing spot check measurements and responding to emergency situations involving therapy units. These procedures should describe:

- Procedures for all administrations requiring a written directive, which address all applicable requirements in 32 Ill. Adm. Code 335.1120.

- Procedures for providing radiation safety instruction to all individuals who operate the unit, as appropriate to the individual's assigned duties. See Section III. Item 10 of this instructional set for additional information.

- Procedures for responding to an abnormal situation when the operator is unable to place the sources in the shielded position or remove the patient or human research subject from the radiation field with controls from outside the treatment room.

- Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions.

- The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure.

- The names and telephone numbers of the authorized users, the authorized medical physicist and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

- The calibration procedures for therapy sources which address the method used to determine the exposure rate (or activity) under specific criteria (e.g., distances used for the measurement, whether the measurement is an "in air" measurement or done using a phantom configuration of the chamber with respect to the source(s) and device, scatter factors used to compute the exposure rate).

- Written procedures established by the authorized medical physicist (AMP) for spot-check measurements of sealed sources and devices used for therapy. Calibration procedures described by the AAPM or any published protocol approved by a nationally recognized body, as applicable, may be used.

Procedures for calibration of therapy sources and spot-check measurements

For sealed sources used in a therapy unit, the licensee must possess a calibrated dosimetry system (e.g., Farmer chamber, electrometer, well-type ionization chamber) that will be used to perform calibration measurements of sealed sources to be used for patient therapy. Dosimetry systems and sealed sources used to calibrate the licensee's dosimetry systems must be traceable to NIST or to a laboratory accredited by AAPM, pursuant to 32 Ill. Adm. Code 335.8080, "Dosimetry Equipment." For sealed sources used in therapy, and in particular, for new types of use, licensees should select dosimetry equipment that will accurately measure the output or the activity of the source. The licensee must maintain records of calibrations of dosimetry equipment for the duration of the license.

Licensees must perform full calibrations before first medical use and at intervals as defined in 32 Ill. Adm. Code 335.8090, 32 Ill. Adm. Code 335.8160, and 32 Ill. Adm. Code 335.8190. In addition, licensees must perform full calibrations whenever one of the following conditions are met:

- spot-check measurements (if required) indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for decay

- following replacement of the sources or reinstallation of the unit in a new location not previously described in the license

- following any repairs of the unit that include removal of sealed sources or major repair of the components associated with the source exposure assembly

The licensee's AMP must perform full calibrations of sealed sources and devices used for therapy in accordance with published protocols currently accepted by nationally recognized bodies (e.g., AAPM, American College of Radiology, ANSI). The calibration procedures for therapy sources should address, in part, the method used to

determine the exposure rate (or activity) under specific criteria (e.g., distances used for the measurement, whether the measurement is an "in air" measurement or done using a phantom configuration of the chamber with respect to the source(s) and device, scatter factors used to compute the exposure rate).

In addition, the licensee must perform spot-check measurements of sealed sources and devices used for therapy in accordance with written procedures established by the AMP (32 Ill. Adm. Code 335.8100, 32 Ill. Adm. Code 335.8170 and 32 Ill. Adm. Code 335.8200). Calibration procedures described by the AAPM or any published protocol approved by a nationally recognized body, as applicable, may be used. See Appendix Q of this instructional set for model procedures for performing spot-checks of remote afterloader devices. In addition, AAPM Report No. 41, "Remote Afterloading Technology (Remote Afterloading Technology Task Group No. 41)," 1993, may also be helpful.

In accordance with 32 Ill. Adm. Code 335.8110, licensees must perform surveys around therapy devices to ensure that the maximum radiation levels and the average radiation levels from the surface of the main source safe with the sources in the shielded position do not exceed the levels stated in the SSD registry.

Procedures for Administrations When a Written Directive Is Required

The requirements for written directives (WD) are set forth in 32 Ill. Adm. Code 335.1110, "Written directives." If a written directive is generated or stored in a computerized system, the licensee must have a method of authenticating the AU's signature (*see "Supplementary Information," Section III, "Summary of Public Comments and Responses to Comments", as published in the Federal Register on April 24, 2002*). Under 32 Ill. Adm. Code 335.1120, "Procedures for administrations requiring a written directive," medical use licensees are required to develop, maintain, and implement written procedures to provide high confidence that, among other items, each administration is in accordance with the WD and the patient's identity is verified. Therefore, licensees should have checks in place to ensure that the correct patient is treated and each component of the WD is met.

Licensees are reminded that procedures should correctly document the program currently in place. Licensees are required to determine if a medical event, as defined in 32 Ill. Adm. Code 335.20, has occurred. For purposes of determining whether medical event reporting is required, licensees should also provide definitive criteria for evaluating the adequacy of the dose delivered or activity implanted to the intended treatment site, compared to the prescribed dose, and the acceptability of the dose delivered to any other organ or tissue, compared to the dose expected from the administration defined in the written directive.

Additionally, under 32 Ill. Adm. Code 335.8230, the licensee must perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies.

At a minimum, written directive procedures for remote afterloaders, teletherapy and GSR units shall address the following items:

- Verifying the identity of the patient or human research subject;
- Verifying that the administration is in accordance with the treatment plan and the written directive;
- Checking both manual and computer-generated dose calculations;
- Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Section 335.2140 or 335.8010; and
- Determining if a medical event, as described in Section 335.1080, has occurred;

The procedures do not need to be submitted to IEMA but must be retained by the licensee for the duration of the license. This gives licensees the flexibility to revise the procedures to enhance effectiveness without obtaining IEMA approval. Appendix S of this instructional set provides guidance on developing the procedures.

Licensees may find the list of informational notices on the U.S. NRC's Medical Uses Licensee Toolkit Web page useful in developing written directive procedures.

Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources

In accordance with 32 Ill. Adm. Code 335.8020 and 32 Ill. Adm. Code 335.8150, licensees must ensure that therapy devices containing sealed sources are installed, maintained, adjusted, repaired, and inspected by persons specifically licensed to conduct these activities. Applicants requesting authorization to install, maintain, adjust, repair, and inspect their own therapy devices containing sealed sources must develop, document, submit, and implement those procedures, in accordance with 32 Ill. Adm. Code 340. 'Maintenance and repair' includes installation, replacement, and relocation or removal of the sealed source(s) or therapy unit that contains a sealed source(s). 'Maintenance and repair' also includes any adjustment involving any mechanism on the therapy device, treatment console, or interlocks that could expose the source(s), reduce the shielding around the source(s), affect the source drive controls, or compromise the radiation safety of the unit or the source(s). IEMA requires that maintenance and repair (as defined above) be performed only by persons specifically licensed by IEMA, the U.S. NRC or an Agreement State to perform such services.

No response is required if the licensee contracts with personnel who are licensed by IEMA, the U.S. NRC or an Agreement State to install, maintain, adjust, repair, and inspect the specific therapy device possessed by the licensee. However, if the applicant requests that one of its own employees, who is trained by the manufacturer, be authorized to perform the aforementioned activities, the applicant must provide sufficient

information to allow IEMA to evaluate and approve such authorization in accordance with 32 Ill. Adm. Code 335.8020 and 32 Ill. Adm. Code 335.8150.

Note: The applicant should specify only those installation, maintenance, inspection, adjustment, and repair functions, as described in a certificate or letter from the manufacturer of the device, that document the employee's training in the requested function(s).

Applicant Response

Commit to the development, implementation and maintenance of procedures for all administrations requiring a written directive, which address applicable requirements in 32 Ill. Adm. Code 335.1120.

Submit procedures required under 32 Ill. Adm. Code 335.8040(a)(4).

Submit the procedures required by 32 Ill. Adm. Code 335.8100, 32 Ill. Adm. Code 335.8170, and 32 Ill. Adm. Code 335.8200, if applicable to the license application.

Provide a description of the following:

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room,
- Area radiation monitoring equipment,
- Viewing and intercom systems (except for LDR units),
- Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room,
- Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons, and
- Emergency response equipment
- If the applicant wishes to perform services under 32 Ill. Adm. Code 335.8020; submit the name of the proposed employee(s), types of activities requested, description of the training and experience demonstrating that the proposed employee is qualified for the use requested, a copy of the manufacturer's training certification and an outline of the training in procedures to be followed, and a written commitment from the licensee that the trained employee will follow manufacturer procedures.

Item 20. Other Medical Uses of Radioactive Material or Radiation from Radioactive Material (Emerging Technologies)

Authorization for use under 32 Ill. Adm. Code 335.2140 requires that the licensee develop, implement and maintain additional procedures for any administrations requiring a written directive, associated safety precautions, and the manner in which patients will be released in accordance with 32 Ill. Adm. Code 335.2110. These procedures should describe, as applicable:

- Procedures for all administrations requiring a written directive, which address all applicable requirements in 32 Ill. Adm. Code 335.1120.
- Procedures for providing radiation safety instruction to staff, patients and visitors. See Section III. Item 10 of this instructional set for additional information.
- Procedures describing the radionuclide, form, activity, and the general safety precautions to be employed
- Procedures describing the expected levels of contamination and how to control them
- Procedures detailing the methodology for measurement of dosages or doses to be administered to patients or human research subjects;
- Procedures to be followed in case of emergency surgery or patient death.

In addition to the procedures described above, 32 Ill. Adm. Code 335.2140 specifically requires applicants seeking authorization for emerging technologies submit the following:

- A request signed by management that is consistent with the requirements of 32 Ill. Adm. Code 340.310(b);
- A description of the facilities, including a diagram, to be utilized
- The necessary equipment and its calibration or maintenance
- Training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officers, authorized users, authorized medical physicists, and ophthalmic physicists, if not already previously submitted;
- If applicable, a description of the sealed source and/or device as per 32 Ill. Adm. Code 330.280(i) and (k), as applicable, or, alternately, identification of the product in the Sealed Source and Device Registry.
- Information regarding any additional aspects of the medical use of radioactive material that are applicable to radiation safety.

- Licensing guidance on the U.S. NRC's Medical Uses Licensee Toolkit Web page or the IEMA website should be reviewed to determine if calibration and use procedures need to be submitted for the particular 32 Ill. Adm. Code 335.2140 medical use.

Procedures for Administrations When a Written Directive Is Required

The requirements for written directives (WD) are set forth in 32 Ill. Adm. Code 335.1110, "Written directives." If a written directive is generated or stored in a computerized system, the licensee must have a method of authenticating the AU's signature (*see "Supplementary Information," Section III, "Summary of Public Comments and Responses to Comments", as published in the Federal Register on April 24, 2002*).

Under 32 Ill. Adm. Code 335.1120, "Procedures for administrations requiring a written directive," medical use licensees are required to develop, maintain, and implement written procedures to provide high confidence that, among other items, each administration is in accordance with the WD and the patient's identity is verified. Therefore, licensees should have checks in place to ensure that the correct patient is treated and each component of the WD is met.

Licensees are reminded that procedures should correctly document the program currently in place. Licensees are required to determine if a medical event, as defined in 32 Ill. Adm. Code 335.20, has occurred. For purposes of determining whether medical event reporting is required, licensees should also provide definitive criteria for evaluating the adequacy of the dose delivered or activity implanted to the intended treatment site, compared to the prescribed dose, and the acceptability of the dose delivered to any other organ or tissue, compared to the dose expected from the administration defined in the written directive.

As applicable, written directive procedures for emerging technologies shall address the following items:

- Verifying the identity of the patient or human research subject;

- Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

- Checking both manual and computer-generated dose calculations;

- Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by Section 335.2140;

- Determining if a medical event, as described in Section 335.1080, has occurred;

- Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-

implantation portion of the written directive, unless a written justification of patient unavailability is documented; and

- Determining, for administrations of I-131 in quantities greater than 1.11 megabecquerel (30 microcuries), the criteria to be used to identify patients required to be tested for pregnancy in accordance with subsection 335.5010(b), including type of pregnancy testing permitted, time in advance of I-131 administration in which the tests shall be conducted, age range of patients to be tested, and criteria a physician may use to determine that a patient is not capable of childbirth.

The procedures do not need to be submitted to IEMA but must be retained by the licensee for the duration of the license. This gives licensees the flexibility to revise the procedures to enhance effectiveness without obtaining IEMA approval. Appendix S of this instructional set provides guidance on developing the procedures.

Licensees may find the list of informational notices on the U.S. NRC's Medical Uses Licensee Toolkit Web page useful in developing written directive procedures.

Release of Patients or Human Research Subjects

If patients administered radioactive material under 32 Ill. Adm. Code 335.2140 require hospitalization; the applicant's procedure should address the hospitalization, release and care of therapy patients. If patients or human research subjects that are administered radioactive materials under this Subpart cannot be immediately released under 32 Ill. Adm. Code 335.2110, procedures should be submitted that detail the specialized staff training, dedicated facilities and operational controls required. Applicants are required to specify if they intend to administer radioactive materials which may require the patient or human research subject to be hospitalized in order to meet the patient release criteria in 32 Ill. Adm. Code 335.2110. Diagrams of use areas submitted under Item 4 should identify any areas which will be utilized, including any patient rooms used when release cannot be afforded under 32 Ill. Adm. Code 335.2110. As applicable, an assessment of potential public dose to adjacent rooms should also accompany the application. The description of training provided under Item 11 should include a description of the safety instructions to be provided to staff that are specific to the proposed use.

As referenced above, the U.S. NRC Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material" Rev. 1 provides additional guidance on release criteria. In addition, the guide includes a section on "Death of a Patient Following Radiopharmaceutical or Implants Administrations," as well as "Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child". A copy is available from the U.S. NRC here, https://www.nrc.gov/docs/ML1923/ML19232A081.pdf

Licensees may wish to review the medical section of the IEMA website (https://www2.illinois.gov/iema/NRS/RadSafety/pages/medical.aspx) for additional guidance on specific administrations.

Applicant Response

- For all administrations requiring a written directive, commit to the establishment of procedures that meet all applicable requirements in 32 Ill. Adm. Code 335.1120. Appendix S of this instructional set provides guidance on developing these procedures.

- If applicable, submit procedures for patient release in accordance with 32 Ill. Adm. Code 335.2110.

- Submit procedures and submittals required under 32 Ill. Adm. Code 335.2140(b) and (c).

Item 21. Personnel Monitoring

Licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure. The use of individual monitoring devices for external dose is required, pursuant to 32 Ill. Adm. Code 340.520(a), for:

- Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in Section 340.210(a);

- Minors who are likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in 32 Ill Adm. Code 340.270

- Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem); and

- Individuals entering a high or very high radiation area

Internal exposure monitoring is required, pursuant to 32 Ill. Adm. Code 340.520(b), for the following:

- Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable annual limit on intake for ingestion and inhalation (ALIs).

  NOTE: ALIs are listed in table 1, columns 1 and 2 of appendix B to 10 CFR 20.

- Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.5 mSv (0.05 rem).

The licensee must reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person in accordance with 32 Ill. Adm. Code 340.210(g). Applicants should review the use of all regulated activities (e.g., X-ray and accelerator operation) when determining, for IEMA licensee requirements, who is an occupationally exposed individual.

Licensee Evaluation of Potential Dose

The licensee must evaluate the exposure of all occupational workers (e.g., nurses, technologists) to determine if monitoring is required. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas.

If this prospective evaluation shows that an adult individual's dose is not likely to exceed 10 percent of an applicable regulatory limit, there are no recordkeeping or reporting requirements in regard to the individual's exposure. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. Only dose that could be received at the facility performing the evaluation need be considered when determining the need for monitoring, and associated recordkeeping and reporting. If it was determined that monitoring was not required, and a subsequent evaluation shows that the 10 percent threshold has or will be exceeded, the dose received when monitoring was not provided should be estimated, recorded, and reported. These estimates can be based on any combination of work location radiation monitoring or survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received. The licensees must also consider the internal and external dose and the occupational worker's assigned duties when evaluating the need to monitor occupational radiation exposure and must have a program in place to sum those exposures in accordance with 32 Ill. Adm. Code 340.220.

If the prospective evaluation shows that the individual adult is likely to exceed 10 percent of an applicable limit, then monitoring is required, regardless of the actual dose received. Licensees must provide individual radiation exposure data to each worker as required by 32 Ill. Adm. Code 400.130.

When evaluating doses from xenon gas or aerosols, licensees may take credit for the reduction of dose resulting from the use of xenon or aerosol traps. Licensees may vent xenon gas or aerosols directly to the atmosphere, as long as the effluent concentration is within 32 Ill. Adm. Code Part 340 limits.

Personnel Monitoring Devices and Exchange Frequency

If external dose monitoring is necessary, the applicant should evaluate the type of personnel dosimetry, such as film badges, optically stimulated luminescence dosimeters (OSLs), and thermoluminescent dosimeters (TLD), that personnel will use. If occupational workers handle licensed material, the licensee should evaluate the need to provide extremity monitors, which are required if workers are likely to receive a dose in excess of 0.05 Sv [5 rems] shallow-dose equivalent, in addition to whole body badges. Additionally, applicants should ensure that their personnel dosimetry program contains provisions that personnel monitoring devices be worn in such a way that the part of the body likely to receive the greatest dose will be monitored.

Some licensees use self-reading or electronic dosimeters in lieu of processed dosimetry. This is acceptable if the regulatory requirements are met, and the dosimeter can accurately assess the types of radiation for which the licensee is authorized. Refer to ANSI N322-1997, "Inspection, Test, Construction, and Performance Requirements For Direct Reading Electrostatic/Electroscope Type Dosimeters" and Regulatory Guide 8.4, "Personnel Monitoring Device—Direct-Reading Pocket Dosimeters," for more information. If pocket dosimeters are used to monitor personnel exposures, applicants should state the useful range of the dosimeters, along with the procedures and frequency for their calibration [32 Ill. Adm. Code 340.510(e)].

When personnel dosimeters that require processing to determine the radiation dose are used to comply with the individual monitoring requirement for external doses in 32 Ill. Adm. Code 340.520(a), dosimeters must be processed by a National Voluntary Laboratory Accreditation Program (NVLAP)-accredited processor [32 Ill. Adm. Code 340.510(d)]. Most licensees use either OSLs, TLDs, or film badges. NUREG-1556 Volume 11, Rev. 1 states the exchange frequency for dosimeters is typically monthly or quarterly. Consistent with nationally recognized guidance, licensees should exchange dosimetry at least quarterly for diagnostic medical use (32 Ill. Adm. Code 335.3010 or 335.4010), excluding PET. For authorized use including PET or any therapeutic use, the magnitude of potential exposures warrants monthly dosimetry exchange. After reviewing the radiation protection program's use and exchange frequency, applicants should obtain technical specifications from their NVLAP-approved processor to determine the appropriate type(s) of dosimetry. The NIST maintains a directory of laboratories that are NVLAP-accredited.

RG 8.40, "Methods for Measuring Effective Dose Equivalent from External Exposure," July 2010, provides guidance for evaluating occupational dose when some exposure is due to X-rays, and dosimeters are used to measure exposure behind lead aprons and elsewhere.

Additional guidance on occupational exposure monitoring is available in Table 8–2 of the U.S. NRC's NUREG 1556, Volume 9, Revision 3.

NOTE: In accordance with 32 Ill. Adm. Code 340.1110, no licensee or registrant shall subtract radiation exposures from official personnel monitoring records without the prior written approval of the Agency.

Applicant Response

The application form provides an area for the licensee to indicate the dosimetry type to be used and the exchange frequency. This may be appropriate for radiation programs of limited scope and authorized use(s). However, complex programs with multiple departments and/or forms of authorized use may determine the need for additional forms of dosimetry and exchange frequencies that vary by department. Occupational exposure monitoring programs that exceed a simple selection of dosimetry type and exchange frequency should be detailed in a procedure.

Appendix T of this instructional set provides model procedures for monitoring external occupational exposure. An applicant may utilize this model procedure or provide an alternate procedure which demonstrates compliance with the referenced regulations. Alternate procedures should include the Radiation Safety Officer's role in the personnel dosimetry program, the established investigational levels and the resulting actions the RSO will take if those levels are met or exceeded.

AND

Provide information for dosimetry to be processed and evaluated by a National Voluntary Laboratory Accreditation Program (NVLAP)-approved processor that is exchanged at a frequency recommended by the processor. Specify the type of dosimetry to be utilized and the associated exchange frequency.

AND

Submit documentation demonstrating that any unmonitored individuals (ancillary staff, housekeeping, security) are not likely to receive, in one year, a radiation dose in excess of the limits in 32 Ill. Adm. Code 340.520.

If pocket dosimeters are used to monitor personnel exposures,

- Provide the useful range of the dosimeters, along with the procedures and frequency for their calibration [32 Ill. Adm. Code 340.510(e)].

If self-reading or electronic dosimeters are used in lieu of processed dosimetry, provide the following:

- A statement that the self-reading or electronic dosimeters are deemed appropriate by the manufacturer for the type(s) of radiation and occupational exposures for which they are being utilized.

- Commit to the development of procedures or operational controls that limit administrative access to exposure data (typically RSO/ARSO and an alternate only).

- Specify the minimum read frequency (dependent upon the types of use and the licensee's evaluation of potential dose). This is typically monthly or quarterly.

- Commit to the establishment of administrative procedures to address failures on read frequencies (e.g., emails/alerts at 1 week prior to deadline, daily reminders after 30 days, physical retrieval no later than 45 days or declaration of unit as lost with assignment of dose to individual's record and reissuance of new unit).

Item 22. Bioassay

It may be necessary to assess the intake of radioactivity for occupationally exposed individuals in accordance with 32 Ill. Adm. Code 340.1240 and 32 Ill. Adm. Code 340.520. Bioassays are typically performed when individuals work with millicurie quantities of unsealed hydrogen-3, iodine-125 or iodine-131. Uptake can be highly dependent upon the chemical and physical form, the licensee's procedures and the equipment used. Significant thyroid uptakes have been detected in individuals who open and prepare I-131 therapeutic doses. Bioassay should also be considered for personnel (e.g., radiation safety, nursing) who are involved in other aspects of therapy procedures. The applicant should indicate the need for bioassay has been thoroughly considered and should describe the proposed bioassay program, if applicable.

If internal dose assessment is necessary, the applicant shall measure the following:

- Concentrations of radioactive material in air in work areas
- Quantities of radionuclides in the body
- Quantities of radionuclides excreted from the body
- Combinations of these measurements

The applicant should describe in its procedures the criteria used to determine the type of bioassay and the frequencies at which bioassays (both in vivo and in vitro) will be performed to evaluate intakes. The criteria should also describe how tables of investigational levels are derived, including the methodology used by the evaluated internal dose assessments (i.e., the empirical models used to interpret the raw bioassay data). The bioassay procedures should provide for baseline, routine, emergency, follow-up and termination bioassays. If a commercial bioassay service will be used, the applicant should ensure that the service is licensed by IEMA, the U.S. NRC or an Agreement State for that service or provide an alternative for review.

Acceptable criteria that applicants may use in developing their bioassay programs are outlined in RG 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," July 1993.

Applicant Response

Appendix O contains a sample procedure to be followed when performing radioiodine bioassay. If radioiodine is to be used, verify that procedures contained in Appendix O will be followed or submit an alternate procedure for Agency review.

Item 23. Part 337 Security Requirements

Indicate if the requested authorizations will result in the licensee possessing an aggregated Category 1 or Category 2 quantity of radioactive material. See Section I.J of

this instructional set for additional requirements for licensees subject to 32 Ill. Adm. Code 337.

Table 1 of Appendix A, "Category 1 and Category 2 Radioactive Materials," to 32 Ill. Adm. Code 337 lists Category 1 and Category 2 threshold quantities of radioactive material. The applicant should refer to this table to determine whether its proposed activities would be subject to the 32 Ill. Adm. Code 337 requirements.

Item 24. License Fees

Refer to 32 Ill. Adm. Code 331 and the appropriate fee schedule to review the applicable fees. You will receive a billing statement from the Agency regarding payment of fees. **Do not send a fee payment with the application.** Note that for new applications however, that although a billing statement will be mailed to new applicants allowing a certain time period to remit the payment, **the license will not be issued until the fee for the new application has been paid.** Therefore, prompt payment upon billing may avoid unnecessary delay in issuing a license. Questions concerning fees should be directed to the Agency's Division of Fiscal Management. The regulations also include a requirement for payment of an annual recovery/remediation fee for use in cases where such costs for decontamination/disposal cannot be recovered from the responsible parties or available financial assurance documents.

Note: The annual and remote site fees listed in Appendix F to Part 331 are nonrefundable and are assessed on a 12-month period.

Applicant response

Populate the fee category applicable to the licensed activities. Guidance on this topic may be obtained by contacting the IEMA Radioactive Materials Branch, Licensing Unit.

Indicate if the applicant or licensee is subdivision of a State, County or Municipality or is an education institution as defined in 32 Ill. Adm. Code 331.110(c).

Item 25. Financial Assurance

Most medical licensees will not be required to post financial assurance because they do not possess radioactive material in quantities exceeding those listed in 32 Ill. Adm. Code 326. The licensee should review Part 326 to ensure they are not required to post financial assurance and indicate such on the application. Should the licensee possess activities requiring financial assurance, the applicant should reference the, "Guidance Document on Financial Assurance" which is available on the Agency's website.

Item 26. Certification

A representative of the corporation or legal entity filing the application must sign and date the application. The application must contain an original signature and date by the applicant, if acting as an individual or by an individual who is authorized by management to sign on behalf of the licensee. A statement signed by facility management granting authority to sign license requests and related documents is required for applications not signed by an officer or the administrator of the facility. Unsigned applications or applications with stamped or computer-generated signatures will be returned for proper signature. For applications not from individuals the Federal Employers Identification Number (FEIN) should be included in the Certification block.

If the individual signing the application is unknown to the Agency (not listed on any license previously), complete the Release and Authorization Full Due Diligence Form to expedite processing of the application. A copy may be obtained from the Agency website and is included as Exhibit A.
https://www2.illinois.gov/iema/NRS/RadSafety/documents/RAM_Documents/BackgroundCheck.pdf

NOTE: Submit the original, signed copy of the application. Retain a copy for reference and records. More detailed instructions are in Section II. HOW TO FILE

IV. LICENSE AMENDMENTS

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The change is not in effect until the amendment has been issued. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date [32 Ill. Adm. Code 330.320]. In case of a medical emergency requiring an expedited license amendment, contact the materials licensing staff at IEMA. Please do not request expedited amendments without first speaking with a member of licensing staff. Note that Type A specific licensees of broad scope authorized for medical use should review the exemptions identified in 32 Ill. Adm. Code 330.270(f).

In accordance with 32 Ill. Adm. Code 335.40, "License amendments," a licensee is required to apply for and receive a license amendment before several activities can occur, including:

- Before using radioactive material for any use not permitted by the license;
- Permitting anyone to work as an authorized user (AU) for medical uses, authorized medical physicist (AMP) or ophthalmic physicist, unless the individual meets one of the exceptions listed in 32 Ill. Adm. Code 335.40(b)

- Changing the RSO

- Permitting an individual to work as an ARSO or before the RSO assigns a current ARSO duties and tasks that differ from those for which this individual is authorized on the license;

- Before receiving radioactive material in excess of the amount, in a different form, or a different radionuclide than is authorized on the license;

- Receiving a sealed source from a different manufacturer or of a different model number than authorized by the license unless the sealed source is used in manual brachytherapy, is listed in the SSD registry, for the quantity and for an isotope authorized by the license

- Before adding to or changing any area of use identified on the license, including changing the shielding in any area approved on the license. This includes areas used in accordance with 32 Ill. Adm. Code 335.3010 or 335.4010 if the change includes addition or relocation of an area where PET radionuclides are used, administered, produced, or stored. If the use area is used only in accordance with 32 Ill. Adm. Code 335.3010 or 335.4010, no amendment is required. However, note the notification requirements in 32 Ill. Adm. Code 335.45.

- Before changing statements, representations and procedures that are incorporated into the license (e.g., "tied down in a license commitment"). These would include, but are not limited to, procedures required to be submitted with the license application (typically those listed in 10 CFR 35.610, 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645)

Requests for license amendments must identify the license by number and clearly describe the exact nature of the changes, additions, or deletions requested. A licensee requesting a license amendment should do the following:

- Use the most recent guidance and current regulations in preparing the amendment request

- Submit the request in letter form or use appropriate Agency forms

- Clearly state the license number and licensee name on the letter

- Identify references to previously submitted information and documents by indicating the applicable date, page, and/or paragraph

- Ensure the request is sent with a valid electronic signature, or physical signature, by an Agency approved contact to the license or the RSO
- Follow Section II. B. "Where to File" for submitting amendment requests via paper or electronically (submission for amendment requests is the same process as applications)

- Licensees must retain a copy of the amendment request submitted to the Agency, no matter the format, for inspection purposes and for the licensee to reference as needed

For all amendments that require a fee, the licensee will be billed by the Agency. Do not send payment or payment information with an amendment request. See Section II. D. for additional information.

V. LICENSE RENEWALS

Timely Renewal

It is the licensee's obligation to keep the license current. In order to continue the license after its expiration date, the licensee must submit an application for license renewal at least 30 days before the expiration date [32 Ill. Adm. Code 330.320(a)]. If the renewal application is timely filed prior to the expiration date, your license will remain in effect until the Agency takes final action regarding the application. This filing will ensure that the license does not expire until final action on the application has been taken by the Agency as provided for by 32 Ill. Adm. Code 330.330. If the licensee has a Reclamation Plan and Cost Estimate for financial assurance filed with the Agency, it must be updated as part of the renewal application. Upon approval of the Cost Estimate, you may need to revise your financial assurance instrument.

It is critical to note that, in accordance with 32 Ill. Adm. Code 330.320(c), if the expiration date passes without license termination requirements having been met by the licensee and/or without a timely renewal application having been filed by the licensee before the expiration date, the authority of the licensee to engage in licensed activities shall expire at the end of the specified expiration date. Immediately upon the passing of the expiration date, a licensee that has neither met license termination requirements nor filed a timely application under subsection (a) shall:

- Cease use of radioactive material;
- Store all radioactive material in a secure location and limit activities involving radioactive material to those necessary for shipping, transferring and disposing of the radioactive material;
- File either a new application for a specific license or provide information equivalent to that required on Agency Form KLM.007 (Certificate Termination and Disposition or Radioactive Material);
- Comply with all applicable Agency regulations;
- Comply with the license conditions of the expired license until either a new license is issued or the termination requirements of Section 330.325 are met; and

- Comply with any orders issued by the Agency in accordance with the Act and 32 Ill. Adm. Code 200 that result from violation of subsection (a) or any other applicable provisions of Agency regulations or the Act.

Complete Renewal Application

Renewals require a complete and up-to-date application, including all required program elements outlined in this instructional set, and current information about the applicant's program. Be sure to use the most recent guidance in preparing a renewal application. Applications should be submitted without reference to documentation and information submitted previously, except for previously approved users. Training documentation for personnel currently listed on the license does not need to be submitted as part of the renewal application as long as the material and uses for each individual are the same as currently authorized on the license. If references to other previously submitted documentation cannot be avoided, they are acceptable provided:

- The reference is made in response to a particular item of required information (e.g., radiation instrument calibration procedures);

- The reference is clear and specific (e.g., title of document, date of submission, page and paragraph); and

- The referenced document contains all information required for a particular item at the time of renewal.

- Any previous exemptions granted to the licensee must be resubmitted in their entirety.

Renewal applications should be submitted in accordance with the procedures outlined in Section II (Filing an Application) of these instructions.

Expedited Renewal Application

In an effort to streamline the license renewal process, the Agency has implemented an Expedited Renewal option. Expedited renewals are available to a licensee whose previous renewal was not expedited, has no significant noncompliance or enforcement history, the management and scope of operations have not substantively changed, and the procedures and facilities utilized by the licensee are expected to remain the same. If the licensee is afforded an expedited renewal, the Agency still expects a comprehensive review of your program. However, the applicant need only submit for Agency review those changes required to update the existing license to reflect current licensed operations and facilities, conform with regulatory requirements, informational notices, and inspection and enforcement activities.

After the desired changes are identified, complete the expedited renewal form "EXPEDITED RENEWAL FORM FOR A MEDICAL RADIOACTIVE MATERIAL LICENSE". Attach all pertinent information pertaining to the desired changes and

submit the form with attachments to the Agency. If no changes appear to be necessary or desired, indicate this on the Expedited Renewal Form, complete the remaining items, and submit it to the Agency. Please reference the requirements for timely renewal discussed above.

The Agency does not discourage licensees from submitting a complete renewal application, in lieu of an expedited application. If there have been significant changes to the regulations, guidance, or your program since the last renewal, you should review the impact of these changes on your program and consider which renewal option to pursue. Periodically, the Agency will require the submittal of a complete renewal application to ensure that all program elements are current.

Licensees are subject to all applicable rules, regulations, representations and orders of the Agency and to any conditions specified on the license.

VI. LICENSE TERMINATIONS

A licensee may request termination of a radioactive material license at any time. However, in accordance with 32 Ill. Adm. Code 330.310(i), a licensee must notify the Agency in writing not later than 60 days after principal activities involving the use of radioactive materials at the site or in a separate building or outdoor area have not occurred for a period of 2 years, and the licensee has not decontaminated the site or area. In accordance with 32 Ill. Adm. Code 340.1310, written notification must be provided to the Agency 30 days in advance of vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material. To terminate a license, the licensee must meet the requirements of 32 Ill. Adm. Code 330.325, which include:

- Cease use of radioactive material;
- Notify IEMA, in writing, within 30 days prior to the expiration date, when a decision is made to permanently cease licensed activities;
- Transfer or dispose of all licensed radioactive material in the licensee's possession in accordance with 32 Ill. Adm. Code 340;
- Certify the disposition/transfer of licensed materials by submission of IEMA Form KLM.007, "Certificate – Termination and Disposition of Radioactive Material," (see Exhibit D); and
- Conduct necessary decommissioning and perform radiation monitoring or the equivalent in accordance with 32 Ill. Adm. Code 330.325(b)(1)(F). Submit copies of the latest leak test results for each source possessed under the license. For sources designed to emit beta/gamma radiation the leak test results shall be within the previous six months and for sources designed to emit alpha radiation the leak test results shall be within the previous three months.

- Submit a record documenting that a licensee noted on KLM.007 received each source transferred.

- If applicable, submit for Agency approval a plan for reclaiming the facility, including decontamination and removal of residual contamination. See additional requirements for detectable levels or residual radioactive contamination in 32 Ill. Adm. Code 330.325(b)(3).

- Identify where records will be retained that are required under 32 Ill. Adm. Code 340.1140 or transfer to the Agency as necessary.

- Pay any outstanding fee or civil penalty owed to IEMA.

In general, most medical licensees use licensed material with short half-lives [e.g., technetium-99m (Tc-99m) with a 6-hour half-life] and sealed sources (e.g., dose calibrator sources and manual brachytherapy sources). Therefore, in these instances, the licensees should submit the following:

- Area radiation level surveys, including a description of instruments used, showing that all areas previously used are at background

- Area contamination wipes, including a description of instruments used, showing that all areas previously used are at background

- Leak tests for all sealed sources transferred or disposed

- Transfer or disposal documentation for all sealed sources (and unsealed material, if applicable)

- Indicate the radionuclides in use and the last dates of use.

The Agency reserves the right to perform confirmatory monitoring of licensed facilities prior to termination.

VI. TIMELY NOTIFICATION OF TRANSFER OF CONTROL OR BANKRUPTCY

Transfer of Control

Licensees must provide all supporting information and obtain IEMA's prior, written consent before transferring control of the license, also referred to as a "change of ownership" and/or "transferring the license." Notification shall be provided to the Agency, including the identity and technical qualifications of the proposed transferee, not later than 90 days prior to the transfer [32 Ill. Adm. Code 330.310(c)(1)]. Transferring control may be the result of mergers, buyouts, or majority stock transfers.

Although it is not IEMA's intent to interfere with the business decisions of licensees, under 32 Ill. Adm. Code 330.310(c), licensees must obtain prior IEMA's written consent before transferring control of the license to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid U.S. NRC licenses or Agreement State licenses.
- Materials are properly handled and secured.
- Persons using these materials are capable, competent, and committed to implementing appropriate radiological controls.
- A clear chain of custody is established to identify who is responsible for disposition of records and licensed material.
- The transferee has the financial resources to decommission the license, if necessary.
- Adequate financial assurance is provided for compliance with the applicable IEMA requirements, if required.
- Public health and safety are not compromised by the use of such materials.

Note that detailed instructions and a worksheet are available on the Agency website to facilitate the submittal of necessary transfer of control information to IEMA.

Notification of Bankruptcy Proceedings

In accordance with 32 Ill. Adm. Code 330.310(j), the Agency must be immediately notified in writing following the filing of a voluntary or involuntary petition for bankruptcy by or against a licensee, an entity controlling the licensee or listing the license or licensee as property of the estate, or an affiliate of the licensee. This notification shall identify the bankruptcy court in which the petition was filed, the date of the filing, the cap.

- The bankruptcy court in which the petition for bankruptcy was filed;
- The date of the filing of the petition;
- The chapter under which the bankruptcy petition has been filed;
- The name, address and phone number of the bankruptcy trustee (if a trustee has been named at the time of the notification);
- Whether the licensed radiation source remains in the possession and control of the licensee and whether any change in possession or control is expected or contemplated;

- The name of the person in possession and control of the licensed radiation source if the licensee no longer maintains possession or control; and

- Whether the Agency has been named in the bankruptcy petition either as a creditor or in some other capacity.

Even though a licensee may have filed for bankruptcy, the licensee remains subject to all applicable IEMA regulatory requirements. IEMA must be notified 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).

APPENDICES

Appendix A.

Document Retention

Note: Other records are required to be maintained and are listed in the regulations. The listing below is for the most common records required to be maintained.

Record	Recordkeeping Requirement	Retention Period
Copy of License, all active amendments and supporting documents (including the application and all tie-down correspondence)	340.1120(a)	duration of the license
Results of Annual Radiation protection program reviews	340.1120(b)	5 years
Results of surveys and calibrations	340.1130(a)	5 years
Results of surveys to determine dose from external sources	340.1130(b)	duration of license
Results of measurements and calculations used to determine individual intakes	340.1130(b)	duration of license
Results of air samplings, surveys,and bioassays	340.1130(b)	duration of license
Results of measurements and calculations used to evaluate therelease of radioactive effluents to the environment	340.1130(b)	duration of license
Determination of prior occupational dose	340.1140	duration of license
Planned special exposure	340.1150	duration of license
Individual monitoring results	340.1160	duration of license
Dose to a declared pregnant woman	340.1160	duration of license
Dose to individual members of the public	340.1170	duration of license
Waste disposal	340.1180	duration of license
Records of information important to the decommissioning of a facility	330.310(k)	duration of license
Records of receipt of byproduct or source material	310.40	duration of license
Records of transfer of byproduct or source material	310.40	duration of license
Records of disposal of byproduct material	310.40	duration of license
Authority and responsibilities of radiation protection program	335.1040(i)	duration of license
Radiation protection program changes	335.1040(h)	5 years
Associate RSO appointment	335.1040(j)	5 years after ARSO is removed from the license
Visiting Authorized Users	335.1060(c)	5 years
Written directives	335.1110(d)	5 years
Radiation survey instrument calibrations	340.1130(a)	5 years

Record	Recordkeeping Requirement	Retention Period
Calibrations of instruments used to measure activity of unsealed byproduct material	335.2010(c)	5 years
Procedures for administrations requiring a written directive	335.1120(c)	duration of license
Dosages of unsealed byproduct material for medical use	335.2030(e)	5 years
Leak tests and inventory of sealed sources and brachytherapy sources	340.1135 and 335.7040(c)	5 years
Surveys for ambient radiation exposure rate	340.1130	5 years
Release of individuals containing unsealed byproduct material or implants containing byproduct material	335.2110(d)	5 years after date of release
Mobile medical services	335.2120(j)	5 years after last provision of service
Surveys of client facilities	335.2120(k)	5 years
Decay-in-storage	340.1045 and 340.1180	duration of license
Molybdenum-99 or strontium-82 orstrontium-85 concentrations	335.4020(c)	5 years
Safety instruction	335.5020, 335.7020 and 335.8040	5 years
Surveys after source implantand removal	335.7060(c)	5 years
Brachytherapy source accountability	335.7040	5 years
Calibration measurements of brachytherapy sources	335.7070(d)	5 years after last use of source
Decay of strontium-90 sources for ophthalmic treatments	335.7080	life of source
Installation, maintenance, adjustment,and repair of remote afterloader units,teletherapy units, and gamma stereotactic radiosurgery units	335.8020(d)	3 years
Emergency procedures for therapy devices containing sealed sources	335.8040(g)	duration of possession of specified equipment
Calibration records for dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	335.8080(c)	duration of license
Calibration records for teletherapy,remote afterloader, and gamma stereotactic radiosurgery full calibrations	335.8090(g), 335.8160(i), and 335.8190(g)	Duration of license for teletherapy, 5 years for HDR and GSR

Record	Recordkeeping Requirement	Retention Period
Periodic spot-checks of teletherapy units	335.8100(h)	5 years
Periodic spot-checks of remoteafterloader units	335.8170(h)	Until licensee no longer possesses the unit
Periodic spot-checks of gamma stereotactic radiosurgery units	335.8200(g)	5 years
Additional technical requirements formobile remote afterloader units	335.8210(e)	5 years
Surveys of therapeutic treatment units	335.8110(c)	duration of use of unit
Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units	335.8150(c)	duration of use of unit
Documentation regarding the trustworthiness and reliability ofindividual employees	337.1020(h)(1)	3 years from the date the individual no longer requires unescorted access
Current access authorization program procedures	337.1020(h)(2)	3 years after the procedure is superseded or no longer needed
List of persons approved for unescorted access authorization	337.1020(h)(3)	3 years after the list is superseded or replaced
Documentation supporting fingerprinting, identification, and criminal history record checks and other elements of background investigations	337.1060(e)	3 years from the date the individual no longer requires unescorted access
Copy of current security plan	337.2020(a)(4)	3 years after the plan is superseded or no longer required
Copy of current security program implementing procedure	337.2020(b)(3)	3 years after the procedure is superseded or no longer required
Documentation of initial and refresher security program training	337.2020(c)(4)	3 years from the date of the training
Documentation for preplanning and coordination of shipment of Category 1 or Category 2 quantities of radioactive material	337.3030(e)	3 years
Record retention when a retention period is not otherwise specified	337.5020	duration of license

See Appendix Y for a Summary of Applicable US DOT Requirements and associated record retention

Appendix B.

Documentation of Training and Experience to Identify Individuals on a License

Discussion

Licensees should use the most current version of the applicable IEMA Training and Experience Documentation Form. Refer to the IEMA Web page for the most current version of the forms and their associated instructions.

The checklist in this Appendix was created to assist applicants in reporting changes to multiple authorized users during a renewal. This checklist may also be used to summarize requested additions for a new application or comply with the reporting requirements of 32 Ill. Adm. Code 335.45. NOTE: Applicants are still required to submit the appropriate completed Training and Experience Documentation Form to show that the individuals meet the correct training and experience criteria for the requested use(s).

The regulations provide multiple pathways which applicants can use to demonstrate that individuals are qualified as an AU, AMP, RSO, and ARSO. Applicants should provide documentation that each individual is qualified under one pathway. There are two primary training and experience routes to qualify an individual as a new AU, AMP, RSO or ARSO. The first is by means of certification by a board recognized by IEMA or the U.S. NRC and listed on the U.S. NRC Web site:

https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

Additional training may also need to be documented for RSOs, ARSOs, AMPs, and AUs under 32 Ill. Adm. Code 335.9010, 32 Ill. Adm. Code 335.9150, 32 Ill. Adm. Code 335.9050, 32 Ill. Adm. Code 335.9080, and 32 Ill. Adm. Code 335.9140. Note: An individual that is board-eligible will not be considered for this pathway until the individual is actually board certified. Further, individuals holding other board certifications, but not certified by a board recognized by IEMA or the U.S. NRC, will not be considered for this pathway.

With the exception of an applicant requesting a proposed individual under the provisions of 32 Ill. Adm. Code 335.9080, board certified applicants do not need to provide a preceptor attestation.

The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements in 32 Ill. Adm. Code 335, Subpart J. Ophthalmic physicists can only qualify under this route as IEMA does not have a regulation under which it recognizes ophthalmic physicist boards. For RSOs, ARSOs and AU's, IEMA requires supervised work experience conducted under the supervision of an authorized individual in a licensed material use program. In this case, a supervisor is an individual who provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of byproduct material. Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice. In some cases, there may be additional training and experience routes and requirements for recognized AUs, AMPs, RSOs or ARSOs to seek additional authorizations.

Recentness of Training

The required training and experience, including board certification and prior approval on a license, described in 10 CFR Part 35 must be obtained within the 7 years preceding the date of the application, or the individual must document having completed related continuing education, and experience since obtaining the required training and experience as described in 10 CFR 35.59. Acceptable continuing education and experience for physicians include the following, to be reviewed on a case-by-case basis:

- successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use (this review may include various types of instruction, including online training, as long as the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested)

- practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization

- practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization

- for therapy devices, experience with the therapy unit and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant

NOTE: Do not include personal or private information (e.g., date of birth, social security number, home address, personal telephone number) as part of the qualification documentation.

Preceptor Attestation

IEMA defines the term "preceptor" in 32 Ill. Adm. Code 335.20, "Definitions," as "an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, a Radiation Safety Officer, or an Associate Radiation Safety Officer." While the supervising individual for the work experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. The preceptor must attest in writing regarding the training and experience of any individual to serve as an authorized individual and attest that the individual has satisfactorily completed the appropriate training and experience requirements and is able to independently fulfill the radiation safety-related duties of an authorized individual. For authorized users, this does not require an attestation of general clinical competency but requires sufficient attestation to demonstrate that the individual is able to independently fulfill the duties of the position for which the attestation is sought. The preceptor also has to meet specific requirements and must have authorization for the same categories that the proposed candidate is seeking. In addition, a residency program director may make the attestation by affirming in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user for the uses requested, and concurs with the attestation provided by the residency program director.

Training and Experience Documentation Worksheet

Item 5A. Individual(s) who will use radioactive materials: Authorized Users (AUs)

☐ **No changes from amendment number _____**

Add	Remove	Previous User	Full Name of Authorized User [1]	32 Illinois Administrative Code 335												Training & Experience Documentation Attached[4] (Or attach a copy of the license on which the AU appears)
							5010 [2]									
				2040	3010	4010	I-131 < 30 µCi for diagnostic procedures	5010 (full)	I-131 ≤ 33 mCi	I-131 > 33 mCi	Parenterals	6010	7010	8010	2140 [3]	

[1] Full name as listed on their registration with the Illinois Department of Professional and Financial Regulations.
[2] Casework required under alternate pathway authorization.
[3] Indicate the emerging technology and provide specific training. See IEMA website and U.S. NRC Emerging Medical Technologies list (https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html).
[4] See U.S. NRC Specialty Board Certification list (https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html#35290).

APPENDIX C.

RADIATION SAFETY OFFICER DUTIES, RESPONSIBILITES, AND DELEGATION

NOTE: Your facility may want, or may be asked by IEMA licensing staff, to provide additional duties and responsibilities depending upon the authorized use(s) being requested. Please review this list and submit additional duties and responsibilities as necessary. Recordkeeping requirements and retention periods can be found in Appendix A.

1. Stop activities involving licensed material that the RSO considers unsafe.

2. Ensure that all radiation safety activities are performed in accordance with licensed approved procedures and regulations.

3. Oversee all activities involving radioactive material, including monitoring and surveying all areas in which radioactive material is used.

4. Ensure that radioactive material possessed by the licensee is commensurate with the authorizations on the license.

5. Maintain, through the amendment request process, an up-to-date license, including submitting requests in a timely manner when there are programmatic, commitment, or staffing changes, and submitting renewal requests before license expiry.

6. Maintain current copies of state regulations and Agency guidance and forms.

7. Develop, distribute, implement, and maintain up-to-date operating, emergency, and security procedures and guidelines in relation the RPP.

8. Ensure that possession, use, and storage of licensed material are consistent with the limitations in the license, regulations, the Sealed Source and Device (SSD) registration certificate(s), and the manufacturer's recommendations and instructions.

9. Verify that individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by the Agency, the U.S. NRC or an Agreement State license before work commences.

10. Instruct personnel in proper radiation protection practices, including time, distance, shielding. and proper dosimetry placement as required.

11. Ensure that radiation exposures are kept as low as is reasonably achievable (ALARA).

12. Establish Investigation Levels or ALARA Action Levels and the resulting actions if individuals meet or exceed those levels.

13. When required, provide personnel monitoring devices or document the demonstration that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of allowable limits.

14. When using personnel monitoring devices, maintain the proper exchange interval and personnel dosimetry records.

15. Document and maintain, through measurement or calculation, that the highest total effective dose equivalent (TEDE) an individual member of the public is likely to receive, from licensed operation, does not exceed the annual limit in 32 Ill. Adm. Code 340.310.

16. Verify or provide personnel training is commensurate with the individual's duties regarding licensed material, including 400.120 training for ancillary staff.

17. Be immediately available to serve as a point of contact with the Agency and the licensee's management during routine operations, inspections, emergencies, or incidents.

18. Investigate and report medical events and precursor events to the Agency, including cause(s) and any appropriate corrective action(s) identified, and that timely corrective action(s) are taken.

19. Perform and document periodic audits of the RPP, at least annually, to ensure that the licensee is complying with all applicable regulations and the terms and conditions of the license.

20. Ensure that the results of audits, identification of deficiencies, and recommendations for changes are documented and provided to management for review; enabling prompt action to correct deficiencies.

21. Develop, document, and implement corrective actions(s) when violation(s) of regulations, license conditions, or program weaknesses are identified.

22. Communicate audit results and corrective actions to all personnel who use licensed material.

23. Investigate and report incidents, accidents, and personnel radiation exposures in excess of 32 Ill. Adm. Code 340 limits to the Agency and other appropriate authorities if required within regulatory time limits.

24. Ensure licensed material is transported, or offered for transport, in accordance with all applicable Agency and Department of Transportation requirements.

25. Ensure radioactive waste is disposed of in accordance with regulations and license conditions.

26. Supervise and coordinate radioactive waste disposal, storage, and transfers, including effluent monitoring and recordkeeping on waste storage and disposal or transfer records.

27. Oversee the storage of radioactive material not in current use, including waste.

28. Properly secure radioactive material to prevent unauthorized access from non-authorized staff or members of the public.

29. If the licensee possesses an aggregated Category 1 or Category 2 quantity of radioactive material, support development and implementation of a security program for radioactive material in accordance with 32 Ill. Adm. Code 337.

30. Notify proper authorities of incidents, such as damage to or malfunction of sources/devices, loss of licensed material, or damage due to flood, fire, theft, etc.

31. Manage the radioactive materials inventory, documenting disposal, transfers, and changes as necessary according to 32 Ill Adm Code 340.810.

32. Maintain appropriate leak testing intervals, as described in the SS&D or other commitments, for all sealed sources.

33. Oversee the calibration of radiation survey instruments in order to maintain this equipment in good working order.

34. Supervise decontamination operations to ensure proper methods, PPE, and survey techniques are utilized.

35. Assigning specific duties and tasks to an ARSO, restricted to the types of use for which the ARSO is listed on the license, if available.

APPENDIX C.

Model Delegation of Authority to Radiation Safety Officer

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed radiation safety officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations, when justified, to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Illinois Emergency Management Agency at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

I accept the above responsibilities,

_____ _____

Signature of Radiation Safety Officer Date

RSO Printed Name _____

RSO Email _____

RSO Work Address _____

RSO Phone and/or Mobile Number _____

_____ _____

Signature of Management Representative Date

cc: Affected department heads

APPENDIX C.

Model Appointment of ARSO

Memo To: Associate Radiation Safety Officer

From: Chief Executive Officer
Radiation Safety Officer

Subject: Appointment of ARSO

You,_____, have been appointed an Associate Radiation Safety Officer. The Radiation Safety Officer, with written agreement from management, will assign specific oversight duties and tasks to you. These duties and tasks are restricted to the types of use for which you are listed on our license.

You are free to raise issues with IEMA at any time. It is estimated that you will spend ___ hours per week conducting Associate Radiation Safety Officer duties and tasks.

You will report to the Radiation Safety Officer, who retains responsibility for oversight of the entire radiation safety program.

_____ _____
Signature of Management Representative Date

_____ _____
Signature of Associate Radiation Safety Officer Date

ARSO Printed Name _____

ARSO Email _____

ARSO Work Address _____

ARSO Phone and/or Mobile Number _____

cc: Names of affected department heads

Appendix D.

Sample Minimum Detectable Activity Calculations

Several references contain discussions of counting statistics for radiation measurements. The formula the Agency recommends using for determining the minimum detectable activity (MDA) with a 95% confidence level is as follows:

$$\mathrm{MDA} = \frac{2.71 + 4.65\sqrt{\mathrm{Bt}}}{\mathrm{tE}}$$

Where:

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

For example, if:

B = 200 cpm
t = 2 minutes
E = 0.1 counts per disintegration (10% efficiency)

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

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

$$= 478.55\ \mathrm{dpm}$$

NOTE: Derivation of equations and discussions of limitations can be found in "Decommissioning Health Physics - A Handbook for MARSSIM Users," Eric W. Abelquist, published by Taylor & Francis Group, 2001

For a copy of the full discussion of the theory and limitations of this test, refer to pages 307-311 in NCRP Report No. 58, A Handbook of Radioactivity Measurement Procedures, issued February 1, 1985 by the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Bethesda, MD 20814.

Detector Efficiency

To determine instrument counting efficiency, a standard source of the same radionuclide as the source being tested or one with similar energy characteristics must be used. The source should be in the same configuration, or geometry, as the sample. Accuracy of the source should be within ± 5% of the stated value and traceable to a primary radiation standard, such as those maintained by the Nation Institute of Standards

and Technology (NIST). The counting rate for the standard is divided by the standard activity to determine the counting efficiency.

Calculate the counting efficiency of the detector using the following equation:

$$\text{Efficiency (E) in} \frac{\text{cpm}}{\text{Ci}} = \frac{(\text{Standard (cpm)} - (\text{Background (cpm)})}{\text{Activity of Standard (Ci)}}$$

Where:

cpm	= counts per minute
std	= standard
B	= background
A	= activity in Curie

Example:

The counting rate for the standard is divided by the standard activity to determine the counting efficiency. When dividing, the two values must be in compatible units. For example, a standard activity in µCi must be converted to dpm by multiplying by a factor of 2.2E+6.

Appendix E.

Calibrating Radiation Detection and Measurement Instruments

NOTE: Licensees must be specifically authorized by the Agency, the U.S. NRC or an Agreement State to calibrate radiation monitoring instruments.

1. Items to be Covered in an Application

An application for a licensee to perform radiation monitoring instrument calibrations should contain the following information:

a) The manufacturer's name and model of the source(s) and the manufacturer's name and model of the calibration instrument to be used.

b) The radionuclide and activity of the radioactive material contained in the source(s) The source should contain a radionuclide that emits radiation of identical or similar type and energy [e.g., cesium-137 (Cs-137), cobalt-60 (Co-60) as the environment in which the calibrated radiation monitoring instrument will be used. Cs-137 sources should be a minimum activity of 85 mCi and Co-60 sources should be a minimum activity of 21 mCi to achieve an appropriate calibration field.

NOTE: Inverse square and radioactive decay laws should be used to account for changes in exposure rate due to distance and decay.

c) The accuracy of the source(s) activity; and documentation that the determination of each source activity is traceable to the National Institute of Standards and Technology - NIST (previously National Bureau of Standards - NBS).

d) A description of the facilities to be used, including room shielding, security, interlocks, signage, remote actuators, viewing systems and the manufacturer's name and model of the operable survey instrument that will be available to the individual performing the calibration.

e) The name and applicable experience of each individual who will perform the calibrations.

f) Calculations related to the calibration procedures.

g) The step-by-step calibration procedures, including associated radiation safety procedures.

h) Copies of records that will be maintained (see Item 4).

i) Verification that the requirements outlined in this appendix will be followed.

2. Recommended Methods for Calibration of Radiation Monitoring Instruments

Electronic calibrations alone are not adequate. Radioactive sealed sources must be used for calibrating dose and dose rate measuring radiation survey instruments. The calibration of radiation monitoring instruments shall be performed in accordance with the following:

a) The radionuclide sources used for calibration shall approximate point sources.

b) The source activities shall be traceable* within +/-5% accuracy to the NIST calibrations.**

NOTE: Sources of cobalt-60 or cesium-137, are appropriate for use in calibrations. The radioactivity of the calibration standard should be sufficient to calibrate the radiation monitoring instruments on all ranges, or at least up to 1 Roentgen per hour on the higher range radiation measurement instruments. If there are higher ranges, they should be checked for operation and an approximate correct response to radiation.

c) The frequency of calibration shall be as specified in 32 Ill. Adm. Code 340.540 (before first use, at intervals not to exceed one year and after servicing/repair that affects the calibration).

d) Each scale of the radiation monitoring instrument shall be calibrated at least at two points such that:

- one point is in each half of the scale; and
- the two points are separated by 50-60% of full scale.

NOTE: Logarithmic and digital readout radiation monitoring instruments with only a single readout scale shall be calibrated, at a minimum, at one point near the midpoint of each decade.

e) The exposure rate measured by the radiation monitoring instrument should not deviate more than +/-10% from the calculated or known value for each point checked. (Read appropriate section of the radiation monitoring instrument manual to determine how to make necessary adjustments to bring the radiation monitoring instrument into calibration.) Readings within +/-20% will be considered acceptable if a calibration chart or graph is prepared and attached to the radiation monitoring instrument. If the radiation monitoring instrument cannot be adjusted so that each reading falls within the +/-20% range, it shall be taken out of service and sent to the manufacturer or to a qualified radiation monitoring instrument laboratory for repair.

f) If an electronic device, such as a pulse generator, is used to calibrate instruments, the instrument with detector must be checked for response to a known source of radiation.

** For purposes of this document, the amount of radioactivity in a source is said to be traceable to a national standard when its radioactivity was determined by comparison with a source of the same radionuclide (or a proper simulated source, isotopically) the activity of which is certified by the NIST.*

*** In lieu of using a traceable radioactive source, a transfer instrument traceable to the NIST, within +/-5%, may be used as an alternative standard. For purposes of this document, a transfer instrument shall meet the definition as contained in the American National Standard Institute publication, ANSI N323A-1997, "American National Standard Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments."*

3. Use of a Reference Check Source for Operational Checks

a) A reference check source of a long half-life (e.g., greater than five years) shall be used to obtain a radiation monitoring instrument response by the licensee. The reading shall be taken with the check source placed in a specific geometry relative to the detector and:

b) Shall be taken before use on each day the instrument is used;

c) Shall be taken after calibration by the licensee or after return to the licensee of a radiation monitoring instrument sent for calibration by a specifically licensed firm authorized to perform radiation monitoring instrument calibrations as a customer service;

d) Shall be taken after maintenance and/or each battery change; and

e) Shall be taken at least quarterly.

If any operational check reading using the reference check source, with the same geometry, is not within +/- 20% of the reading measured immediately after calibration (or upon receipt from a calibration firm), the radiation monitoring instrument shall be removed from service and recalibrated.

4. Records

Records for items 2, 3(b), 3(c) and 3(d) of this procedure shall be maintained. Records for item 2 shall include, at a minimum:

a) Radionuclide used;

b) Activity and assay date of source;

c) Present activity;

d) Calculated and measured radiation values, including the percent of difference;

e) Respective distance from source for each calculated and measured radiation value;

f) Necessary scale correction factors (required if calculated and measured radiation values do not agree within +10%);

g) Make, model and serial number of radiation monitoring instrument being calibrated;

h) Name of individual performing the calibration; and

i) Date radiation monitoring instrument calibration was performed.

Records for items 3(b), 3(c) and 3(d), of this procedure shall include, at a minimum:

a) Radionuclide used;

b) Activity and assay date of the radionuclide used;

c) Reading of check source at time of calibration;

d) Geometry of check source relative to detector (position);

e) Date of calibration;

f) Make, model and serial number of the radiation monitoring instrument;

g) Date reference check was performed; and

h) Name of individual who performed the reference check.

5. Use of Inverse Square Law and Radioactive Decay Law

A calibrated source will have a calibration certificate giving its output at a given distance measured on a specific date by the manufacturer or National Institute of Standards and Technology (NIST).

a) The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.

b) The Radioactive Decay Law may be used to calculate the output at other times after the specified date.

INVERSE SQUARE LAW:

Exposure rate at P_2:

$$R_2 = \frac{(P_1)^2 \; x \; (R_1)}{(P_2)^2}$$

where: S is the point source

R_1 and R_2 are the exposure rates at P_1 and P_2 in the same units (*e.g., mR/hr or R/hr*).
P_1 and P_2 are the distances from the point source in the same units (*e.g., centimeters, feet, etc*.)

RADIOACTIVE DECAY LAW:

$$R_t = R_o \, e^{-(0.693 \, t \, / \, T_{½})}$$

where: R_o and R_t are in the same units (*e.g., mR/hr or R/hr*)

R_o is exposure rate on specified calibration date (*i.e., time zero*)

R_t is exposure rate "t" units of time later

$T_{1/2}$ and t are in the same units (*e.g., years, months, days, etc*.)

$T_{1/2}$ is the half-life of the radionuclide

t is the time elapsed between the source calibration (assay) date and the radiation monitoring instrument calibration date (i.e., present time)

Example: Source output is given by calibration certificate as 100 mR/hr at 1 foot on December 10, 2008. Radionuclide half-life is 5.27 years.

Question: What is the output at 3 feet on December 10, 2010 (2.0 years later)?

Output at 1 foot, 2.0 years after calibration date:

$$R_{(1\ ft)} = 100\ mR/hr\ [\exp^{-((0.693 \times 2.0)/5.27)}]$$

$$= 100\ mR/hr\ (0.77)$$

$$= 77\ mR/hr \text{ at } 1 \text{ foot on December 10, 2010}$$

Output at 3 feet, 2.0 years after calibration date:

$$R_{(3\ ft)} = \frac{(1\ foot)^2}{(3\ feet)^2}\ (77mR/hr)$$

$$= 1/9\ (77\ mR/hr)$$

$$= 8.6\ mR/hr \text{ at } 3 \text{ feet on December 10, 2010}$$

Appendix F.

Model Procedure for Dose Calibrator Calibration

The model procedure provides acceptable methods for dose calibrator testing when measuring photon emitting radionuclides. Applicants may either adopt this model procedure or develop an alternative procedure in accordance with manufacturer's instructions or a nationally recognized standard pursuant to 32 Ill. Adm. Code 335.2010. For instance, ANSI N42.13 2004 – Calibration and Usage of "Dose Calibrator" Ionization Chambers for the Assay of Radionuclides may be ordered at ansi.org.

The tests should be performed at the indicated frequency:

- constancy, at least once each day prior to assay of patient dosages (+/− 10%)
- linearity, at installation and at least annually thereafter (+/− 10%)
- geometry dependence, at installation (+/− 10%)
- accuracy, at installation and at least annually thereafter (+/− 10%)

The dose calibrator will be repaired, replaced, or corrected arithmetically if the dose calibrator falls outside the suggested tolerances. For example, a licensee shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent and shall mathematically correct dosage readings [for dosages greater than 1.11 megabecquerels (MBq) or 30 microcurie(μCi)] if the geometry or linearity error exceeds 10 percent. In addition, after repair, adjustment, or relocation to another building, the dose calibrator tests will be repeated before use.

Constancy means reproducibility in measuring a constant source over a long period of time. Atleast one relatively long-lived source, such as cesium-137 (Cs-137), cobalt-60, cobalt-57 (Co-57), or radium-226 will be assayed using reproducible geometry each day before using thecalibrator. The source activity will normally be in the low millicurie to hundreds of microcuries range. Two sources with different photon energies and activities may also be used to ensure the photon energy range for radionuclides used is covered.

1. Assay each reference source using the appropriate dose calibrator setting (e.g., use theCs-137 setting to assay Cs-137).

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

3. For each source used, record (e.g., plot, log) the activity measured, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, the date of the check, and the name of the individual who performed the test.

4. Using one of the sources, repeat the above procedure for all commonly used radionuclide settings. Record (e.g., plot, log) the results.

5. Notify the radiation safety officer (RSO) or the authorized user if the test results falloutside +/− 10% of the expected results. For instance, the Cs-137 value should be compared to the reference activity, corrected for decay. Other radionuclides (e.g., Tc-99m) should be compared to the value determined during the last accuracytest, corrected for the reference standard's decay.

Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. The linearity of a dose calibrator will be ascertained over the range of its use between the

maximum activity administered and 1.11 MBq [30 μCi]. This test will be performed using a vial or syringe of technetium-99m (Tc-99m) or other readily available radionuclide whose activity is at least as large as the maximum activity normally assayed for administration. Tc-99m is routinely used due to its ready availability and lower energy, and therefore lower exposure to licensee personnel, as compared to higher energy radionuclides like those used in Positron Emission Tomography and Iodine-131.

TIME DECAY METHOD

1. Assay the Tc-99m syringe or vial in the dose calibrator and subtract background to obtain the next activity in millicuries. Record the date, time to the nearest minute, and net activity on the dose calibrator linearity test form.

2. Repeat the assay at approximately 4-hour intervals during the workday. Continue on subsequent days until the assayed activity is less than 1.11 MBq [30 μCi]. For dose calibrators on which the range is selected with a switch, select the range that would normally be used for the measurement.

3. Convert the time and date information that was recorded to hours elapsed since the first assay.

4. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, the date(s) of the test, and the name of the individual who performed the test.

5. Notify the RSO, if the deviation is more than +/− 10%.

SHIELD METHOD

"Sleeves" of various thicknesses are used to test for linearity. However, they must first be calibrated. The applicant should review the procedure for calibrating sleeves against the manufacturer's instructions. Some sleeve manufacturer's procedures indicate that various sleeves should be stacked to achieve a desired attenuation. The following procedure should be modified to allow for stacking of sleeves:

1. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps 2 through 4 below must be completed within 6 minutes (i.e., approximately 1 percent of decay of Tc-99m).

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

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

4. Continue for all sleeves.

5. Complete the decay method linearity test Steps 2 through 5 above.

6. From the data recorded in step 4 of the decay method, 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 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 3.

8. Continue for all sleeves.

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.

1. Assay the Tc-99m syringe or vial in the dose calibrator and subtract background to obtain the net activity. Record the net activity.

2. Steps 3 through 5 below must be completed within 6 minutes.

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

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

5. Continue for all sleeves.

6. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, the date(s) of the test, and the name of the individual who performed the test.

7. Notify the RSO if the greatest deviation is more than +/− 10%.

Geometry independence means that the indicated activity does not change with volume or configuration. The test for geometry independence will be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections or administrations, and a vial similar in size, shape, and construction to the generator and radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3 cubic centimeter (cc) plastic syringes and that radiopharmaceutical kits are made in 30 cc glass vials and the predetermined safety margin is +/− 10%. If 5 cc syringes, 10 cc glass vials, or any other geometric variations are used, the geometry testing will include these.

***Note**:* If these volumes are not used, change the procedure so that the syringes and vials are tested throughout the range of volumes commonly used.

1. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 millicuries (mCi)/milliliter. Set out a second small beaker or vial with water.

2. To test the geometry dependence for a 3 cc syringe, draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and activity (e.g., mCi) indicated.

3. Remove the syringe from the calibrator, draw an additional 0.5 cc of water and assay again. Record the volume and activity indicated.

4. Repeat the process until a 2.0 cc volume has been assayed.

5. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal 10% error lines above and below the chosen “standard volume.”

6. Record the model number and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the name of the individual who performed the test.
7. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the +/− 10% error lines.
8. To test the geometry dependence for a 30 cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and activity indicated.
9. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of water and assay again. Record the volume and activity indicated.
10. Repeat the process until a 19.0 cc volume has been assayed. The entire process must be completed within 10 minutes.
11. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal 10% error lines above and below the chosen "standard volume."
12. Record the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the name of the individual who performed the test.
13. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the +/- 10% error lines.

Accuracy means that, for a given calibrated reference source, the indicated activity (e.g., mCi) value is equal to the activity 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 the NIST and from many radionuclide suppliers. At least one source with a principal photon energy between 100 kiloelectron-volts (keV) and 500 keV (e.g., Co-57 or barium-133) will be used. At least one reference source whose activity is within the range of activities normally assayed will be used.

1. Assay a calibrated reference source at the appropriate settings (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record the net activity.
2. The measurement should be within +/− 10% of the certified activity of the reference source, mathematically corrected for decay.
3. Repeat the procedure for any other calibrated reference sources possessed.
4. Record the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the name of the individual who performed the test.
5. Notify the RSO if the test results do not agree, within +/− 10%, with the certified value of the reference source(s).
6. 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 radionuclide settings.

Appendix G

Model Procedures for Radioactive Gases and Volatile Material

32 Ill. Adm. Code 340.820 and 32 Ill. Adm. Code 340.830 specify requirements for the storage and control of radioactive gases and volatile materials. Additive to requirements in other parts, criteria are detailed for proper storage, posting areas of use and storage, monitoring and waste disposal. Radioactive gases and volatile material (such as xenon and sodium iodide, respectively) also present a source of worker exposure that must be calculated and is often not adequately characterized by dosimetry. When evaluating the potential dose, licensees may take credit for the reduction of dose resulting from the use of xenon or aerosol traps. Licensees may vent xenon gas or aerosols directly to the atmosphere, as long as the effluent concentration is within 10 CFR Part 20 limits. Since I-131 sodium iodide is volatile in either liquid or capsule form, applicants should also consider establishing appropriate radiological controls. In general, though, the amount of I-131 sodium iodide that may become volatile is greatly reduced when encapsulated and is a fraction of a percent of the capsule activity; and therefore, fume hoods may not be necessary for storage.

Licensees should review the forms of radioactive material in use and commit to the establishment and implementation of procedures for proper control, storage and occupational exposure monitoring. A licensee may commit to the use of this model procedure or develop and submit alternate procedures for Agency review.

The following information must be submitted in support of requests to use radioactive gas/volatile material:

1. We will collect spent gas in a shielded trap through a reusable collection system and follow the procedures detailed below.

    a. We will only use or store radioactive gases in rooms that are at negative pressure compared to surrounding rooms or hallways.

    b. For reusable collection systems that employ an effluent air contamination monitor, we will follow the manufacturer’s instructions for checking its accuracy and constancy.

    c. In accordance with 32 Ill. Adm. Code 340.830(f), we will check the operation of reusable collection systems monthly according to the manufacturer’s instructions.

    d. If trap effluent is monitored by a radiation detector designed to monitor effluent gas, we will check the detector monthly according to the manufacturer's instructions and keep a record of the checks ([32 Ill. Adm. Code 340.830]).

    e. If the trap effluent is not monitored, we will check it on receipt and once each month. During at least one patient study, we will collect the effluent from the trap in a plastic bag. Then monitor the activity in the bag by holding the bag against a camera (or radiation survey instrument), with the camera/instrument adjusted to detect the noble gas. We will compare its counts per minute (cpm) to background cpm without any other radioactivity in the area. A record will be maintained of the check, including the date, background cpm, and bag cpm.

f. The Radiation Safety Officer will establish an action level based on cpm or on a multiple of the background cpm. If a significant increase in the bag cpm is measured, we will consider the trap as breaking down and will take appropriate action to have the trap replaced in accordance with the manufacturer's instructions.

g. We will store opened containers from which material is extracted in a properly functioning, ventilated device such as a glove box or fume hood. In accordance with 32 Ill. Adm. Code 340.830(f), we will measure the ventilation rates of fume hoods and glove boxes in areas of use at intervals not to exceed 6 months.

h. We will maintain for inspection record of these checks and measurements for 5 years. The record shall include the model and serial number of the collection system, results of all checks recommended by the manufacturer of the collection system, the ventilation rates measured, the date of the checks and measurements, and the identity of the individual who performed the checks and measurements.

i. Contaminated charcoal trap filters, air handling systems and respiratory equipment shall be disposed of in accordance 32 Ill. Adm. Code Part 340, Subpart K.

j. We will calculate the necessary clearance time as detailed below in "*Spilled Gas Clearance Time*" and post in areas of use.

OR

2. We are not monitoring trap effluent or spent gas is exhausted to the atmosphere. We will estimate worker dose by calculation. We will follow the sample calculations below for "*Calculations of Minimum Ventilation Rates for Restricted Areas*", "*Air Concentrations of Radioactive Gas/Volatile Material in Unrestricted Areas*" and "*Spilled Gas Clearance Time*"

<u>CALCULATIONS OF MINIMUM VENTILATION RATES FOR RESTRICTED AREAS REQUIRED BY PART 340</u>

a. Determine the highest dose to an individual from all external radiation for the previous 12-month period by reviewing personnel monitoring records (OSL, TLD, etc.) or based on activity, distance and duration of handling. If necessary, modify the dose to account for an anticipated increase or decrease in potential exposure.

b. Modify the DAC value to allow for the estimated annual external dose. A simplified method is to subtract the estimated external dose from the occupational dose limit of 50 mSv (5 rems) and divide this number by 50 mSv (5 rems). This yields the fraction of the dose limit of 50 mSv (5 rems) that would still be permitted from internal sources. Multiplying this fraction by the DAC value yields a modified DAC. These DAC values are provided in Appendix B to 10 CFR 20.

Example:

A new room is being designed where Xe-133 will be used. If the annual external dose is 2 rems, the modified DAC value should be based on 3 rems that could still be incurred from internal exposure. The listed DAC value for Xe-133 is $1E^{-4}$ µCi/ml.

$$DAC_{(modified)} = \frac{3 \text{ rems}}{5 \text{ rems}} \times 1E^{-4} \text{ µCi/ml} = 6E^{-5} \text{ µCi/ml}$$

If the facility in question plans to use 5.2×10^6 µCi of Xe-133 per year, what ventilation rate is required to ensure compliance with 32 Ill. Adm. Code 340.210?

Maximum Activity:

$A_0 = 5.2 \times 10^6$ µCi/year

Assume a loss rate (f) of 20%

$A = A_0 \times f$

$A = (5.2 \times 10^6 \text{ µCi/year}) \times 0.2$

$A = 1 \times 10^6$ µCi/year

Required Ventilation Rate:

$V = A \div C$

Where, $C = DAC = 6 \times 10^{-5}$ µCi/ml

$$V = \frac{1 \times 10^6 \text{ µCi/year}}{6 \times 10^{-5} \text{ µCi/ml}}$$

$V = 1.7 \times 10^{10}$ ml/yr

$$V = \frac{1.7 \times 10^{10} \text{ ml}}{\text{year}} \times \frac{1 \text{ yr}}{52 \text{ wks}} \times \frac{1 \text{wk}}{40 \text{ hrs}} \times \frac{1 \text{ hr}}{60 \text{ min}} \times \frac{1 \text{ ft}^3}{2.832 \times 10^4 \text{ ml}} =$$

$V = 4.8 \text{ ft}^3/\text{min}$

The answer shows that, in order to meet the requirements of 32 Ill. Adm. Code 340.210, the nuclear medicine laboratory (RESTRICTED AREA) must have a ventilation rate of <u>at least</u> 5.0 ft^3/min with no recirculation of air. To ensure adequate negative pressure, this resulting value must be increased to overcome the supply air from HVAC systems along with any seasonal variations in supplied air flow. As a result, the ventilation rate should be greater than that shown necessary by the calculations which represent an ideal scenario. Consider every alternative in order to maintain the air concentration of Xe-133 as low as is reasonably achievable.

If the ventilation rate is inadequate to meet the requirements of 32 Ill. Adm. Code 340.210, methods of increasing ventilation or reducing the activity must be implemented.

AIR CONCENTRATIONS OF RADIOACTIVE GAS/VOLATILE MATERIAL IN UNRESTRICTED AREAS

Licensees who make releases of radioactive gas/volatile material to *unrestricted areas* during use, storage and disposal are required to perform monitoring (measurements or calculations) to ensure compliance with 32 Ill. Adm. Code 340.310. Many facilities do not have sufficient air flow to achieve the necessary dilution to unrestricted areas. The following procedure may be used to estimate the concentrations of radioactive gases in effluent to unrestricted areas:

a. Perform an initial evaluation to determine the location of the release point relative to the nearest window or fresh air intake to prevent recirculation. Record the distance.

b. Estimate the maximum amount of radioactive gas/volatile material to be released per year (A). This should include all anticipated losses during use, storage and disposal.

c. Determine the flow rate of the exhaust system and calculate the air flow per year (V).

d. For unrestricted areas, 32 Ill. Adm. Code 340.1010(a)(2) requires that the air concentration (C):

$$C = \frac{A}{V} \leq \text{Max. concentration listed in Table II, Column I of 10 CFR Part 20 Appendix B}$$

Example:

A nuclear medicine laboratory plans to use 5.2×10^6 µCi of Xe-133 per year (10 mCi per patient and 10 studies per week). A fume hood is available for the release of Xe-133 and has a measured airflow of 168 ft/min. with an opening of 8 ft^2. What is the average concentration of Xe-133 at the point of release from the fume hood exhaust (assuming all Xe-133 from collection bags, filters, etc. has been released)?

Volume:

($1\ ft^3/min = 1.7 \times 10^6$ ml/hr $= 6.8 \times 10^7$ ml/40-hr wk $= 1.5 \times 10^{10}$ ml/yr)

$V = 168\ ft/min \times 8\ ft^2$

$$V = 1344\ ft^3/min \times 1.5 \times 10^{10} \frac{ml/yr}{ft^3/min}$$

$V = 2.02 \times 10^{13}$ ml/yr

Concentration:

$$C = \frac{5.2 \times 10^6\ \mu Ci/year}{}$$

2.02×10^{13} ml/yr

$C = 2.6 \times 10^{-7}$ µCi/ml

The concentration of radioactive gas vented to the atmosphere is less than the maximum concentration of 5×10^{-7} µCi/ml listed in Table II, Column I of 10 CFR Part 20 Appendix B.

SPILLED GAS CLEARANCE TIME

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

a. Determine the highest activity (A) in a single container, in microcuries

b. Determine total airflow supply (S) from each vent in the room, in milliliters per minute. If different during heating and cooling seasons, use the lesser value.

c. Determine the flow rate of the exhaust system (Q), in milliliters per minute, by summing the airflow to each exhaust vent in the room.

   NOTE: The exhaust should be vented and not recirculated within the facility. This may be either the normal air exhaust or a specially installed gas exhaust system

d. Determine the maximum permissible air concentrations (C) in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1 x 10-4 µCi/ml in restricted areas and 5 x 10-7 µCi/ml in unrestricted areas. For other gases, see Appendix B to 10 CFR Part 20.

e. Establish the volume of the room (V) in milliliters.

f. For each room the following calculations will be made

   i. The airflow supply must be less than the airflow exhaust to ensure that the room is at negative pressure and comply with 32 Ill. Adm. Code 340.830(c).

   ii. The evacuation time, $t = (-V/Q) \times (\ln (CV/A))$, where ln is the natural logarithm.

g. Post the clearance time in the room.

Appendix H

Model Training Program

The following training program will be adopted and provided to individuals working in, or the performance of whose duties requires access to, any portion of a restricted area or who frequent areas where radioactive material is used or stored. Instruction will be provided before individuals assume duties with, or in the vicinity of, radioactive materials, during annual refresher training, and whenever there is a significant change in duties, procedures or potential radiation hazards. These instructions shall be of sufficient detail to avoid radiological health protection problems and shall be given directly to each worker either in writing or in an orientation course, with the workers signing a statement that they have received the information listed in 32 Ill. Adm. Code 400.120(a) and understand it. The content of this training will be reviewed with changes in applicable regulations, terms of the license, or the type(s) of radioactive material or therapy device used.

Records of worker training will be maintained for 5 years as part of the radiation protection program in accordance with 32 Ill. Adm. Code Part 340.1120. Records of training will include the following: date of instruction, name of instructor, scope of instruction provided and signature of each participant that indicates that he/she has received and understood the information presented in the training program that is applicable to his/her duties. Refresher training that covers all required topics listed in 32 Ill. Adm. Code 400.120(a) shall be provided at intervals not to exceed 12 months.

Model radiation safety training topics appear below. Topics are to be chosen for training based on the experience, duties, and previous training of trainees. The topics chosen will depend on the purpose of the training, the audience,and background knowledge of the audience. These may also be useful to identify topics for annual refresher training. Refresher training should include topics with which the individual is not involved frequently and topics that require reaffirmation. Topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses. Licensees should review Section III Item 10 of this instructional set for specific content requirements based on the licensee's authorized use. Guidance on requirements for training and experience for authorized medical physicists (AMP), ophthalmic physicists (OP), and authorized users (AU) for medical use who engage in certain specialized practices is also included.

Training for Individuals Involved in the Medical Use of Radioactive Material

In addition to the instructions to workers required in 32 Ill. Adm. Code 400.120(a), training for professional staff [e.g., AU, AMP, ophthalmic physicist (OP), radiation safety officer (RSO), associate radiation safety officer (ARSO), nurse, dosimetrist, technologist, therapist] will contain the following elements for those who provide or are involved in the care of patients during diagnostic or therapeutic procedures, as *commensurate with their duties*:

1. Basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues).

2. Basic radiation protection to include concepts of time, distance, and shielding.

3. Concept of maintaining exposure as low as is reasonably achievable (ALARA).

4. Risk estimates, including comparison with other health risks.

5. Posting requirements.

6. Proper use of personnel dosimetry (when applicable).

7. Access control procedures.

8. Proper use of radiation shielding, if used.

9. Patient release procedures

10. Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interferewith or be in lieu of appropriate patient care.

11. Occupational dose limits and their significance.

12. Dose limits to the embryo/fetus, including instruction on declaration of pregnancy.

13. Worker's right to be informed of occupational radiation exposure.

14. Each individual's obligation to report unsafe conditions to the RSO.

15. Worker's right to contact the regulatory agency with concerns.

16. Applicable regulations, license conditions, information notices, bulletins, etc.

17. Where copies of the applicable regulations, the IEMA license, and its application are posted or made available for examination.

18. Proper recordkeeping required by IEMA regulations.

19. Appropriate surveys to be conducted.

20. Proper calibration of required survey instruments.

21. Emergency procedures.

22. Decontamination and release of facilities and equipment.

23. Dose to individual members of the public.

24. Licensee's operating procedures (e.g., survey requirements, instrument calibration,waste management, sealed-source leak testing).

25. Hazardous Materials (HAZMAT) training for preparing shipments of radioactive material.(49 CFR Part 172)

26. Security (32 Ill. Adm. Code Part 337) for Category 1 or Category 2 sources or aggregated quantities of material

Training for Individuals Involved in Nonmedical Use of Radioactive Material

In addition to the instructions to workers required in 32 Ill. Adm. Code 400.120(a), training for staff working with radioactive material for nonmedical uses or animals containing radioactive material will include, as appropriate, the elements that are listed above for medical uses. All training should be commensurate with the individual's duties.

Training for Staff Directly Involved in Administration to or Care of Patients Administered Radioactive Material for Which a Written Directive is Required (Including Greater-than-30 microcuries of I-131); Training for Staff Involved in Therapeutic Treatment Planning

In addition to the topics identified above, the following topics will be included in instruction for staff involved in the therapy treatment of patients (e.g., nursing, RSO, AMP, AU, and dosimetrist), *commensurate with their duties*:

1. leak testing of sealed sources, as applicable

2. emergency procedures (including emergency response drills) (32 Ill. Adm. Code 335.5020, 32 Ill. Adm. Code 335.7020, 32 Ill. Adm. Code 335.8040 and 32 Ill. Adm. Code 335.2140, as applicable)

3. operating instructions (32 Ill. Adm. Code 335.1050, 32 Ill. Adm. Code 335.8040, and 32 Ill. Adm. Code 335.2140, as applicable)

4. computerized treatment planning system (32 Ill. Adm. Code 335.7090, 32 Ill. Adm. Code 335.8230 and 32 Ill. Adm. Code 335.2140, as applicable)

5. dosimetry protocol (32 Ill. Adm. Code 335.8230 and 32 Ill. Adm. Code 335.2140, as applicable)

6. detailed pretreatment quality assurance checks (32 Ill. Adm. Code 335.1050, 32 Ill. Adm. Code 335.8040, and 32 Ill. Adm. Code 335.2140, as applicable)

7. safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources (32 Ill. Adm. Code 335.5020, 32 Ill. Adm. Code 335.7020 and 32 Ill. Adm. Code 335.2140, as applicable)

8. patient control procedures (32 Ill. Adm. Code 335.5020, 32 Ill. Adm. Code 335.7020, 32 Ill. Adm. Code 335.8040 and 32 Ill. Adm. Code 335.2140, as applicable)

9. visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room) (32 Ill. Adm. Code 335.5020, 32 Ill. Adm. Code 335.7020, 32 Ill. Adm. Code 335.8040 and 32 Ill. Adm. Code 335.2140, as applicable)

10. licensee's written directive (WD) Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources, applicators, and collimators to ensure that treatment is to the correct site (32

Ill. Adm. Code 335.1110, 32 Ill. Adm. Code 335.1120 and 32 Ill. Adm. Code 335.2140 as applicable)

11. proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources) (32 Ill. Adm. Code 335.7020, 32 Ill. Adm. Code 335.8040 and 32 Ill. Adm. Code 335.2140, as applicable)

12. size and appearance of different types of sources and applicators (32 Ill. Adm. Code 335.7020, 32 Ill. Adm. Code 335.8040 and 32 Ill. Adm. Code 335.2140, as applicable)

13. previous incidents, events, and/or accidents for remote afterloaders, teletherapy units,and GSR units

14. licensee operational safety training (to new staff and annually to all individuals operating the unit) that is device model-specific and includes (32 Ill. Adm. Code 335.8040 and 32 Ill. Adm. Code 335.2140, as applicable)

    a. vendor training (prior to first use of a new unit or after manufacturer upgrades that affect operation and safety of the unit)

    b. design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms

    c. hands-on training in actual operation of the device under the direct supervisionof an experienced user, including “dry runs” (using dummy sources) of routine patient set-up and treatment and implementation of the licensee’semergency procedures

    d. a method, such as practical examinations, to determine each trainee’scompetency to use the device for each type of proposed use

Additional Training for Authorized Medical Physicists and Ophthalmic Physicists

Applicants for licenses to include AMPs and OPs who plan to engage in certain tasks requiring special training should ensure that the AMP is trained in the activities specific to the different types of uses listed in 32 Ill. Adm. Code 335.9150(b)(1) and 32 Ill. Adm. Code 335.7100 and that the OP is trained in the activities specific to 32 Ill. Adm. Code 335.7100. Note, for example, that additional training is necessary for AMP planning tasks such as remote afterloader therapy, teletherapy, GSR therapy, the use of the treatment planning system that applicants contemplate using, as well as the calculation of activity of strontium-90 sources used for ophthalmic treatments and assisting the licensee in developing, implementing and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive (32 Ill. Adm. Code 335.7100). Medical physicists must also have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system, as required in 32 Ill. Adm. Code 335.9150(d).

Additional Training for Authorized Users for Medical Uses of Byproduct Materials for Which a Written Directive Is Required

Applicants for licenses should carefully consider the type of radiation therapy that is contemplated. In addition to the training and experience requirements of 32 Ill. Adm. Code 335.9050, 32 Ill. Adm. Code 335.9070, 32 Ill. Adm. Code 335.9080, 32 Ill. Adm. Code 335.9100, 32 Ill. Adm. Code 335.9120, 32 Ill. Adm. Code 335.9140 and 32 Ill. Adm. Code 335.2140, as applicable, attention should be focused on the additional training and experience necessary for treatment planning, quality control systems, and clinical procedures.

Training for Ancillary Staff

For the purposes of this section, ancillary staff includes personnel engaged in janitorial and/or housekeeping, dietary, laboratory, security, and life-safety services. In addition to the instructions to workers required in 32 Ill. Adm. Code 400.120(a), the training program for ancillary staff will include instruction commensurate with potential radiological health protection problems present in the workplace.

Topics of instruction will include the following, as commensurate with the individual's duties:

1. storage, transfer, or use of radiation and/or radioactive material

2. potential biological effects associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding)

3. the applicable provisions of IEMA regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material)

4. responsibility to report promptly to the licensee any condition that may lead to or cause a violation of IEMA regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues)

5. appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material

6. radiation exposure reports that workers may request, as per 32 Ill. Adm. Code 400.130 "Notifications and reports to individuals"

Appendix I

Ordering and Receiving Radioactive Material Packages

- The Radiation Safety Officer (RSO) or qualified designee must approve or place all orders for radioactive material.
- The RSO must ensure that the requested material, quantities, manufacturer, and model designations are authorized by the license and that possession limits are not exceeded.
- Establish and maintain a system for ordering and receiving radioactive material; include the following information:
  - records that identify the AU or department, radionuclide, physical and/or chemical form, activity, and supplier
  - confirmation, through the above records, that material received was ordered through proper channels
- Packages of radioactive material containing in excess of a Type A quantity as defined in 49 CFR 173.435 or subject to 32 Ill. Adm. Code Part 337 require arrangements to receive the package. See 32 Ill. Adm. Code 340.960 and 32 Ill. Adm. Code Part 337, if applicable.
- During normal working hours, the RSO or their designee must be notified immediately upon delivery of radioactive packages. The packages must be taken to the radioactive material storage area for inspection. Instruct carriers to deliver radioactive packages directly to a specified area and provide contact information to the carrier for any questions (e.g., delivery area not accessible, staff not present to receive package).
- During off-duty hours, security or other designated trained personnel must accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below. Develop a similar memorandum for delivery of packages to other departments.

SAMPLE MEMORANDUM

FOR: Security Personnel

FROM: Facility Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

If the package appears to be damaged, immediately contact the facility's RSO. Ask the carrier to remain at the facility until it can be determined that neither the carrier nor the vehicle is contaminated.

Any packages containing radioactive material that arrive outside normal working hours shall be signed for by the Security guard or another designated trained individual on duty and taken immediately to the designated storage area/room. Unlock the door, place the package in the designated secured storage area and relock the door.

RADIATION SAFETY OFFICER (RSO): _____
OFFICE PHONE: _____
CELL PHONE: _____
ILLINOIS EMERGENCY MANAGEMENT AGENCY 24-HOUR PHONE: (217) 782-7860

Appendix J

Safely Opening Radioactive Material Packages

Refer to the regulatory requirements for radioactive material packages in 32 Ill. Adm. Code 340.960. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as defined in 49 CFR 173.435. Such packages must be received expeditiously when the carrier offers them for delivery or when the carrier notifies the licensee that the package has arrived at the carrier's terminal. For these and other packages for which monitoring is required, check for external radiation levels and surface contamination within 3 hours of receipt, if received during working hours, or no later than 3 hours from the beginning of the next working day, if received after working hours, in accordance with the requirements of 32 Ill. Adm. Code 340.960. Notify the final delivery carrier and IEMA's operations center (217) 782-7860, by telephone, when:

1. A package or its radioactive contents are lost or missing,

2. Removable radioactive surface contamination exceeds the limits of 49 CFR 173.443;

3. External radiation levels exceed the limits of 49 CFR 173.441.

For packages received under the specific license, authorized individuals shall implement procedures for opening each package as follows:

1. Put on gloves to prevent hand contamination.

2. Visually inspect the package for any sign of damage (e.g., crushed). If damage is noted, stop and notify the Radiation Safety Officer (RSO). Accordingly, the licensee should implement their emergency procedures and obtain technical assistance from the Agency and arrange for a timely evaluation of the source integrity following receipt of a damaged package.

3. Monitor the external surfaces of a labeled* package for radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form. See 32 Ill. Adm. Code 340.960.

   **Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations*.

4. Monitor the external surfaces of a labeled package for radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity.

5. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged. Monitoring for radiation levels and leakage shall be performed as soon as practicable after receipt of the package, but not later than three (3) hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours; or if received outside normal working hours, no later than three (3) hours after the beginning of the next business day.

6. Check U.S. Department of Transportation (DOT) White I, Yellow II, or Yellow III label or packing slip for activity of contents, to ensure that the shipment meets the activity as requested by the order and does not exceed license possession limits.

7. Open the outer package, if applicable, (following supplier's directions if provided) and remove packing slip to verify contents (compare requisition, packing slip and device label). Check integrity of the final source container (inspecting for damage, broken seals or vials, loss of liquid, condensation or discoloration of the packing material). Check also that the shipment does not exceed license possession limits or differ in the form, type, manufacturer, model, etc. as that authorized by the radioactive material license. If anything is other than expected, stop and notify the RSO.

8. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. Use an appropriate instrument with sufficient sensitivity to assay the sample* For example, a sodium iodide crystal and rate meter, a liquid scintillation counter, or a proportional flow counter may be used for these assays. Convert wipe sample from counts per minute to disintegrations per minute.

   ***Note**: *A dose calibrator is not sufficiently sensitive for this measurement.* Take precautions against the potential spread of contamination.

9. Check the user request to ensure that the material received is the material that was ordered.

10. Monitor the packing material and the empty packages for contamination with a radiation survey meter before discarding. If contaminated, treat this material as radioactive waste. If not contaminated, remove or obliterate the radiation labels before discarding.

11. Make a record of the receipt, package survey, and wipe test results.

12. Place the package in the designated secured storage area.

13. Maintain records of receipt.

14. If applicable, comply with the National Source Tracking System reporting requirement, as described in 32 Ill. Adm. Code 330.950.

Appendix K

General Rules for the Safe Use of Radioactive Material

1. When using radioactive material, wear laboratory coats or other appropriate protective clothing at all times.

2. Wear disposable gloves while handling radioactive material or potentially contaminated items.

3. Monitor hands and clothing for contamination with an appropriate monitoring instrument, in a low-background area, after each procedure or before leaving the area.

4. Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these and other exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle).

5. Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is used or stored.

6. Do not store food, drink or personal items in any area where radioactive material is used or stored. This does not include food/drink specifically meant for patients to facilitate the administration of radiopharmaceuticals.

7. In accordance with 32 Ill. Adm. Code 335.2030, determine and record the activity of each patient dose before medical use. If any dose differs from the prescribed dose by greater than ±20%, notify an authorized user and do not administer without an authorized user's written approval.

8. For therapeutic doses, in addition to assaying the dose, check the patient's name, the radionuclide, the chemical form, and the activity against the written directive. Verify the administration is being conducted in accordance with the physician's written directive and the licensee's written directive procedures. Consider labeling the dose with the type of study and patient's name to avoid mistakes.

9. Secure all areas where radionuclides are stored from unauthorized access when unattended (not under constant surveillance and immediate control of an individual authorized under the license or such individual's designee).

10. Wear whole body dosimetry (OSL, TLD or film badges) at all times while in areas where radioactive material is used or stored. Whole body dosimetry should be worn on the front of the body, in the area of the main torso, anywhere from neck to waist, where the highest exposure is expected. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the workplace in a designated low-background area.

11. Wear extremity dosimetry (finger rings, finger badges), turned inward towards material, when handling RAM (e.g. during elution of a generator or preparation, assay, and injection of radiopharmaceuticals). Extremity dosimetry is always worn on the finger likely to receive the most dose. Extremity dosimetry, when not in use, shall be stored in the workplace in a designated low-background area.

12. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

13. Never pipette by mouth.

14. Wipe-test unsealed byproduct material storage, preparation, and administration areas at least once per week for removable contamination. Decontaminate these areas as necessary.

15. Survey all areas where liquid radiopharmaceuticals were prepared for use or administered, including the generator storage, kit preparation, and injection areas, for contamination using a survey instrument at the end of each day of use. If necessary, decontaminate the area. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed at the end of each day of use in accordance with 32 Ill. Adm. Code 335.2080 (except when administering therapy dosages in patients' rooms when patients cannot be released under 32 Ill. Adm. Code 335.2110).

16. Always keep calibration, transmission, and reference sources, syringes, waste, and other radioactive material in shielded containers.

17. Store radioactive solutions in shielded, lidded, containers that are clearly labeled with the name of the compound, radionuclide, date, activity, radiation level, and affix a trefoil when applicable.

18. Always transport radioactive material in shielded containers.

Appendix L

Emergency Procedures

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

This model provides acceptable procedures for responding to emergencies involving spills or patients administered therapeutic amounts of radionuclides. These model procedures also include instructions for autopsy or cremation of patients who have permanent implants or handling a deceased individual with a nuclear pacemaker. Applicants using unsealed licensed material may either adopt this model or develop alternative procedures to meet the requirements of 32 Ill. Adm. Code 340.110. Applicants using therapeutic sealed sources should develop procedures specific to each use. Applicants using permanent implants can use the sample procedure in conjunction with facility-specific therapeutic sealed source emergency procedures.

The name and telephone number of the radiation safety officer (RSO) should be posted conspicuously in areas of use, so that they are readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills.

EMERGENCY CONTACT INFORMATION			
RADIATION SAFETY OFFICER (RSO):			
OFFICE PHONE:		HOME PHONE:	
ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RSO:			
IEMA 24-hour Response (217) 782-7860			

The decision to implement a major spill/contamination procedure instead of a minor spill/contamination procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated, and radiotoxicity of the spilled material. For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than five times the lowest annual limit on intake (ALI), an alternative spill/contamination procedure may be to restrict access, pending complete decay. In most cases, determination of a major versus minor spill should be based on the lowest ALI for the radionuclide(s) involved in the spill or contamination.

The licensee should estimate the amount of radioactivity spilled and initiate a major or minor spill/contamination procedure. Use the table below as general guidance to determine whether a major spill/contamination procedure or a minor spill/contamination procedure will be implemented. Spills above these millicurie (mCi) amounts should be considered major, and spills below these levels should be considered minor. A report to IEMA may be necessary in accordance with 32 Ill. Adm. Code 340.1220.

Relative Hazards of Common Radionuclides					
Radionuclide	**mCi**	**MBq**	**Radionuclide**	**mCi**	**MBq**
nitrogen-13	100	3700	technetium-99m	100	3700
carbon-14	10	370	indium-111	10	370
oxygen-15	100	3700	iodine-123	10	370
fluorine-18	100	3700	iodine-125	1	37
phosphorus-32	1	37	iodine-131	1	37
gallium-67	10	370	samarium-153	10	370
rubidium-82	10	370	ytterbium-169	10	370
strontium-82	1	37	mercury-197	10	370
strontium-85	10	370	gold-198	10	370
strontium-89	1	37	thallium-201	100	3700
yttrium-90	1	37	Alpha emitters	*	*
*For radiopharmaceuticals where the primary emission is alpha, consider implementing major spill precautions.					

MINOR SPILLS

1. NOTIFY: Notify persons in the area that a spill has occurred.
2. PREVENT THE SPREAD: Cover the spill with absorbent material and prevent access to the area by unauthorized personnel.
3. CLEAN UP: Wear gloves and protective clothing, such as a lab coat and booties, and clean up the spill using absorbent paper. Clean up the spill by wiping from the perimeter of the spill to the center of the spill. Carefully fold the absorbent material and place into a plastic bag. Insert other appropriate contaminated materials, such as disposable gloves, into the bag and dispose of in the radioactive waste container.
4. SURVEY: Use a low-range radiation detection instrument sufficiently sensitive to detect the radionuclide (e.g., thin window, G-M survey meter) to survey the area. Survey for removable contamination to ensure contamination levels are below trigger levels. Survey the area around the spill.
5. REPEAT: Continue to clean up the spill and re-survey until radiation levels and removable contamination are below trigger levels. Survey hands, clothing, and shoes for contamination prior to leaving the area.
6. REPORT: Report incident to the Radiation Safety Officer (RSO).
7. Cooperate and follow the instructions of the RSO and the RSO staff (e.g., criteria for returning to the work area, investigation of root cause, provision of requested bioassay samples, decontamination techniques, surveys, requested documentation).

Reminders to RSO

1. Follow up on the decontamination activities and document the results.
2. As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.
3. If necessary, notify IEMA.

MAJOR SPILLS

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.
2. PREVENT THE SPREAD: Cover the spill with absorbent material, but do not attempt to clean it up. Ideally, the absorbent paper is labeled, "caution radioactive material". Paper should be dampened, if solids are spilled. To prevent further spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.
3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.
5. CALL FOR HELP: Notify the RSO immediately.
6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the RSO. If the spill is on the skin, flush thoroughly with lukewarm water, then wash with mild soap and lukewarm water. Injured persons should be decontaminated, and first aid performed as necessary. If life threatening injuries are present, the individual should be given immediate lifesaving first aid and transported to a hospital for further medical treatment regardless of any contamination present. The hospital should be given prior notification that the patient is contaminated so that the appropriate controls can be implemented. Document personnel decontamination efforts.
7. Cooperate and follow the instructions of the RSO and the RSO's staff (e.g., criteria for returning to the work area, investigation of root cause, provision of requested bioassay samples, decontamination techniques, surveys, requested documentation).

Reminders to RSO

1. Supervise and 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.
2. Document decontamination results, including all surveys, location of surveys, and decontamination results.
3. Evaluate and determine personnel radiation exposure. Beta emitting radionuclides could have a potential for resulting in a shallow-dose exposure in excess of regulatory limits from μCi quantities of contamination.
4. Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.
5. If necessary, notify IEMA.

EXPOSURE TO SOURCES OF RADIATION

1. Terminate the source of exposure and prevent others from being exposed.

2. Use additional shielding as needed.
3. Notify the RSO so the nature and extent of exposure can be determined.
4. Seek medical attention if severe exposure is suspected.

Reminders to RSO

1. Supervise corrective measures and confirm exposures have returned to appropriate levels. Review security of sources and measures to prevent unauthorized access.
2. Document time and proximity of associated personnel to sources of radiation. Document all surveys including the location of surveys.
3. Evaluate and determine personnel radiation exposure. Beta emitting radionuclides could have a potential for resulting in a shallow-dose exposure in excess of regulatory limits from μCi quantities of contamination.
4. Determine cause and needed corrective actions.
5. If necessary, notify IEMA.

LOSS, THEFT OR DAMAGE TO A SOURCE OF RADIOACTIVE MATERIAL

In addition to following the applicable procedures outlined above, notify the RSO immediately and the Illinois Emergency Management Agency (217) 782-7860.

EMERGENCY SURGERY OF PATIENTS WHO HAVE RECEIVED THERAPEUTIC AMOUNTS OF RADIONUCLIDES

For emergency surgery or autopsy of patients administered byproduct material, National Council on Radiation Protection and Measurements (NCRP) Report No. 155, "Management of Radionuclide Therapy Patients," December 2006, may contain helpful information.

If emergency surgery is performed within the first 24 hours following the administration of iodine-131 sodium iodide, fluids (e.g., blood, urine) will be carefully removed and contained in a closed system.

Protective eyewear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable).

The radiation safety staff will direct personnel in methods to keep doses as low as reasonably achievable (ALARA) during surgical procedures.

If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed of any possible radiation hazard.

AUTOPSY OF PATIENTS WHO HAVE RECEIVED THERAPEUTIC AMOUNTS OF RADIONUCLIDES

1. Immediately notify the authorized user (AU) in charge of the patient and the RSO upon death of a therapy patient.

2. An autopsy will be performed only after consultation and permission from the RSO. Radiation safety staff should evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures to keep doses ALARA during the autopsy.

3. Protective eyewear should be worn by the pathologist and assisting staff for protection from possible splashing of radioactive material. Consider the need for protection against exposure from high-energy beta rays in cases involving therapy with phosphorus-32 and yttrium-90.

4. Remove tissues containing large activities early to help reduce exposure of autopsy personnel. Shield and dispose of contaminated tissues in accordance with license conditions. In some cases, exposure reduction may be accomplished by removing tissues for dissection to a location where the exposure rate is lower.

5. If an injury occurs during the autopsy that results in a cut or tear in the glove, monitor the wound and decontaminate as appropriate to the situation; inform radiation safety staff.

AUTOPSY OR CREMATION OF PATIENTS WHO HAVE PERMANENT IMPLANTS

Patients treated with seed implants will not usually represent a radiation hazard to persons dealing with the body unless there is to be an autopsy or cremation. For autopsy or cremation of patients with permanent implants, NCRP Report No. 155, "Management of Radionuclide Therapy Patients," December 2006, may contain helpful information. If an autopsy or cremation is to be performed:

1. Immediately notify the AU in charge of the patient and the RSO upon death of a therapy patient.

2. Consult and get permission from the RSO.

3. Instruct pathologist to excise tissue containing radioactive seeds.

    a. Make pathologist aware seeds may have migrated and additional tissue may need to be removed.

    b. Instruct pathologist to consult with RSO about the possibility of slicing through a seed and contaminating the facility.

4. Seek municipal approval, if required, because the very high temperatures used in modern crematoria may cause seeds to burst, releasing radioactivity into the plume.

NUCLEAR PACEMAKERS

Medical licensees are often the first to come into contact with plutonium-powered pacemakers or the first to be contacted by nursing homes and funeral homes when a patient with an implanted pacemaker dies. In such cases, and when the licensee is not responsible for control or disposal of the pacemaker, notify IEMA and attempt to contact the hospital where the pacemaker was implanted to arrange for explantation. The licensee that implanted the device is responsible for the follow-up, explantation, and return of the pacemaker to the manufacturer for proper disposal. Information Notice (IN) 98-12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers," April 3, 1998, provides additional information.

Appendix M

Testing Sealed Sources for Leakage and/or Contamination

Applicants who wish to perform their own tests for leakage and/or contamination (leak/wipe tests), including the procurement and the analysis of the test samples, must submit the following descriptive information in support of the application.

Training

Before allowing an individual to perform leak testing, the licensee will ensure sufficient classroom and on-the-job training to show competency in performing leak tests independently. Records for training on the applicable leak-test procedures should be maintained.

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

1. Principles and practices of radiation protection;
2. Radioactivity measurements, monitoring techniques, and the use of instruments;
3. Mathematics and calculations basic to the use and measurement of radioactivity;
4. Biological effects of radiation.

Appropriate on-the-job-training consists of:

1. Observing authorized personnel collecting and analyzing leak test samples and
2. Collecting and analyzing leak-test samples under the supervision and in the physical presence of an individual authorized to perform leak test and sample analysis

Frequency of Leak Testing

The frequency is specified in the 32 Ill. Adm. Code 340.410, which may refer to the source's sealed source and device registry sheet. If a sealed source is not registered, leak tests should be conducted at 6-month intervals, unless a different interval is established during the licensing process. Leak testing of sealed sources may be required by license condition.

Instrumentation

1. Select an instrument that is sensitive enough to detect 185 Bq (0.005 microcurie) of the radionuclide contained in the device.
2. To ensure the required sensitivity of measurements is achieved, analyze leak tests in a low background area.
3. A NaI(Tl) well counter system with a single or multichannel analyzer should be used to count samples from devices containing gamma-emitters (e.g., Cs-137, Co-60).

4. A liquid scintillation or gas-flow proportional counting system should be used to count samples from devices containing beta-emitters (e.g., Sr-90) or alpha emitters (e.g., Am-241).

5. Describe all instrumentation, which will be used for the analysis of the test samples. The descriptive information should include:

   a. The manufacturer, model and serial number of each instrument;

   b. The types and energies of detectable radiation, as applicable to each instrument;

6. 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 percent of the stated value and traceable to a primary radiation standard such as those maintained by the National Institutes of Standards and Technology (NIST).

   Efficiency Calculation Example:

   $$\frac{[(\text{CPM from std}) - (\text{CPM from bkg})]}{\text{activity of std in Bq or } \mu\text{Ci}} = \text{efficiency in CPM/Bq or CPM/}\mu\text{Ci}$$

   **CPM = Counts per minute*

7. The minimum sensitivity of each instrument, for each type of radioactive material to be tested, including the supportive calculations documenting such minimum sensitivity. At a minimum, the instrument used must be capable of detecting 185 Bq (0.005 μCi) of the radioactive material being tested. For radium-226, the instrument must be sensitive enough to detect 185 Bq (0.005 μCi) external radon-daughter contamination or the escape of radon at the rate of 37 Bq (0.001 μCi) per 24 hours.

Procedures

1. Wear gloves.

2. Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.

3. Identify the calibration standards to be used in the analysis of each radioactive material to be tested. The identification shall include the manufacturer, model, radionuclide and activity of each standard. Such standards shall be traceable to a national standard.

4. Describe the calibration procedures and the frequency of calibration for each instrument

5. Use a survey meter to monitor exposure.

6. For each source to be tested, list identifying information such as device/source serial number, manufacturer, model, radionuclide, and activity.

7. Describe the material or leak/wipe test kit to be used in collecting the leak/wipe test samples.

8. Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.

9. Number each wipe to correlate with identifying information for each source.

10. Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.

11. Describe in detail the procedure for performing the analysis of the leak/wipe test samples.

12. Submit sample calculations showing the conversion of the raw counting data to units of becquerels or microcuries.

13. To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.

14. Using the selected instrument, count and record background count rate.

15. Count each wipe sample; determine net count rate.

16. For each sample, calculate and record estimated activity in Bq (or microcuries).

$$\frac{[(\text{CPM from wipe sample}) - (\text{CPM from bkg})]}{\text{Efficiency}} = \text{Activity on sample}$$

17. If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO so that the source can be withdrawn from use and disposed of properly. Also notify IEMA.

18. Describe the method for disposing of contaminated leak/wipe test samples.

Records

1. Describe the records to be maintained for each leak/wipe test. These shall include:

    a. The location of the source, which was leak/wipe tested;

    b. The date the sample was collected;

    c. The individual collecting the sample;

    d. The person performing the analysis;

    e. The date the analysis was performed;

    f. The unique identification of the source tested; e.g., manufacturer, model, serial number, etc.

    g. The radionuclide and the activity of radioactive material contained in the source; and

    h. The results of the test expressed in units of becquerels or microcuries. Actual test results shall be reported unless such results are less than 185 Bq (0.005 μCi).

Appendix N

Procedures for the Therapeutic Use of Radiopharmaceuticals

In addition to those procedures required by the regulations and those identified as general safety precautions, the following additional procedures will be followed when handling therapeutic radiopharmaceuticals or when handling hospitalized patients treated with therapeutic radiopharmaceuticals:

a) Written procedures will be developed and maintained for all administrations requiring a written directive. The procedures will meet all applicable requirements in 32 Ill. Adm. Code 335.1120, including the criteria used to identify if a reportable medical event has occurred.

b) *[Include only if applicable. The following pertains only to applicants that indicate they will administer I-131 only in capsule form and have elected not to institute a bioassay program.]*

A bioassay program has been evaluated and is not being implemented at this time due to the form and quantities of unsealed radiopharmaceuticals in use. However, consistent with Reg Guide 8.9, Rev. 1, suspected abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption will be evaluated on a case-by-case basis.

The following conditions will result in non-routine bioassay monitoring of occupationally exposed individuals:

i. An incident in which an occupationally exposed individual is potentially exposed to a quantity of radioactive material which could result in an uptake equivalent to 10% of the annual limit on intake (ALI).
ii. Identified conditions that result in the cumulative exposure to airborne radioactivity, since the most recent bioassay measurement, reaching > 0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life less than 2 hours should be excluded from the evaluation since external exposure is generally controlling for these radionuclides.

The following conditions will result in the licensee evaluating the need for emergency bioassay measurements:

i. The presence of unusually high levels of facial and/or nasal contamination,
ii. Entry into airborne radioactivity areas without appropriate exposure controls,
iii. Operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity),
iv. Known or suspected incidents of a worker ingesting radioactive material,
v. Incidents that result in contamination of wounds or other skin absorptions,
vi. Evidence of damage to or failure of a respiratory protective device.

In order to implement the criteria above, we have identified a provider of emergency bioassay analysis and a manner of testing in which timely analysis can be accomplished.

NOTE: An individual's baseline measurement of radioactive material within the body should be conducted prior to initial work activities that involve exposure to radioactive materials, for which monitoring is required. Failure to maintain a baseline measurement of occupationally exposed workers may lead to a mischaracterization of the amount of uptake in accident scenarios.

c) *[Include only if applicable. The following pertains only to applicants that indicate they will administer radiopharmaceuticals identified in 32 Ill. Adm. Code 335.5010 and anticipate all patients/human research subjects will be able to be released in accordance with 32 Ill. Adm. Code 335.2110.]*

Additional contingency procedures will be developed and maintained to accommodate incidents in which a therapeutic administration of radiopharmaceuticals results in a patient/human research subject condition which does not allow patient release under 32 Ill. Adm. Code 335.2110 (e.g., an exposure rate exceeding the release rate specified in U.S. NRC Reg Guide 8.39, Rev. 1).

i. If applicable and identified in an actionable timeframe, radiopharmaceuticals identified in 32 Ill. Adm. Code 335.5010 will not be administered if the patient is not a candidate for release; or
ii. The patient/human research subject will be transferred / sent to another licensed facility that is properly equipped. A memorandum of understanding or equivalent document to that effect is attached.

d) All therapy doses of I-131, not in capsule form, will be opened in an operating fume hood.

e) Either after each procedure or before leaving the area, monitor hands for contamination in a low-background area using an appropriate survey instrument.

f) Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these and other exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle).

g) Survey all areas of licensed material use, including the generator storage, kit preparation, and injection areas, for contamination using a survey instrument each day of use. If necessary, decontaminate the area. Areas used to prepare and administer radiopharmaceuticals must be surveyed daily in accordance with 32 Ill. Adm. Code 335.2080 (except when administering therapy dosages in patients' rooms when patients are confined).

h) Radiopharmaceutical multi-dose diagnostic and therapy vials, syringes, and unit dosages must be labeled in accordance with 32 Ill. Adm. Code 335.2060, and 32 Ill. Adm. Code 340.940. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities listed in Appendix C to 10 CFR Part 20, "Quantities of Licensed Material Requiring Labeling," the syringe or vial need only be labeled to identify the radioactive drug (32 Ill. Adm. Code 335.2060). To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.

i) Always keep calibration, transmission, and reference sources, syringes, waste, and other radioactive material in shielded containers.

j) Secure all licensed material when not under the constant surveillance and immediate control of an individual authorized under the license (or such individual's designee).

k) For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it (32 Ill. Adm. Code 335.2030).

l) Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ±20% from the prescribed dosage, except as approved by an authorized user.

m) When measuring the dosage, licensees need not consider the radioactivity that adheres to the syringe wall or remains in the needle.

n) The large surfaces in the room and toilet areas that are more likely to be contaminated will be covered with absorbent pads or protective material as appropriate to the amount of contamination to be expected. Attention will be given to objects likely to be touched by the patient (e.g., telephones, doorknobs and other items that would be difficult to decontaminate).

o) Attending personnel will wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins or other items contacting material from the patient's body.

p) Disposable items should be used in the care of these patients, whenever possible.

q) If a nurse, who is a declared pregnant worker, an attendant or anyone else knows or suspects that his or her skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer (RSO) or his designee immediately. This person should remain in the area and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and lukewarm water.

r) Nurses shall read and follow the posted restrictions before caring for a therapy patient.

s) The Nuclear Medicine Department staff, medical physics staff or the RSO will answer any questions about the care of therapy patients. Nursing personnel who attend the patient will wear personnel monitoring devices.

t) If a therapy patient should need emergency surgery or should die, notify the RSO or the Nuclear Medicine Department staff immediately.

The following apply to in-patient administrations of unsealed radioactive material requiring (i.e., those patients who cannot be immediately released according to 32 Ill. Adm. Code 335.2110):

u) The form, "Nursing Instructions for Patients Treated with Phosphorous-32, Gold-198 or Iodine-131" (or a similar form containing all the requested information) will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

v) No nurse, who is a declared pregnant worker, visitor or attendant who is pregnant will be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard or unless otherwise noted on the precaution sheet on the patient's chart. Female visitors will be asked whether they are pregnant.

w) Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet (or 1 meter) from the patient.

x) Patients containing radioactive material are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department staff, medical physics staff or the RSO.

y) If urine and vomitus from I-131 therapy patients are collected for medical analysis, they will be stored for decay in the radioactive waste storage area. Such stored waste will be retained until it has reached background levels, as measured with a low-level monitoring instrument. It will then be released to the sanitary sewer system.

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH PHOSPHORUS-32, GOLD-198, OR I-131			
Patient's Name:		Room #:	
Physician's Name:		Radionuclide Administered:	
Time and Date of Source Administration:		AM/PM	
Dosage:		Method of Administration:	
Signature:			

RADIATION EXPOSURE RATES						
Instrument Used:	Make:		Model:		Serial Number:	
Unrestricted Areas:	Door:	mR/hr	Room:	mR/hr	Adj. Room:	mR/hr
Patient Supine in Bed or:						

Date:	Time:	Bedside:	3 feet from bed:	Door:
	AM/PM	mR/hr	mR/hr	mR/hr
	AM/PM	mR/hr	mR/hr	mR/hr
	AM/PM	mR/hr	mR/hr	mR/hr

	VISITOR RESTRICTIONS:		NURSING RESTRICTIONS:
	No visitors.		Patient is restricted to room.
	No visitors under 18 or pregnant.		No nurse, who is a declared pregnant worked, may render care.
	____ minutes per day maximum per visitor.		____ minutes per day per nurse in the room.
	Visitors must stay behind line on floor at all times.		

	PATIENT CARE:
	Wear disposable gloves. Wash hands after caring for patient.
	Discard linen, bedclothes, plates, utensils, dressings, etc. in boxes in room.
	Collect urine in containers provided. Discard urine and feces in toilet. Flush 3 times.
	Housekeeping personnel are not permitted in the room.
	Only the RSO may release room to admitting office.
	Wear your radiation monitor when caring for patient. Leave monitor at nursing station at the end of your shift. You must use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.

In case of emergency, or if you have questions, call:							
RSO:		Work:		Home:		Pager:	
M.D.:		Work:		Home:		Pager:	

Appendix O

Radioiodine Bioassay Procedures

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

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

1. adequate equipment to perform bioassay measurements,
2. procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or μCi units,
3. the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue),
4. the interval between bioassays, differentiating between routine and special bioassays,
5. documentation of baseline bioassay measurements before assignment of duties with therapeutic quantities of radioactive material,
6. action levels, and
7. the actions to be taken at those levels

The following model procedures provide information which a licensee may utilize in the development of a bioassay program. Both the U. S. Nuclear Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program" and NUREG 1556 Volume 11, Rev. 1, provide additional information on the construct of bioassay programs. This includes development of bioassay programs for unsealed radioactive material other than sodium iodide.

Frequency of Required Bioassay Measurements

Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential and the physical and chemical characteristics of the radioactive material and the route of entry to the body. Consider the following elements:

- potential exposure of the individual
- retention and excretion characteristics of the radionuclides
- sensitivity of the measurement technique
- acceptable uncertainty in the estimate of intake and committed dose equivalent

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 10 percent ALI criterion is consistent with 32

Ill. Adm. Code 340.520(b), which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10 percent of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults). Separate categories of bioassay measurements, routine measurements and special measurements further determine the frequency and scope of measurements.

Routine Measurements

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose. The method of bioassay selected (for example, whole body counting, urinalysis, etc.) and the samples collected will vary according to the radionuclides and the compound to which it is attached. Sample collection procedures should be developed to ensure that appropriate types, sizes, and numbers of samples are collected that will provide appropriate physiological information for the dose assessment. An individual's baseline measurement of radioactive material within the body should be conducted before beginning work that involves exposure to radiation or radioactive materials for which monitoring is required.

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements should be made when the cumulative exposure to airborne radioactivity since the most recent bioassay measurement is > 0.02 ALI (40 derived air concentration hours). Noble gases and airborne particulates with a radioactive half-life of less than 2 hours should be excluded from the evaluation, since external exposure generally, controls these radionuclides.

At a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

When an individual is no longer subject to the bioassay program because of change in employment status, termination bioassay measurement should be made, when practicable, to ensure that any unknown intakes are quantified.

Special Monitoring

Because of uncertainty in the time of intakes and the absence of other data related to the exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to actual intakes for routine measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption, should be evaluated on a case-by-case basis. When determining whether potential intakes should be evaluated, consider the following circumstances:

- the presence of unusually high levels of facial and/or nasal contamination
- entry into airborne radioactivity areas without appropriate exposure controls
- operational events with a reasonable likelihood that a worker was exposed to unknown
- quantities of airborne radioactive material (e.g., loss of system or container integrity)
- known or suspected incidents of a worker ingesting radioactive material

- incidents that result in contamination of wounds or other skin absorption
- evidence of damage to or failure of a respiratory protective device

Calibration

This bioassay procedure uses a sodium iodide crystal and single channel analyzer (such as an uptake probe) to determine thyroid burden. Calibration of the system will be performed annually.

a) Set Window or Region of Interest

1. The window or region of interest must be set to detect emissions for the radionuclide you are trying to detect. In the case of I-131, the region of interest must be in the area of 364 keV.

2. Using the minimum detectable activity calculations described in Appendix D, demonstrate that the system you are using can detect 1.48 kBq (0.04 μCi) of I-131. (Submit these calculations with Exhibit B.)

b) Establish Background

1. Hold probe on thigh (ensure thigh and/or lab coat are not contaminated) for a 1-minute count. Record results.

c) Count Standard

1. A known (measured) amount of radioactivity must be used as the standard. When assaying for I-131, an I-131 standard (or a standard source of known activity that emits photons of approximately the same energy as I-131, e.g., Ba-133) must be used. I-131 liquid or capsule may be used and must be measured and corrected for decay. Place the standard in a thyroid phantom*. Hold probe against the phantom in an established geometry, similar to the geometry to be used when performing a bioassay on an individual, for required amount of time (1 min.). Record results.

2. Note: Specifications for design of a neck phantom can be found in American National Standard ANSI N44.3-1973, "Thyroid Radioiodine Uptake Measurements Using a Neck Phantom."

d) Establish System Efficiency

Standard CPM - Background CPM = Net Standard CPM

$$\frac{\text{Net Standard CPM}}{\text{Standard Activity (μCi)}} \times \frac{100}{2.2 \times 10^6 \text{ DPM/μCi}} = \text{\% Efficiency}$$

Investigation Limits

a) Establish In-House Investigation Limits

1. The Radiation Safety Officer (RSO) shall be notified whenever the thyroid burden at the time of measurement exceeds 37 kBq (1.0 μCi) of I-131. The RSO shall perform an investigation

into the cause of the exposure and the potential for further exposure and develop corrective actions to prevent recurrence.

2. The RSO shall be notified immediately whenever the thyroid burden at the time of measurement exceeds 185 kBq (5.0 μCi) of I-131. The RSO must perform an investigation, as described above, and must perform weekly bioassay on the individual until the individual's thyroid burden is less than 37 kBq (1.0 μCi) of I-131.
3. Note: In-house investigation limits are adopted from U. S. Nuclear Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program."

Measurement

a) Measure Thyroid Gland

1. Perform measurements in a low-background area.
2. Hold probe on thigh (ensure thigh and/or lab coat are not contaminated) for a 1-minute count. Record results.
3. Hold probe in the center of neck near Adam's apple for required amount of time (1 min). Record results.
4. Subtract background from thyroid gland count to obtain net counts. Record results.
5. Calculate and record the amount of radioactivity in thyroid by using the equation below:

$$\frac{\text{Net counts (CPM) x 100}}{\text{\% Efficiency x 2.2 x } 10^6 \text{ DPM/μCi}} = \text{X μCi}$$

The intake retention fraction (t = 24 hours) for I-131 is 0.133.

$$\frac{\text{X μCi}}{0.133} = \text{X(i) μCi (estimate of intake)}$$

The inhalation ALI for I-131 is 50 μCi.

$$\frac{\text{X(i)}}{\text{50 μCi}} = \text{\% of CEDE}$$

6. If results are less than the investigation limits established above, you are finished with this procedure.
7. If results are more than the investigation limits established above, notify the RSO immediately. The RSO may restrict the employee's further handling of I-131 until the thyroid burden is measured to be below the reporting limits established above.

Appendix P

Procedures for the Therapeutic Use of Brachytherapy Sources

In addition to those procedures required by the regulations and those identified as general safety precautions, the following additional procedure will be followed when handling brachytherapy sources and patients treated with brachytherapy sources:

a) Written procedures will be developed and maintained for all administrations requiring a written directive. The procedures will meet all applicable requirements in 32 Ill. Adm. Code 335.1120, including the criteria used to identify if a reportable medical event has occurred. For permanent implant brachytherapy, we will determine within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

NOTE: For purposes of determining whether medical event reporting is required, definitive criteria will be established for evaluating the adequacy of the dose delivered or activity implanted to the intended treatment site, compared to the prescribed dose, and the acceptability of the dose delivered to any other organ or tissue, compared to the dose expected from the administration defined in the written directive.

b) We will develop and maintain procedures which address the applicable requirements in 32 Ill. Adm. Code 335.1120 and, as applicable 32 Ill. Adm. Code 335.7100.

c) Never touch needles, capsules or unshielded containers holding brachytherapy sources.

d) If needles, containers or capsules become loose or fall out or are removed by the patient, do not try to replace them. Use long forceps and put them in the shielded container provided or in a corner of the room. Immediately contact the Radiation Therapy Department, the Radiation Safety Officer (RSO) or the physician in charge.

e) Immediately after the sources are implanted, the form "Nursing Instructions for Patients Treated with Brachytherapy Sources" (or a similar form containing all the requested information) will be completed and placed on the patient's chart.

f) Special restrictions shall be noted on the precaution sheet on the patient's chart. Nurses shall read and follow these instructions before caring for a therapy patient. The Radiation Therapy Department staff, medical physics staff or the RSO will answer any questions about the care of therapy patients. Nursing personnel who attend the patient will wear personnel monitoring devices.

g) No nurse, who is a declared pregnant worker, visitor or attendant who is pregnant will be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard or unless otherwise noted on the precaution sheet on the patient's chart. Female visitors will be asked whether they are pregnant.

h) Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet (or 1 meter) from the patient.

i) Patients containing radioactive material are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department staff, medical physics staff or the RSO.

j) All items that may have been in contact with the patient must be checked with a radiation monitoring instrument before being removed from the patient's room to ensure that no dislodged sources are inadvertently removed.

k) If a therapy patient should need emergency surgery or should die, immediately notify the RSO, the Nuclear Medicine Agency staff or the medical physics staff.

l) Emergency equipment, appropriate for responding to a source dislodged from a patient or a source lodged within the patient following removal of the source applicator, will be maintained and available near each treatment room. The licensee has the flexibility to determine the type of emergency response equipment needed to respond but should include shielded storage containers, remote handling tools and, as appropriate, supplies necessary to remove applicators or sources from the patient.

Responders will also have ready access to an appropriate survey instrument, which is typically needed for locating dislodged sources and/or for assessing doses to people from dislodged sources.

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH BRACHYTHERAPY SOURCES					
Patient's Name:				Room #:	
Physician's Name:				Radionuclide Administered:	
Time and Date of Source Administration:		AM/PM		Number of Sources:	
Total Activity:		Sources Will Be Removed at Approximately:			AM/PM
Signature:					

RADIATION EXPOSURE RATES						
Instrument Used:	Make:		Model:		Serial Number:	
Unrestricted Areas:	Door:	mR/hr	Room:	mR/hr	Adj. Room:	mR/hr
Patient Supine in Bed or:						
Date:	Time:		Bedside:	3 feet from bed:	Door:	
	AM/PM		mR/hr	mR/hr	mR/hr	

Release Certification: Patient may not be released from the hospital until the following certification is signed and dated by the Radiation Safety Officer (RSO) or the attending physician:

I have removed and counted _____ individual sources from this patient. A low-range instrument (i.e. GM) survey of the patient indicated no remaining sources in the patient.

Signature:		Date:	

VISITOR RESTRICTIONS:		NURSING RESTRICTIONS:	
	No visitors.		Patient is restricted to room.
	No visitors under 18 or pregnant.		Patient is restricted to bed.
	____ minutes per day maximum per visitor.		Patient must not move.
	Visitors must stay behind line on floor at all times.		No nurse, who is a declared pregnant worked, may render care.
			____ minutes per day per nurse in the room.

PATIENT CARE:	
	Wear your radiation monitor when caring for patient. Leave monitor at nursing station at the end of your shift. You must use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
	If a source appears dislodged, call the attending physician and the RSO immediately.
	Omit bed bath.
	No perineal care. Pad may be changed as necessary.
	Save surgical dressings for disposal by attending physician or RSO.
	See special oral hygiene care instructions.

In case of emergency, or if you have questions, call:

RSO:		Work:		Home:		Pager:	
M.D.:		Work:		Home:		Pager:	

Appendix Q

Model Procedures for Remote Afterloader Spot-Checks

This model provides acceptable procedures for performing spot-checks of Remote Afterloader unit equipment, and facilities as required in 32 Ill. Adm. Code 335.8170. This procedure applies to high dose-rate, medium dose-rate, pulsed dose-rate, or low dose-rate (LDR) remote afterloader units. Applicants may either adopt these model procedures or develop alternative procedures.

Periodic Spot-Checks for Remote Afterloader Units

Before the first use on a given day (or before each patient treatment for LDR remote afterloaders) and after each source installation, the following spot-checks will be performed:

1. Electrical Interlocks at Each Room Entrance

   Proper functioning of the treatment room door interlock will be performed using the remote afterloader source.

   Expose the remote afterloader source inside the treatment room, open the treatment room door, and verify that the source retracts. The source should retract immediately, the area radiation monitor should alarm, and the control console should indicate that the door is open. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

2. Source Exposure Indicator Lights

   a. Treatment Console Indicators and Status Lamps.

      Turn on the remote afterloader unit and verify that the indicator lights flash to show proper function. In addition, when the source is exposed for the electrical interlock test above, verify that the source status indicator lights on the treatment console are lit to indicate an exposed source.

   b. Remote Afterloader Indicators and Status Lamps

      Turn on the remote afterloader unit and verify that the indicator lights flash on the remote afterloader to show proper function. In addition, when the source is exposed for the electrical interlock test above, verify that the source status indicator lights on the remote afterloader are lit to indicate an exposed source.

3. Viewing and Intercom Systems

   a. Viewing System

      Turn on the camera(s). Check that the camera(s) is (are) operable and that the treatment area can be viewed from the treatment console. Adjust, if necessary.

   b. Intercom System

Turn on the intercom system. The intercom system will be tested using a two-person method. One person will be at the treatment console while another person is in the treatment room. Both individuals will speak and confirm that theother is heard.

4. Emergency Response Equipment

   Verify the presence of the emergency equipment within the treatment room. This equipment includes but is not limited to a mobile lead container large enough to hold the largest applicator, long-handled forceps, wire cutter, flashlight, suture removal kit, and timer (timer located at unit console). If a portable radiation survey meter is included, verify the presence, current calibration of the meter and check the operability using a radioactive check source.

5. Radiation Monitors Used to Indicate the Source Position

   Verify that the area radiation monitor located inside the treatment room is on with the indicator light flashing green. Expose the remote afterloader source inside the treatment room with the door closed and verify that the indicator light flashes red; indicating the presence of radiation. This test will be performed with the area radiation monitor on A/C power and on battery backup power.

6. Timer Accuracy

   Expose the remote afterloader source inside the treatment room with the door closed. Immediately start a stopwatch when the control console indicates that the source is exposed. Stop the stopwatch when the control console indicates that the source is retracted. Compare the stopwatch measured time to the irradiation time indicated on the control console. Verify that the comparison is within 1 percent.

7. Clock Date and Time in the Computer for the Remote Afterloader

   Verify clock date and time printed on the control console documentation of the pretreatment checks against the actual date and time. The date must be exact, and the time may be within 1 hour.

8. Decayed Source Activity in the Computer for the Remote Afterloader

   Verify the source activity (or decay factor) displayed on the remote afterloader control console matches to within 0.5 percent of the manufacturer's provided decay table for today's date.

If the results of the above checks indicate the malfunction of any system, the control console shall be locked in the off position, as required by 32 Ill. Adm. Code 335.8170(e), and not used except as may be necessary to repair, replace, or check the malfunctioning system.

In addition, consideration will be given to testing the following before the first use of the remote afterloader unit on a given day:

9. Treatment Interrupt Button

   Press the "Interrupt" button on the control console while source is exposed. Verify that the source retracts immediately, and the control console indicates an alarm. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

10. Emergency Off Button

    Press the “Stop” button on the control console while the source is exposed. Verify that the source retracts immediately, and the control console indicates an alarm. Repeat the test for all wall mounted “Stop” buttons. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

11. Dual Use Switch

    An X-ray unit is also used in the remote afterloader treatment room, and a selector switch to limit operation to only one unit at a time is installed.

    With the key switch on the wall set to X-ray, attempt to expose the remote afterloader source. Verify that the area radiation monitor and the control console source indicator lights do not illuminate; indicating that the source did not expose. Switch the key to remote afterloader. Expose the remote afterloader source and confirm that the area radiation monitor illuminates. With the remote afterloader source still exposed, switch the key back to X-ray, and confirm that the remote afterloader source retracts and the area radiation monitor flashes green. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

12. Misconnected or Missing Transfer Tube and/or Applicator

    Misconnect a transfer tube to the remote afterloader. This may either be performed by connecting the transfer tube to the wrong channel or by not fully inserting the transfer tube into the correct channel. Attempt to expose the remote afterloader source and verify that the source does not expose as indicated by the area radiation monitor.

    Additionally, verify that an error is indicated on the control console for the misconnection. Repeat the test with an applicator intentionally misconnected to a transfer tube that is correctly inserted into the remote afterloader.

13. Mechanical Integrity of Applicators, Transfer Tubes, Connectors

    Perform a visual inspection of all applicators, transfer tubes, and connectors to be used for patient treatments that day. Check for any potential mechanical defects. Replace if a defect is noted.

14. Position of Remote Afterloader Within the Treatment Room

    For some remote afterloader units located within minimally shielded rooms, the location of use within the room may have been specified in the application to ensure that the regulatory limits in 32 Ill. Adm. Code 340.310 will not be exceeded. If this is the case, verify that the positioning of the remote afterloader unit within the treatment room is in accordance with the commitments made in the application.

REFERENCES AND RESOURCES:

AAPM Report No. 41, “Remote Afterloading Technology (Remote Afterloading Technology Task Group No. 41),” 1993

Appendix R

MODEL PROCEDURES FOR WASTE DISPOSAL BY DECAY-IN-STORAGE, GENERATOR RETURN, LICENSED MATERIAL RETURN AND DISPOSAL OF LIQUIDS INTO SANITARY SEWERAGE

This model provides acceptable procedures for waste disposal. Most licensees will dispose of material that fall within these procedures. Note that some short half-life radionuclide products [e.g., technetium (Tc)-99m/molybdenum (Mo)-99 generator columns and some yttrium (Y)-90 microspheres] may contain long half-life contaminants that may preclude disposal by decay-in-storage and may require disposal by alternate methods, such as return to the manufacturer. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of Subpart K, "Waste Disposal," to 32 Ill. Adm. Code Part 340, and 32 Ill. Adm. Code 340.110.

Model Procedure for Decay-In-Storage

Regulations in 32 Ill. Adm. Code 340.1045, "Decay-in-storage," describe the requirements for decay-in-storage. Applicants should ensure that adequate space and facilities are available for the storage of waste for decay-in-storage (DIS). Storage should be designed to allow for segregation of wastes with different half-lives (e.g., multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at as low as is reasonably achievable (ALARA) levels. Storage areas must be in a secure location.

1. Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.

2. Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.

3. Liquid and solid wastes should be stored separately.

4. If possible, use separate containers for different types of waste (e.g., needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Because the waste will be surveyed with all shielding removed, the containers in which the waste will be placed must not provide any radiation shielding for the material.

5. When the container is full, seal it and attach an identification tag that includes the date sealed and the longest-lived radionuclide in the container.

6. The container should be labeled in accordance with 32 Ill. Adm. Code 340.940 and 32 Ill. Adm. Code 340.950. The container may be transferred to the DIS area. When large quantities are held for DIS, measurable activities may be present even after many half-lives and persons performing surveys should be aware of the potential for measurable radiation.

7. The contents of the container should be allowed to decay for a period of time after which it is expected that the radiation levels would not be distinguishable from background. The period of time depends on both the half-life of the radionuclide(s) and the original amount present.

8. Prior to disposal as ordinary or biomedical waste, monitor and record the results of monitoring of each container as follows:

    a. Use a survey instrument on the lowest setting that is appropriate for the type and energy of the radiation being measured.

    b. Check the radiation survey meter for proper operation and current calibration status.

    c. Monitor in a low-level background radiation area away from all sources of radioactive material, if possible.

    d. Remove any shielding from around the container or generator column.

    e. Monitor, at contact, all surfaces of each individual container.

    f. Remove or deface any radioactive material labels (unless the containers will be managed as biomedical waste after they have been released from the licensee, as described in 32 Ill. Adm. Code 340.1045).

    g. Discard as in-house ordinary or biomedical waste only those containers that cannot be distinguished from background radiation. Containers may include trash bags full of waste, generator columns, and biohazard (needle) boxes. Record the disposal date, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

    h. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized byproduct material recipient.

    i. Short half-life radionuclide products, such as samarium-153 (Sm-153), Tc-99m/Mo-99 generator columns, and Y-90 microspheres may contain long half-life contaminants that may preclude disposal by decay-in-storage. Licensees need to perform surveys and dispose of long half-life contaminants in accordance with 32 Ill. Adm. Code Part 340 and 32 Ill. Adm. Code Part 335 requirements.

NOTE: Check for any calibration sources with half-lives greater than 120 days (e.g., cobalt-57, germanium-68, gadolinium-153), as these may not be held for decay-in-storage and must be disposed of in accordance with 32 Ill. Adm. Code Part 340 and 32 Ill. Adm. Code Part 330.

Model Procedure for Returning Generators to the Manufacturer

Used Mo/Tc-99m, strontium-82/rubidium-82, or germanium-68/gallium-68 generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 32

Ill. Adm. Code Part 341 and U.S. Department of Transportation (DOT) regulations. Perform the following actions when returning generators:

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container.

2. Assemble the package in accordance with the manufacturer's instructions.

3. Perform the dose-rate and removable contamination measurements.

4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

5. Retain records of receipts and transfers in accordance with 32 Ill. Adm. Code Part 310.40, "Records."

Model Procedure for Return of Licensed Material to Authorized Recipients

Perform the following steps when returning licensed material to authorized recipients:

1. In accordance with 32 Ill. Adm. Code 330.400(b)(4), confirm that persons are authorized to receive radioactive material prior to transfer (e.g., obtain a copy of the transferee's IEMA, U.S. Nuclear Regulatory Commission or Agreement State license that authorizes the radioactive material).

2. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container.

3. Assemble the package in accordance with the manufacturer's instructions.

4. Perform the dose-rate and removable contamination measurements.

5. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

6. Retain records of receipts and transfers in accordance with 32 Ill. Adm. Code Part 310.40, "Records."

Model Procedure for Disposal of Liquids into Sanitary Sewerage

1. Confirm that the sewer system is a public system, not a private sanitary sewer, septic system or leach field.

2. Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.

3. Calculate the amount of each radionuclide that can be discharged by using the information from prior, similar discharges and the information in 10 CFR Part 20, Appendix B.

4. Make sure that the amount of each radionuclide does not exceed the monthly and annual discharge limits specified in 32 Ill. Adm. Code 340.1030(a)(4) and 10 CFR Part 20, Appendix B, Table 3.

5. If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of each radionuclide to the corresponding limit for each radionuclide in 10 CFR Part 20, Appendix B, Table 3 must not exceed unity.

6. Confirm that the total quantity of licensed material and other radioactive material released into the sanitary sewerage system in a year does not exceed 185 gigabecquerel (GBq) [5 Curies (Ci)] of tritium (H-3), 37 GBq [1 Ci] of carbon (C)-14, and 37 GBq [1 Ci] of all other radioactive materials combined.

   NOTE: 32 Ill. Adm. Code 340.1030(a)(4) further limits the disposal of H-3, C-14, and "other radioactive material" to the limits noted above even when sewerage totals determined under 32 Ill. Adm. Code 340.1030(a)(3), and as noted in the bullet above, may have allowed a higher sanitary sewerage disposal activity.

7. Record the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the name of the individual discharging the waste.

8. Liquid waste should be discharged only via designated sinks, toilets, or other release points.

9. Discharge liquid waste slowly, to minimize splashing, with water running to be sure that the material moves out of the sink and into the sewer system.

10. Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces.

11. Decontaminate all areas or surfaces if found to be contaminated.

12. Maintain records of releases of licensed material to the sanitary sewer system. These records should include, for each release, the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the initials of the individual discharging the waste. For the licensed facility as a whole, records should be maintained of the quantity and concentration of radionuclides that are released into the sewer system that demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

Appendix S

MODEL PROCEDURES FOR DEVELOPING, MAINTAINING, AND IMPLEMENTING WRITTEN DIRECTIVES

This model provides acceptable procedures for administrations that require written directives (WD). Applicants may either adopt this model procedure or develop their own procedure to meet the requirements of 32 Ill. Adm. Code 335.1110.

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require WDs. This model does not restrict the use of other guidance in developing, implementing, and maintaining written procedures for administrations requiring a WD. Such procedures are to provide high confidence that the objectives specified in 32 Ill. Adm. Code 335.1120 will be met.

The WD must be prepared for any administration of iodine-131 sodium iodide greater than 1.11 megabecquerels [30 microcuries], any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from radioactive material. The WD must contain the information described in 32 Ill. Adm. Code 335.1110 and be retained for five years in accordance with 32 Ill. Adm. Code 335.1110(d).

Discussion

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department, when the authorized user (AU) prescribes a high dose-rate treatment, the delivery process may involve a team of medical professionals, such as an authorized medical physicist (AMP), a dosimetrist, and a radiation therapist (radiation therapist is defined in 32 Ill. Adm. Code 401.20). Treatment planning may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, and film verifications to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. To help ensure that all personnel involved in the treatment fully understand instructions in the WD or treatment plan, the licensee should instruct all workers to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be completed before administration, rather than continuing a procedure when there is any doubt. Licensees should also consider verification of WDs or treatment plans by at least one qualified person (e.g., an oncology physician, AMP, ophthalmic physicist, nuclear medicine technologist, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials can involve a number of treatment modalities (e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery (GSR),

and future emerging technologies). For each such modality for which 32 Ill. Adm. Code 335.1110 requires, or would require, a WD (as defined in 32 Ill. Adm. Code 335.20, "Definitions"), the licensee should develop, implement, and maintain written procedures to meet the requirements and objectives of 32 Ill. Adm. Code 335.1110, 32 Ill. Adm. Code 335.1120, and 32 Ill. Adm. Code 335.2030, outlined below:

1. Confirm that the WD is signed and dated by the AU prior to the administration, in accordance with 32 Ill. Adm. Code 335.1110, and includes the name of the patient or human research subject.

2. Verify the identity of the patient or human research subject prior to each administration.

3. Verify that the administration is in accordance with the treatment plan, if applicable, and the WD.

4. Check both manual and computer-generated dose calculations.

5. Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices authorized by 32 Ill. Adm. Code 335.8010 or 32 Ill. Adm. Code 335.2140.

6. Determine if a medical event, as described in 32 Ill. Adm. Code 335.1080, has occurred.

7. Determine, for permanent implant brachytherapy, within 60 calendar days from the date of implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implant portion of the written directive. If the patient is unavailable to the licensee within 60 days from the day that the implant was performed and the licensee cannot perform this assessment, the licensee is required to provide a written justification that explains why the patient was unavailable.

   NOTE: In accordance with the guidance provided in Part 3, "*Guidance for the Final Rule "Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments*", it is permissible for the licensee to verify source positioning on the same day as the implant procedure (for instance, verifying source positioning based on a CT scan performed immediately after a patient is discharged from the post-implant recovery area).

8. Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

9. Determining, for administrations of I-131 in quantities greater than 1.11 MBq (30μCi), the criteria to be used to identify patients required to be tested for pregnancy in accordance with subsection 335.5010(b), including type of pregnancy testing permitted, time in advance of I-131 administration in which the tests shall be conducted, age range of patients to be tested, and criteria a physician may use to determine that a patient is not capable of childbirth.

The following procedures are provided as assistance in meeting the above objectives.

Procedures for Any Therapeutic Dose or Dosage of a Radionuclide or Any Dosage of Quantities Greater than 30 Microcuries of Iodine-131 Sodium Iodide

Develop, implement, and maintain the following procedures to meet the objectives of 32 Ill. Adm. Code 335.1110 and 32 Ill. Adm. Code 335.1120:

1. An AU must date and sign a WD prior to the administration of any dose or dosage. WDs may be maintained in patients' charts and must be available for inspection and retained for 5 years in accordance with 32 Ill. Adm. Code 335.1110(d).

2. Prior to administering a dose or dosage, the identity of a patient or human research subject will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or other forms of identification. Asking or calling the patient's name does not constitute positive patient identity verification.

3. The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (e.g., radionuclide, total source strength, total dose, or dosage) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include (i) measuring the activity in the dose calibrator, (ii) checking the serial number of the sealed sources behind an appropriate shield, (iii) using color-coded sealed sources, or (iv) using clearly marked storage locations.

4. The licensee shall establish criteria to be used to identify patients required to be tested for pregnancy in accordance with subsection 335.5010(b), including type of pregnancy testing permitted, time in advance of I-131 administration in which the tests shall be conducted, age range of patients to be tested, and criteria a physician may use to determine that a patient is not capable of childbirth. Prior to administrations of I-131 in quantities greater than 1.11 MBq (30μCi), the licensee shall conduct a pregnancy test and obtain the results consistent with established criteria and the requirements in 32 Ill. Adm. Code 335.5010(b).

Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources

Licensees are required under 32 Ill. Adm. Code 335.1110 and 32 Ill. Adm. Code 335.1120 to have WDs for certain administrations of doses and to have procedures for administrations for which a WD is required. Model procedures for meeting these requirements appear below.

Complete the WD in accordance with 32 Ill. Adm. Code 335.1110. For temporary implants, before implantation, record the treatment site, radionuclide, and dose, as required by 32 Ill. Adm. Code 335.1110(b)(7)(A), and after implantation but before completion of the procedure, record the radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose), and date, as required by 32 Ill. Adm. Code 335.1110(b)(7)(B). For permanent implants, before implantation, record the treatment site, radionuclide, and total source strength, as required by 32 Ill. Adm. Code 335.1110(b)(6)(A), and after implantation but before the patient leaves the post-treatment recovery area, record the treatment site, the number of sources implanted, the total source strength implanted, and the date, as required by 32 Ill. Adm. Code 335.1110(b)(6)(B). The WD may be maintained in the patient's chart.

To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign the treatment plan, indicating approval. The treatment plan should provide sufficient information and direction to meet the objectives of the WD.

For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, ophthalmic physicist, oncology physician, dosimetrist, or radiation therapist), preferably an individual who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:

1. for computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions)

2. for computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times)

3. for manually generated dose calculations, verifying

    a. no mathematical errors

    b. appropriate transfer of data from the WD, treatment plan, tables, and graphs

    c. appropriate use of nomograms (when applicable)

    d. appropriate use of all pertinent data in the calculations

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment-planning or dose-calculating computer program that could be used for dose calculations.

Acceptance testing will be performed before the first use of a treatment-planning or dose-calculating computer program for therapy dose calculations. Each treatment-planning or dose-calculating computer program will be assessed, based on specific needs and applications. A check of the acceptance testing will also be performed after each source replacement or when spot-check measurements indicate that the source output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay.

Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either

1. an individual who did not perform the full calibration (the individual will meet the requirements specified in 32 Ill. Adm. Code 335.9150) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in 32 Ill. Adm. Code 335.8080), or

2. an AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5 percent

For GSR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.

For emerging technologies (e.g., Yttrium-90 microsphere use, Leksell Gamma Knife Perfexion®), the licensee should review the applicable guidance on the IEMA website and U.S. NRC's Medical Uses Licensee Toolkit Web page to ensure the written directive contains all necessary components.

A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's treatment plan includes (i) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or (ii) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.

A weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, ophthalmic physicist, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetical errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.

Treatment-planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused and must be relabeled in accordance with the manufacturer's instructions.

Review of Administrations Requiring a Written Directive

As required by 32 Ill. Adm. Code 335.1120, determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable, and whether a medical event, as described in 32 Ill. Adm. Code 335.1080, has occurred. For permanent implant brachytherapy, determine, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implant portion of the WD, to evaluate whether a medical event, as described in 32 Ill. Adm. Code 335.1080, has occurred. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified.

Determine, for administrations of I-131 in quantities greater than 1.11 MBq (30μCi), if the criteria used to identify patients required to be tested for pregnancy in accordance with subsection 335.5010(b), including type of pregnancy testing permitted, time in advance of I-131 administration in which the tests shall be conducted, age range of patients to be tested, and criteria a physician may use to determine that a patient is not capable of childbirth; are properly documented and followed.

Conduct periodic reviews of each applicable program area (e.g., radiopharmaceutical therapy, high dose-rate brachytherapy, implant brachytherapy, teletherapy, and emerging technologies). The number of patient cases to be sampled should be based on the number of treatments performed and be representative of each treatment modality performed in the institution.

If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work.

Regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

Reports of Medical Events

Notify IEMA by telephone at 217-782-7860 no later than the next calendar day after discovery of a medical event and submit a written report to IEMA within 15 days after the discovery of the medical event, as required by 32 Ill. Adm. Code 335.1080, “Report and notification of a medical event.” Also, notify the referring physician and the patient as required by 32 Ill. Adm. Code 335.1080.

Appendix T

MODEL PROCEDURES FOR OCCUPATIONAL DOSE MONITORING PROGRAM

This model provides acceptable procedures for an external occupational dose monitoring program and references and resources for developing an internal occupational dose monitoring program. Applicants may either adopt these model procedures for an occupational dose monitoring program or develop alternative procedures to meet the requirements of 32 Ill. Adm. Code 340.110 and Subparts C ("Occupational Dose Limits") and F ("Surveys and Monitoring") of 32 Ill. Adm. Code Part 340. The model includes guidance as well as a discussion of regulatory requirements that are to be reflected in the elements of an occupational dose monitoring program.

"Dosimetry" is a broad term commonly applied to the use of monitoring devices, bioassay, and other methods to measure or otherwise quantify radiation doses to individuals. The licensee must control occupational doses and provide individuals with monitoring devices in accordance with the requirements of 32 Ill. Adm. Code 340.520(a). The occupational dose limits for adults are provided in 32 Ill. Adm. Code 340.210, while 32 Ill. Adm. Code 340.520, "Conditions requiring individual monitoring of external and internal occupational dose," provides, in part, that adults likely to receive in a year a dose in excess of 10 percent of those dose limits must be provided with dosimetry. Definitions of relevant terms, such as total effective dose equivalent (TEDE), deep-dose equivalent (DDE), and committed effective dose equivalent (CEDE) can be found in 32 Ill. Adm. Code 310.20, "Definitions." In addition, if monitoring is required pursuant to 32 Ill. Adm. Code 340.520, each licensee shall maintain records of doses received (see 32 Ill. Adm. Code 340.1160, "Records of individual monitoring results"). Also, if monitoring is required pursuant to 32 Ill. Adm. Code 340.520, the licensee must provide individuals with an annual report of their doses, if their occupational dose exceeds 1 mSv [100 mrem] TEDE or 1 mSv [100 mrem] to any individual organ or tissue or the individual requests their annual dose report (see 32 Ill. Adm. Code 400.130(b), "Notifications and reports to individuals").

The licensee must consider the dose that an individual may receive in the current year from all sources of employment where the individual's assigned duties involve exposure to sources of radiation. See Reg Guide 8.7, Rev. 4, "Instructions for Recording and Reporting Occupational Radiation Dose Data," May 2018.

If an individual may receive more than 10 percent of the annual dose limit, IEMA 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 or her dose.

The As Low As Reasonably Achievable "ALARA" Program

Regulations in 32 Ill. Adm. Code 340.110 state that "each licensee shall develop, document, and implement a radiation protection program that ensures compliance with the provisions [32 Ill. Adm. Code Part 340]" 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 public doses that are as low as is reasonably achievable (ALARA)." Additionally, 32 Ill. Adm. Code 340.110 requires that licensees review, at intervals not to exceed 12 months, the radiation protection program content and implementation.

External Exposure

It is necessary to assess doses to radiation workers to demonstrate compliance with regulatory limits for 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 as part of the overall requirements for radiation protection.

There are three dose limits included in 32 Ill. Adm. Code 340.210 that apply to external exposure: deep dose to the whole body [5 rem or 0.05 Sievert (Sv)], shallow dose to the skin or extremities [50 rem or 0.5 Sv], and dose to the lens of the eye [15 rem or 0.15 Sv]. According to the definitions in 32 Ill. Adm. Code 310.20, the DDE to the whole body is considered to be at a tissue depth of 1 centimeter (cm) [1,000 milligram (mg)/square centimeters (cm^2)], shallow-dose equivalent (SDE) to the skin or extremities at 0.007 cm [7 mg/cm^2], and lens of the eye dose equivalent (defined in 32 Ill. Adm. Code 340.30) at 0.3 cm [300 mg/cm^2]. In evaluating the lens of the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses or other protection factors.

Under 32 Ill. Adm. Code 340.520(a), the use of individual monitoring devices is required for the following:

- Adults likely to receive, in a year, from sources external to the body, a dose in excess of 10 percent of the occupational dose limits in 32 Ill. Adm. Code 340.210(a). Monitoring devices are accordingly required for adults likely to receive an annual dose in excess of:
    - 0.5 rem [0.005 Sv] DDE
    - 1.5 rem [0.015 Sv] lens (of the eye) dose equivalent
    - 5 rem [0.05 Sv] SDE to the skin
    - 5 rem [0.05 Sv] SDE to any extremity

- Minors who are likely to receive an annual dose in excess of:
    - rem [1.0 millisievert (mSv)] DDE
    - 0.15 rem [1.5 mSv] lens (of the eye) dose equivalent
    - 0.5 rem [5 mSv] SDE to the skin, or
    - 0.5 rem [5 mSv] SDE to any extremity

- Declared pregnant women likely to receive an annual dose in excess of 0.1 rem [1.0 mSv] DDE during the entire pregnancy.

- Individuals entering a high- or a very-high-radiation area.

To demonstrate that monitoring of occupational exposure is not necessary for a group of radiation workers, it must be demonstrated that doses will not exceed 10 percent of the applicable limits. In these cases, IEMA does not require licensees to monitor radiation doses for this class of worker.

The following methods may be used to demonstrate that doses are expected to be within 10 percent of regulatory limits:

- Prior Experience: Reviews of radiation dose histories for workers in a specific work area (typically spanning three to five years) show that they are not likely to receive a dose in excess of 10 percent of the limits.

- Area Surveys: Demonstrate through the conduct of appropriate radiation level surveys [e.g., using a radiation survey meter or area thermoluminescent dosimeters (TLDs)] in the work area, combined with estimates of occupancy rates and calculations, that doses to workers are not likely to exceed 10 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 10 percent of the limits.

External dose is determined by using individual monitoring devices, such as film badges, optically stimulated luminescence dosimeters (OSLs), or TLDs. These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program-approved, as required by 32 Ill. Adm. Code 340.510.

The device for monitoring the whole-body dose, eye dose, skin dose, or extremity dose shall be placed near the location expected to receive the highest dose during the year [32 Ill. Adm. Code 340.210(c)]. 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 nonuniform, 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. For additional guidance, see Reg Guide 8.40, "Methods for Measuring Effective Dose Equivalent from External Exposure," July 2010.

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

Records of individual monitoring results must be maintained as described in 32 Ill. Adm. Code 340.1160. For additional guidance, see Reg Guide 8.7, Rev. 4, "Instructions for Recording and Reporting Occupational Radiation Dose Data," May 2018.

Exchange Frequency

Radiation protection programs of limited scope and authorized uses may elect to assign a single dosimetry type and exchange frequency. However, complex programs with multiple departments and/or forms of authorized use may determine the need for additional forms of dosimetry and exchange frequencies that vary by department.

Determining the appropriate frequency of dosimeter exchange depends upon both the exposure potential and the manufacturer's recommendations for the dosimetry in use. Consider the following elements:

- the forms and types of radiation to be monitored
- potential exposure of the individual
- sensitivity of the dosimetry in use
- acceptable uncertainty in the estimate of external exposures

Exchange and timely analysis of dosimetry should be conducted often enough to identify and quantify potential exposures, during any year, that are likely to exceed 10 percent of the occupational limits specified in 32 Ill. Adm. Code 340.210. The 10 percent criterion is consistent with 32 Ill. Adm. Code 340.520(a), which requires licensees to monitor occupational doses for exposed individuals who are likely to exceed 10 percent of the applicable limit. Additionally, licensees should also consider the magnitude of potential exposures with relation to investigational limits set by the licensee or NVLAP processor.

NOTE: This assessment should also account for any internal exposures resulting from uptake of airborne or volatile radioactive material.

NUREG-1556 Volume 11, Rev. 1 states the exchange frequency for dosimeters is typically monthly or quarterly. Consistent with nationally recognized guidance, licensees should exchange dosimetry at least quarterly for diagnostic medical use (32 Ill. Adm. Code 335.3010 or 335.4010), excluding PET. For authorized use including PET or any therapeutic use, the magnitude of potential exposures warrants monthly dosimetry exchange. After reviewing the radiation protection program's use and exchange frequency, applicants should obtain technical specifications from their NVLAP-approved processor to determine the appropriate type(s) of dosimetry.

The exchange frequencies above are based on expectations of typical use and patient throughput. Should workload or worker duties change that warrant a deviation from the frequencies above, alternate frequencies should be specified.

Licenses which include non-medical use may warrant dosimetry sensitive to specific types of radiation (beta or neutron). The licensee should detail in the dosimetry procedures the criteria which will be used to select appropriate dosimetry and assign exchange frequency. Type A broad scope licensees or applicants that want the flexibility to revise their personnel monitoring program without amendment of the license, as discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of NUREG-1556 Vol. 11, Rev. 1, should describe the process they will use to revise and implement their submitted personnel monitoring program.

Finally, 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 thorough in their effort to recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

Investigational Levels – External Dose Monitoring

IEMA has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in International Commission on Radiological Protection (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.

When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in the table below (i.e., 10 percent of the annual limit for occupational exposure), the radiation safety officer (RSO) 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 the Investigational Level II in the table below (i.e., 30 percent of the annual limit for occupational exposure), the RSO or the RSO's designee should 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		
Part of Body	**Investigational Level I (mrem/yr)**	**Investigational Level II (mrem/yr)**
whole body, head, trunk including male gonads, arms above the elbow, or legs above the knee	500 [5 mSv]	1,500 [15 mSv]
hands, elbows, arms below the elbow, feet, knees, legs below the knee, or skin	5,000 [50 mSv]	15,000 [150 mSv]
lens of the eye	1,500 [15 mSv]	4,500 [45 mSv]

Review and record on Agency form IL 473-0299 (IDNS Form 5), or an equivalent form (e.g., dosimeter processor's report), the results of personnel monitoring. Take the actions listed below when the investigation levels listed in the table above are reached:

Personnel dose less than Investigational Level I

Except when deemed appropriate by the RSO or the RSO's designee, no further action will be taken, if an individual's dose is less than the table 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 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. Consider investigating the factors that led to the radiation exposure and the radiation doses and work habits of other individuals engaged in similar tasks to determine if improvements or additional safety measures are needed to reduce exposures. Evaluate, in the context of ALARA program quality, and record the results of investigations and evaluations.

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. The RSO should consider actions 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.

Reestablishment of Investigational Level II to a level above that listed in the table

In cases where a worker's dose or the dose for a group of workers needs 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.

Declared Pregnancy and Dose to Embryo/Fetus

Regulations in 32 Ill. Adm. Code 340.280, "Dose equivalent to an embryo/fetus," state that the licensee shall ensure that the dose equivalent to an embryo or 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 or fetus shall be taken as the sum of

- the DDE 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

Licensees should reference Reg Guide 8.13, Rev. 3, "Instructions Concerning Prenatal Radiation Exposure," June 1999, for information to help pregnant women and other personnel make decisions regarding radiation exposure during pregnancy and Reg Guide 8.36, "Radiation Dose to the Embryo/Fetus," July 1992, for calculating the radiation dose to the embryo/fetus.

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 a year (32 Ill. Adm. Code 340.520). Values for radionuclide intakes by means of inhalation and ingestion (i.e., derived air concentration (DAC) and ALI) are provided in Table 1 of Appendix B of 10 CFR Part 20.

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 DAC for each class of radionuclide is the concentration of airborne radioactivity in microcurie (μCi)/milliliter that, if an occupational worker were to be continuously exposed to it for 2,000 hours [1 year], would result in one ALI.

The TEDE concept makes it possible to combine both the internal and external doses. The ALI and DAC numbers in 10 CFR Part 20 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." Per 10 CFR Part 20, Appendix B, when an ALI is defined by the stochastic dose limit, this value alone is given. When the ALI is determined by the nonstochastic 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. Definitions for stochastic and nonstochastic effects can be found in 32 Ill. Adm. Code 340.30.

See the discussion and model procedures for a bioassay program in Section III. Item 22 and Appendix O, respectively for additional information.

For additional guidance on developing occupational dose-monitoring programs, refer to the following:

- Reg Guide 8.2, Rev. 1, "Administrative Practices in Radiation Surveys and Monitoring," May 2011.
- Reg Guide 8.7, Rev. 4, "Instructions for Recording and Reporting Occupational Radiation Dose Data," May 2018.
- Reg Guide 8.9, Rev. 1, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program," July 1993.
- Reg Guide 8.20, Rev. 2, "Applications of Bioassay for Radioiodine," September 2014.
- Reg Guide 8.34, Rev. 1, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses," July 1992.
- Reg Guide 8.40, "Methods for Measuring Effective Dose Equivalent from External Exposure," July 2010.
- National Council on Radiation Protection and Measurements (NCRP) Report No. 87, "Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition," February 1987.
- NUREG/CR–4884, "Interpretation of Bioassay Measurements," July 1987.
- NUREG–1400, "Air Sampling in the Workplace," September 1993.

Changes to an Individuals Record of Dose

If an individual's dosimeter is lost, the licensee needs to perform and document an evaluation of the dose the individual received and add it to the employee's dose record, to demonstrate compliance with occupational dose limits in 32 Ill. Adm. Code 340.210. 32 Ill. Adm. Code 340.1110(c) requires that licensees first obtain Agency authorization before modifying an employee's dosimetry record. Sometimes the most reliable method for estimating an individual's dose is to use his or her recent dose history. In other cases, particularly if the individual does nonroutine types of work, it may be better to use doses of coworkers 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.

Requests for modification of dosimetry records should be submitted to the Agency either in writing or electronically to ema.speclic@illinois.gov. Social security numbers or other personally identifiable information should not be submitted electronically. To the extent possible, exclude social security numbers and utilize only account numbers or other unique identifiers. The licensee's request should provide sufficient details on the investigation performed and adequately support the basis of the request.

The licensee should provide data from the employee's previous personnel monitoring results to estimate the radiation exposure for the subject monitoring period. While there is no standard on how far back the dosimetry records need to go, historically the Agency has used three years. The licensee shall certify that there has not been a change of duties or a significant increase in workload during this monitoring period or provide appropriate calculations for adjustment.

If the licensee is claiming the dosimeter was misplaced during the wear-period and it was subsequently analyzed and found to have a high exposure, it would be appropriate to have a certification from the dosimetry processor (if possible) to state that the exposure conditions were static, dynamic, or in contamination conditions.

NOTE: For some dosimeter models, this may only be available if the OSL returned an exposure in excess of 500 mR.

Recordkeeping

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by 32 Ill. Adm. Code 340.1160. For additional information on recordkeeping and reporting occupational exposure data, including intakes, refer to Reg Guide 8.7, Rev. 4, "Instructions for Recording and Reporting Occupational Radiation Dose Data," May 2018.

Summation of External and Internal Doses

Pursuant to 32 Ill. Adm. Code 340.220, "Compliance with requirements for summation of external and internal doses," the external and internal doses must be summed, if required to monitor both under 32 Ill. Adm. Code 340.520. Reg Guide 8.40, "Methods for Measuring Effective Dose Equivalent from External Exposure," contains helpful information regarding occupational doses.

Appendix U

Model Medical Licensee Audit

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to the licensee's activities, and activities that have not occurred since the last audit need not be reviewed at the next audit. Also, the audit notes may not be complete for nonmedical uses authorized on the license. Licensees should review audit lists in other volumes of the U.S. NRC's NUREG–1556 series, as appropriate, when completing the audit list that is specific to nonmedical uses.

Date of this audit: _____

Date of last audit: _____

Date of next audit: _____

Auditor:

_____ _____
Signature Date

Management Review:

_____ _____
Signature Date

License (License Condition)

1. License Number
2. Current Amendment Number
3. Are all of the tie-down documents on file?
4. Has the Legal Entity having control over licensed activities changed since the last audit?
5. Are materials, uses, and locations of use confined to those specifically described in the license?

Audit History

1. Were previous audits conducted annually [32 Ill. Adm. Code 340.110(c)]?
2. Were records of previous audits maintained [32 Ill. Adm. Code 340.1120(b)]?
3. Were any deficiencies identified during previous audit?
4. Were corrective actions taken? (Look for repeated deficiencies.)
5. Any previous problem/deficiency not corrected or repeated?
6. What corrective actions from previous audits, if any, are still in progress?

Organization and Scope of Program

1. Radiation Safety Officer (RSO)
   a. If the RSO was changed, was the license amended [32 Ill. Adm. Code 335.40(c)]?

b. Does the new RSO meet IEMA training requirements [32 Ill. Adm. Code 335.9010, 32 Ill. Adm. Code 335.9160, 32 Ill. Adm. Code 335.9180]?
c. If the scope of the program expanded, does the RSO have training in radiation safety, regulatory issues, and emergency procedures for the new uses [32 Ill. Adm. Code 335.9010(e)]?
d. Is the RSO fulfilling all duties and responsibilities [32 Ill. Adm. Code 335.1040(e)]?
e. If the scope of the program expanded, have the RSO duties been updated to reflect the scope of the program [32 Ill. Adm. Code 335.1040(e)]?
f. Is the written agreement in place for the new RSO [32 Ill. Adm. Code 335.1040(b)]?
g. Has IEMA been notified about a temporary RSO [32 Ill. Adm. Code 335.45(b)(2)]?
h. Are the written agreements and duties and responsibilities in place for the temporary RSO [32 Ill. Adm. Code 335.1040(b), (c), (e), (g), and (h)]?

2. Associate Radiation Safety Officer (ARSO):
   a. If the ARSO was changed, was the license amended [32 Ill. Adm. Code 335.40(d)]?
   b. Does the new ARSO meet training requirements [32 Ill. Adm. Code 335.9010, 32 Ill. Adm. Code 335.9160, 32 Ill. Adm. Code 335.9180]?
   c. If the scope of the program expands, did the RSO assign duties for the expanded program and does the ARSO have training in radiation safety, regulatory issues, and emergency procedures for the new uses [32 Ill. Adm. Code 335.9010(e)]?
   d. Is the ARSO fulfilling all duties and tasks [32 Ill. Adm. Code 335.1040]?
   e. Is the written appointment in place for a new ARSO [32 Ill. Adm. Code 335.1040(b)]?

3. Multiple places of use? If yes, list locations. [License Condition (L/C)]

4. Are all locations listed on license? (L/C)

5. Were annual audits performed at each location? If no, explain.

6. Describe the scope of the program (e.g., staff size, number of procedures performed)

7. Licensed Material: (L/C)
   a. Isotope, chemical form, physical form, quantity, and use as authorized?
   b. Does the total amount of radioactive material possessed require financial assurance [32 Ill. Adm. Code 326.70]? If so, is financial assurance current?
   c. Calibration, transmission, and reference sources [32 Ill. Adm. Code 335.2040]?
      i. Sealed sources manufactured and distributed by a person licensed pursuant to 32 Ill. Adm. Code 335.30, equivalent U.S. NRC or Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources, and sources do not exceed 1.11 gigabecquerel (GBq) [30 millicuries (mCi)] each [32 Ill. Adm. Code 335.2040(a) and (b)]?
      ii. Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq [15 mCi] [32 Ill. Adm. Code 335.2040(c)]?
      iii. Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq [200 microcuries (μCi)] or 1,000 times the quantities in Appendix B of Part 30 [32 Ill. Adm. Code 335.2040(d)]?
      iv. Technetium-99m (Tc-99m) in individual amounts as needed [32 Ill. Adm. Code 335.2040(e)]?
      v. The sources are not used for medical use except in accordance with the requirements in 32 Ill. Adm. Code 335.6010 (32 Ill. Adm. Code 335.2040)?
      vi. The sealed sources are not combined (bundled or aggregated) to create an activity greater than the maximum activity listed above [32 Ill. Adm. Code 335.2040]?

d. Unsealed materials used under 32 Ill. Adm. Code 335.3010, 32 Ill. Adm. Code 335.4010, and 32 Ill. Adm. Code 335.5010 are:
    i. Obtained from a manufacturer or preparer licensed under 32 Ill. Adm. Code 330.260?

OR

    ii. Obtained from a producer of Positron Emission Tomography radioactive drugs under 32 Ill. Adm. Code 330.260(c)(23)?

OR

    iii. Prepared by a physician authorized user (AU), an authorized nuclear pharmacist (ANP), or an individual under the supervision of an ANP or physician AU?

OR

    iv. Obtained and prepared for research in accordance with 32 Ill. Adm. Code 335.3010, 32 Ill. Adm. Code 335.4010, and 32 Ill. Adm. Code 335.5010, as applicable?

8. Are the sealed sources possessed and used under 32 Ill. Adm. Code 335.6010, 32 Ill. Adm. Code 335.7010, and 32 Ill. Adm. Code 335.8010 approved in the Sealed Source and Device Registry? Are the sealed sources used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry? Are manufacturers' manuals for operation and maintenance of medical devices possessed?

9. Are the actual uses of medical devices consistent with the authorized uses listed on the license? (L/C)

10. If places of use/storage changed, was the license amended [32 Ill. Adm. Code 335.40]?

11. If control of the license was transferred, was IEMA's prior consent obtained or notification made [32 Ill. Adm. Code 330.310(c))]?

12. If bankruptcy was filed, was IEMA immediately notified [32 Ill. Adm. Code 330.310(j))]?

13. Is radioactive material regulated under 32 Ill. Adm. Code 335.2140 used in accordance with the license conditions and tie-down commitments? (L/C)

Radiation Safety Program

1. Changes to program [32 Ill. Adm. Code 330.340(b)(5)]?

2. Records of actions taken by the licensee's management maintained for 5 years [32 Ill. Adm. Code 335.1040(h)]?

3. Content and implementation reviewed annually by the licensee [32 Ill. Adm. Code 340.110(c)]?

4. Records of reviews maintained [32 Ill. Adm. Code 340.1120(a)(2)]?

Nationally Tracked Sources

1. Reports of transactions involving nationally tracked sources submitted to National Source Tracking System [32 Ill. Adm. Code 330.950]?

Use by Authorized Individuals (L/C)

1. Authorized User [32 Ill. Adm. Code 335.9160, 32 Ill. Adm. Code 335.9180, 32 Ill. Adm. Code 335.9030, 32 Ill. Adm. Code 335.9040, 32 Ill. Adm. Code 335.9050, 32 Ill. Adm. Code 335.9060, 32 Ill. Adm. Code 335.9070, 32 Ill. Adm. Code 335.9080, 32 Ill. Adm. Code 335.9100, 32 Ill. Adm. Code 335.9120, 32 Ill. Adm. Code 335.9130, 32 Ill. Adm. Code 335.9140]:
    a. Listed on facility license?

b. Each AU only uses material for which they are authorized?

2. Authorized Medical Physicist [32 Ill. Adm. Code 335.9150, 32 Ill. Adm. Code 335.9160, 32 Ill. Adm. Code 335.9180]:
   a. Listed on a facility license?
   b. Each AMP only uses material for which they are authorized?
   c. If applicable, performs tasks described in 32 Ill. Adm. Code 335.7100(c), 32 Ill. Adm. Code 335.8090, 32 Ill. Adm. Code 335.8160, and 32 Ill. Adm. Code 335.8190, as appropriate?

3. Ophthalmic Physicist [32 Ill. Adm. Code 335.7100]
   a. Listed on facility license?
   b. Only uses material for which they are authorized?
   c. Performs tasks described in 32 Ill. Adm. Code 335.7100(c)?

4. Nonmedical use authorized users [32 Ill. Adm. Code 330.250(a)(1)]:
   a. Listed on facility license for same materials and uses?

Mobile Medical Service

1. Operates services per 32 Ill. Adm. Code 335.2120, 32 Ill. Adm. Code 335.8210?

2. Compliance with public dose limits evaluated and met [32 Ill. Adm. Code 340.310, 32 Ill. Adm. Code 340.320]?

3. Are all base locations listed on the license? (L/C)

4. Mobile Medical Agreement letter signed by management of each client [32 Ill. Adm. Code 335.2120(a)]?

5. Licensed material not delivered to client's address, unless client was authorized [32 Ill. Adm. Code 335.2120(h)]?

6. Dosage measuring instruments checked for proper function before use at each address of use or on each day of use, if more frequent [32 Ill. Adm. Code 335.2120(d)]?

7. Survey instruments checked for proper operation before use at each address of use [32 Ill. Adm. Code 335.2120(f)]?

8. Survey all areas of use prior to leaving each client address [32 Ill. Adm. Code 335.2120(e)]?

9. Adequate security maintained for mobile trailer? Keypad codes changed, or keys retrieved when an employee terminates employment [32 Ill. Adm. Code 340.810(a) and 32 Ill. Adm. Code 340.810(b)]?

10. AUs briefed on responsibilities for supervising the use of licensed material [32 Ill. Adm. Code 335.1050]?

11. Compliance with additional technical requirements for mobile remote afterloaders evaluated and met, including record retention [32 Ill. Adm. Code 335.8210]?

Amendments Since Last Audit [32 Ill. Adm. Code 335.40]

1. Any Amendments since last audit [32 Ill. Adm. Code 335.40]?

2. Security-related sensitive information was properly marked?

Notifications Since Last Audit [32 Ill. Adm. Code 335.45]

1. Any notifications since last audit [32 Ill. Adm. Code 335.45]?

2. Appropriate documentation provided to IEMA for AMP, ophthalmic physicist, or AU, no later than 30 days after the individual starts work [32 Ill. Adm. Code 335.45(a)]?

3. IEMA notified within 30 days after: AU, AMP, ophthalmic physicist, or RSO/ARSO stops work or changes name; licensee's mailing address changes; licensee's name changes without a transfer of control of the license; or licensee has added to or changed an area of use for 32 Ill. Adm. Code 335.3010 or 335.4010 use; the licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number [32 Ill. Adm. Code 335.45].

Training, Retraining, and Instructions to Workers

1. Briefly describe the training program.

2. Is the training program implemented? Have workers been provided with required instructions [32 Ill. Adm. Code 400.120, 32 Ill. Adm. Code 335.1050, 32 Ill. Adm. Code 335.5020, 32 Ill. Adm. Code 335.7020, 32 Ill. Adm. Code 335.8040, 32 Ill. Adm. Code 335.2140, as appropriate]?

3. Is the individual's understanding of current procedures and regulations adequate?

4. Do appropriate individuals have adequate understanding of appropriate:
   a. Operating procedures [32 Ill. Adm. Code 335.1050, 32 Ill. Adm. Code 335.5020, 32 Ill. Adm. Code 335.7020, 32 Ill. Adm. Code 335.8040]?
   b. Emergency procedures [32 Ill. Adm. Code 335.1050, 32 Ill. Adm. Code 335.5020, 32 Ill. Adm. Code 335.7020, 32 Ill. Adm. Code 335.8040]?

5. Do appropriate individuals have an up-to-date copy of the licensee's operating use and emergency procedures?

6. Periodic training required and implemented [32 Ill. Adm. Code 335.5020, 32 Ill. Adm. Code 335.7020, 32 Ill. Adm. Code 335.8040]?

7. Vendor operational and safety training provided prior to first patient treatment of a new or upgraded remote afterloader, teletherapy, or gamma stereotactic radiosurgery unit [32 Ill. Adm. Code 335.8040]?

8. Were all individuals working in, or the performance of whose duties requires access to, any portion of a restricted area or who frequent areas where radioactive material is used or stored; instructed and was refresher training provided, as needed [32 Ill. Adm. Code 400.120]?

9. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives (WD), as appropriate [32 Ill. Adm. Code 335.1050]?

10. Are initial and periodic training records maintained for each individual for five years [32 Ill. Adm. Code 335.5020, 32 Ill. Adm. Code 335.7020, 32 Ill. Adm. Code 335.8040]?

11. Hazardous Materials (HAZMAT) training [49 CFR Part 172]?

12. Do additional therapy device instructions/training include:
    a. Unit operation, inspection, associated equipment, survey instruments?
    b. License conditions applicable to the use of the unit?
    c. Emergency drills [32 Ill. Adm. Code 335.8040]?

13. Are workers cognizant of requirements for:
    a. Radiation Safety Program [32 Ill. Adm. Code 335.1040, 32 Ill. Adm. Code 340.110]?
    b. Annual dose limits [32 Ill. Adm. Code 340.210, 32 Ill. Adm. Code 340.310, 32 Ill. Adm. Code 340.320]?
    c. 10 percent monitoring threshold [32 Ill. Adm. Code 340.520]?
    d. Dose limits to embryo/fetus and declared pregnant worker [32 Ill. Adm. Code 340.280]?
    e. "Grave Danger" Posting [32 Ill. Adm. Code 340.920 (c)]?
    f. Procedures for opening packages [32 Ill. Adm. Code 340.960]?

14. Is supervision of individuals by AU in accordance with 32 Ill. Adm. Code 335.1050?

15. Was training provided for workers involved with emerging technologies in accordance with the IEMA license and tie-downs?

Training for Manual Brachytherapy and Use of Unsealed Byproduct Material for Which a Written Directive Is Required

1. Does safety instruction to personnel include [32 Ill. Adm. Code 335.5020, 32 Ill. Adm. Code 335.7020]:
    a. Control of patient and visitors?
    b. Routine visitation to patients in accordance with 32 Ill. Adm. Code 340.310?
    c. Contamination control and size/appearance of sources?
    d. Safe handling and shielding instructions?
    e. Waste control?
    f. RSO and AU notification, if patient had a medical emergency or died?
    g. Records retained [32 Ill. Adm. Code 335.5020, 32 Ill. Adm. Code 335.7020]?

Facilities

1. Facilities, as described in license application? (L/C)

2. Therapy device facilities provided with electrical interlock system, viewing and intercom systems, radiation monitor, source retraction mechanism, and source indicator lights?

3. Emergency source recovery equipment available [32 Ill. Adm. Code 335.7030, 32 Ill. Adm. Code 335.8050]?

4. Storage areas:
    a. Materials secured from unauthorized removal or access [32 Ill. Adm. Code 340.810]?
    b. Locations appropriately shielded to control public and occupational exposures in accordance with 32 Ill. Adm. Code Part 340?

5. Therapy unit operation:
    a. Unit, console, console keys, and treatment room controlled adequately [32 Ill. Adm. Code 340.810, 32 Ill. Adm. Code 335.8040(a)(1)]?
    b. Restricted to certain source orientations and/or gantry angles? (L/C)
    c. Ceases to operate in restricted orientation(s)? (L/C)
    d. Only one radiation device can be placed in operation at a time within the treatment room [32 Ill. Adm. Code 335.8040(a)(3)]?

Dose or Dosage Measuring Equipment

1. Possession, use, and calibration of instruments to measure activities of unsealed radionuclides [32 Ill. Adm. Code 335.2010]:
   a. Types of equipment listed?
   b. Approved procedures for use of instrumentation followed?
   c. Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer's instructions?
   d. Instrument repaired or replaced or dosages mathematically corrected, as required, when tests do not meet the performance objectives provided in the nationally recognized standard or manufacturer's instructions (e.g., ±10 percent)?
   e. Records maintained and include required information [32 Ill. Adm. Code 335.2010(c)]?

2. Determination of dosages of unsealed byproduct material [32 Ill. Adm. Code 335.2030]?
   a. Each dosage determined and recorded prior to medical use [32 Ill. Adm. Code 335.2030 (a)]?
   b. Measurement of unit dosages of alpha, beta, or photon emitting radionuclides made either by direct measurement [32 Ill. Adm. Code 335.2030(b)], or by decay correction of the activity provided by the licensed producer?
   c. For other than unit dosages of alpha, beta, or photon emitting radionuclides, measurement made by direct measurement of radioactivity [32 Ill. Adm. Code 335.2030(c)] or by combination of radioactivity or volumetric measurement and calculation using the activity provided by the licensed producer?

3. Licensee uses generators?
   a. Each eluate tested for molybdenum-99 (Mo-99) breakthrough [32 Ill. Adm. Code 335.4020(b)(1)]?
   b. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 kilobecquerel (kBq) per MBq [0.15 µCi per mCi] of Tc-99m [32 Ill. Adm. Code 335.4020(a)(1)]?
   c. Before first patient use of day eluate tested for strontium (Sr)-82 and strontium-85 (Sr-85) when eluting rubidium (Rb)-82 [32 Ill. Adm. Code 335.4020(b)(2)]?
   d. No radiopharmaceuticals administered with Sr-82 concentrations over 0.02 kBq per MBq [0.02 µCi per mCi] of Rb-82 or Sr-85 concentrations over 0.2 kBq per MBq [0.2 µCi per mCi] of Rb-82 [32 Ill. Adm. Code 335.4020(a)(2) and (3)]?
   e. Each measurement that exceeds the limits in paragraph b or d above reported to IEMA and distributor of the generator in accordance with 32 Ill. Adm. Code 335.4020(d)?
   f. Records maintained [32 Ill. Adm. Code 335.4020(c)]?

4. Confirmation of source output or activity for manual brachytherapy sources? Alternatively, the manufacturer's measurements may be accepted, if the criteria in 32 Ill. Adm. Code 335.7070(b) have been met.

5. Dosimetry Equipment [32 Ill. Adm. Code 335.8080]:
   a. Calibrated system available for use [32 Ill. Adm. Code 335.8080(a)]?
   b. Calibrated by National Institute of Standards and Technology or an American Association of Physicists in Medicine (AAPM)-accredited lab within previous 2 years and after servicing [32 Ill. Adm. Code 335.8080(a)(1)] or calibrated by intercomparison per 32 Ill. Adm. Code 335.8080(a)(2)?
   c. Calibrated within the previous 4 years [32 Ill. Adm. Code 335.8080(a)(2)]?
   d. Licensee has available for use a dosimetry system for spot-check measurements [32 Ill. Adm. Code 335.8080(b)]?
   e. Record of each calibration, intercomparison, and comparison maintained [32 Ill. Adm. Code 335.8080(c)]?

Radiation Protection and Control of Radioactive Material

1. Use of radiopharmaceuticals:
   a. Protective clothing worn?
   b. Personnel routinely monitor their hands?
   c. No eating/drinking in use/storage areas?
   d. No food, drink, or personal effects kept in use/storage areas?
   e. Proper dosimetry worn?
   f. Radioactive waste disposed of in proper receptacles?
   g. Syringe shields and vial shields used and are specific to the energy emitted?
   h. Proper use of remote-handling tools and radiation shields?

2. Leak tests and inventories:
   a. Leak test performed on sealed sources and brachytherapy sources at appropriate intervals [32 Ill. Adm. Code 340.410 or leak test license condition]?
   b. Inventory of sealed sources and brachytherapy sources performed semiannually [32 Ill. Adm. Code 340.810(c)]?
   c. If applicable, transactions associated with nationally tracked sources entered into the NSTS, including annual reconciliation [32 Ill. Adm. Code 330.950]?
   d. Records maintained [32 Ill. Adm. Code 340.810(e), 32 Ill. Adm. Code 340.1135]?

Radiation Survey Instruments

1. Survey instruments used to show compliance with 32 Ill. Adm. Code Part 340 and 32 Ill. Adm. Code 33.250(a)(2):
   a. Appropriate operable survey instruments possessed or available [32 Ill. Adm. Code Part 340]?
   b. Calibrations [32 Ill. Adm. Code 340.510(b), 32 Ill. Adm. Code 340.1130, 32 Ill. Adm. Code 340.540]:
      i. Before first use, annually, and after repairs?
      ii. Within 20 percent on each scale or decade of interest, as applicable?
      iii. Instrument sent to a licensed instrument service provider?
      iv. Copy of instrument service provider license on file?

2. Records maintained [32 Ill. Adm. Code 340.1130(a)]?
   a. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements [32 Ill. Adm. Code 340.510, 32 Ill. Adm. Code 335.2080]?
   b. Daily in all areas where unsealed radiopharmaceuticals are prepared or administered (except patient rooms) [32 Ill. Adm. Code 335.2080]?
   c. Weekly in all areas where radiopharmaceuticals or wastes are stored?
   d. Weekly for wipes in all areas where radiopharmaceuticals are routinely prepared, administered, or stored?
   e. Trigger levels for surveys established?
   f. Corrective action taken and documented if trigger level exceeded?
   g. Techniques can detect 0.1 milliroentgen/hour, 2,000 disintegrations per minute?
   h. Surveys made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the sources(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry [32 Ill. Adm. Code 335.8110(a)] and records maintained [32 Ill. Adm. Code 335.8110(c)]?
      i. After new source installation?

ii. Following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s)?

Public Dose

1. Is licensed material used in a manner to keep doses below 1 mSv [100 mrem] in a year [32 Ill. Adm. Code 340.310(a)(3)]?
2. Has a survey or evaluation been performed, per 32 Ill. Adm. Code 340.510(a)?
3. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
4. Do unrestricted area radiation levels exceed 0.02 mSv [2 mrem] in any 1 hour [32 Ill. Adm. Code 340.310(a)(1)]?
5. Is licensed material used or stored in a manner that would prevent unauthorized access or removal [32 Ill. Adm. Code 340.810]?
6. Are records maintained [32 Ill. Adm. Code 340.1130, 32 Ill. Adm. Code 340.1170]?

Patient Release

1. Individuals released when total effective dose equivalent (TEDE) is less than 5 mSv [0.5 rem] [32 Ill. Adm. Code 335.2110(a)]?
2. Instructions to the released individual, including breastfeeding women, include required information [32 Ill. Adm. Code 335.2110(b)]?
3. Release records maintained [32 Ill. Adm. Code 335.2110(d)]?
4. Records of instructions given to breastfeeding women maintained, if required [32 Ill. Adm. Code 335.2110(d)(3)]?

Unsealed Byproduct Material for Which a Written Directive Is Required

1. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls [32 Ill. Adm. Code 335.5030(a)]?
2. RSO and AU promptly notified if patient had a medical emergency or died [32 Ill. Adm. Code 335.5030(a)(9)]?

Brachytherapy or Brachytherapy Source Use

1. Safety precautions implemented to include patient facilities, posting, stay times, and emergency response equipment [32 Ill. Adm. Code 335.7030]?
2. Survey immediately after implant [32 Ill. Adm. Code 335.7060(a)]?
3. Patients surveyed immediately after removing the last temporary implant source [32 Ill. Adm. Code 335.7060(b)]?
4. RSO and AU promptly notified if patient had a medical emergency or died [32 Ill. Adm. Code 335.7030(c)]?

5. Records maintained [32 Ill. Adm. Code 335.7060(c)]?

Radioactive Waste

1. Disposal:
   a. Decay-in-storage [32 Ill. Adm. Code 340.1045]?
   b. Procedures followed?
   c. Labels removed or defaced [32 Ill. Adm. Code 340.940(b), 32 Ill. Adm. Code 340.1045]?

2. Special procedures performed as required?

3. Authorized disposals [32 Ill. Adm. Code 340.1010]?

4. Records maintained [32 Ill. Adm. Code 340.1130(a), 32 Ill. Adm. Code 340.1180, 32 Ill. Adm. Code 340.1045]?

5. Effluents:
   a. Release to sanitary sewer [32 Ill. Adm. Code 340.1030]?
      i. Material is readily soluble or readily dispersible [32 Ill. Adm. Code 340.1030(a)(1)]?
      ii. Monthly average release concentrations do not exceed 10 CFR Part 20, Appendix B, Table 3 values?
      iii. No more than 5 curies (Ci) (185 GBq) of tritium (H-3), 1 Ci (37 GBq) of carbon-14, and 1 Ci (37 GBq) of all other radionuclides combined, released in a year [32 Ill. Adm. Code 340.1030(a)(4)]?
      iv. Procedures to ensure representative sampling and analysis implemented [32 Ill. Adm. Code 340.510]?
   b. Release to septic tanks [32 Ill. Adm. Code 340.1030]? Within unrestricted limits [10 CFR Part 20, Appendix B, Table 3]?
   c. Waste incinerated?
      i. Exhaust directly monitored?
      ii. Airborne releases evaluated and controlled [32 Ill. Adm. Code 340.320, 32 Ill. Adm. Code 340.510]?
   d. Air effluents and ashes controlled [32 Ill. Adm. Code 340.110, 32 Ill. Adm. Code 340.210, 32 Ill. Adm. Code 340.310, 32 Ill. Adm. Code 340.510, 32 Ill. Adm. Code 340.1010]? (See also U.S. NRC Inspection Procedure 87102, RG 8.37.)
      i. Air effluent less than 0.10 mSv [10 mrem] constraint limit [32 Ill. Adm. Code 340.110]?
         1. If no, reported appropriate information to IEMA?
         2. If no, corrective actions implemented and on schedule?
      ii. Description of effluent program:
   e. Monitoring system hardware adequate?
   f. Equipment calibrated, as appropriate?
   g. Air samples/sampling technique (e.g., charcoal, high-efficiency particulate air) analyzed with appropriate instrumentation?

6. Waste storage:
   a. Protection from elements and fire?
   b. Control of waste maintained including constant surveillance of waste not in storage and secure from unauthorized removal or access for waste in storage [32 Ill. Adm. Code 340.810]?
   c. Containers properly labeled and area properly posted [32 Ill. Adm. Code 340.920, 32 Ill. Adm. Code 340.940]?

d. Package integrity adequately maintained?

7. Waste disposal:
   a. Sources transferred to authorized individuals [32 Ill. Adm. Code 340.1060, 32 Ill. Adm. Code 340.1010, 32 Ill. Adm. Code 330.400]?
   b. Name of organization: _____.
   c. Copy of waste disposal recipient's license on file?

8. Records of surveys and material accountability maintained [32 Ill. Adm. Code 340.1130, 32 Ill. Adm. Code 340.1180, 32 Ill. Adm. Code 340.1045]?

Receipt and Transfer of Radioactive Material

1. Description of how packages are received and by whom?

2. Written package-opening procedures established and followed [32 Ill. Adm. Code 340.960(e)]?

3. All incoming packages with a U.S. Department of Transportation (DOT) label monitored for radioactive contamination, unless exempted (gases and special form) [32 Ill. Adm. Code 340.960 (b)(1)]?

4. Incoming packages surveyed [32 Ill. Adm. Code 340.960(b)(2)]?

5. Monitoring in (3) and (4) performed within time specified [32 Ill. Adm. Code 340.960(c)]?

6. Transfer(s) performed per [32 Ill. Adm. Code 330.400]?

7. All sources surveyed before shipment and transfer [32 Ill. Adm. Code 340.510(a)]?

8. Records of surveys and receipt/transfer maintained [32 Ill. Adm. Code 340.1130(a), 32 Ill. Adm. Code 310.40]?

9. Package receipt/distribution activities evaluated for compliance with 32 Ill. Adm. Code 340.310?

Transportation (32 Ill. Adm. Code Part 341 and 49 CFR 171-178)

1. Shipments are:
   a. Delivered to common carriers?
   b. Transported in own private vehicle?
   c. Both?
   d. No shipments since last audit?

2. Return radiopharmacy doses to drug manufacture or commercial nuclear pharmacy or sealed sources to source or device manufacturer?
   a. Licensee assumes shipping responsibility?
   b. If "NO," describe arrangements made between licensee and radiopharmacy for shipping responsibilities.

3. Packages:
   a. Authorized packages used [49 CFR 173.415, 49 CFR 416]?
   b. Performance test records on file?
      i. DOT-7A packages
      ii. Special form sources

c. Two labels (White-I, Yellow-II, Yellow-III), on opposite sides not to include the bottom, with Transport Index (TI), Nuclide, Activity, and Hazard Class? [49 CFR 173.403, 49 CFR 415, 49 CFR 416]
d. Properly marked [Shipping Name, United Nations (UN) Number, Weight, Package Type, Reportable Quantity, "This End Up" (liquids), Name and Address of consignee] [49 CFR 172.403, 49 CFR 172.441, 49 CFR 173.471]?
e. Closed and sealed during transport [49 CFR 173.475(f)]?

4. Shipping Papers:
   a. Prepared and used [49 CFR 172.200(a)]?
   b. Contain proper entries (Shipping Name; Hazard Class; Identification Number (UN Number); Total Quantity; Package Type; Nuclide; Reportable Quantity; Physical and Chemical Form; Activity; Category of Label; TI; Shipper's Name, Certification and Signature; Emergency Response Telephone Number; "Limited Quantity" {(if applicable); "Cargo Aircraft Only" (if applicable)} [49 CFR 172.200-204]?
   c. Readily accessible during transport [49 CFR 177.817(e)]?

5. Any incidents reported to DOT [49 CFR 171.15, 171.16]?

Teletherapy and Gamma Stereotactic Radiosurgery (as permitted under 32 Ill. Adm. Code Part 335.8010)

1. Full-inspection servicing performed following source replacement or at intervals not to exceed 5 years for each teletherapy unit and not to exceed 7 years for each gamma stereotactic radiosurgery unit [32 Ill. Adm. Code 335.8150(a)]?

2. Needed service arranged for as identified during the inspection?

3. Service performed by persons specifically authorized to do so [32 Ill. Adm. Code 335.8150(b)]?

4. Were security requirements implemented, if applicable? [32 Ill. Adm. Code Part 337]

Full Calibration-Therapeutic Medical Devices

1. Proper protocol(s) used (e.g., AAPM Task Group (TG)–21 (TG-21), AAPM 54, AAPM TG-56, AAPM TG-40)?

2. Performed prior to first patient use [32 Ill. Adm. Code 335.8090(a)(1), 32 Ill. Adm. Code 335.8160(a)(1), 32 Ill. Adm. Code 335.8190(a)(1)]?

3. At intervals not to exceed 1 year for teletherapy, gamma stereotactic radiosurgery (GSR), and low dose-rate (LDR) remote afterloader; at intervals not exceeding 1 quarter for high dose-rate, medium dose-rate (MDR), and pulsed dose-rate (PDR) remote afterloaders [32 Ill. Adm. Code 335.8090(a)(3), 32 Ill. Adm. Code 335.8160(a)(3) and 32 Ill. Adm. Code 335.8160(a)(4), 32 Ill. Adm. Code 335.8190(a)(3)]?

4. Whenever spot-checks indicate output differs from expected by ±5% [32 Ill. Adm. Code 335.8090(a)(2)(A), 32 Ill. Adm. Code 335.8190(a)(2)(A)]?

5. After source exchange, relocation, and major repair or modification [32 Ill. Adm. Code 335.8090(a)(2), 32 Ill. Adm. Code 335.8160(a)(2), 32 Ill. Adm. Code 335.8190(a)(2)]?

6. Performed with properly calibrated instrument [32 Ill. Adm. Code 335.8090(c), 32 Ill. Adm. Code 335.8160(c), 32 Ill. Adm. Code 335.8190(c)]?

7. Includes:
    a. For teletherapy:
        i. Output measured within ±3% of expected for the range of field sizes, range of distances [32 Ill. Adm. Code 335.8090(b)(1)]?
        ii. Coincidence of radiation field and field light localizer [32 Ill. Adm. Code 335.8090(b)(2)]?
        iii. Uniformity of radiation field and beam angle dependence [32 Ill. Adm. Code 335.8090(b)(3)]?
        iv. Timer accuracy and linearity over the range of use [32 Ill. Adm. Code 335.8090(b)(4)]?
        v. On-off error [32 Ill. Adm. Code 335.8090(b)(5)]?
        vi. Accuracy of all measuring and localization devices [32 Ill. Adm. Code 335.8090(b)(6)]?
    b. For remote afterloaders:
        i. Output measured within ±5% of expected [32 Ill. Adm. Code 335.8160(b)(1)]?
        ii. Source positioning accuracy within ±1 millimeter [32 Ill. Adm. Code 335.8160(b)(2)]?
        iii. Source retraction with backup battery upon power failure [32 Ill. Adm. Code 335.8160(b)(3)]?
        iv. Length of source transfer tubes [32 Ill. Adm. Code 335.8160(b)(4)]?
        v. Timer accuracy and linearity over the typical range of use [32 Ill. Adm. Code 335.8160(b)(5)]?
        vi. Length of the applicators [32 Ill. Adm. Code 335.8160(b)(6)]?
        vii. Function of source transfer tubes, applicators, and transfer tube-applicator interfaces [32 Ill. Adm. Code 335.8160(b)(7)]?
        viii. Autoradiograph quarterly of the LDR source(s) to verify source(s) arrangement and inventory [32 Ill. Adm. Code 335.8160(e)]?
    c. For gamma stereotactic radiosurgery:
        i. Output measured within ±3% of expected [32 Ill. Adm. Code 335.8190(b)(1)]?
        ii. Helmet factors [32 Ill. Adm. Code 335.8190(b)(2)]?
        iii. Isocenter coincidence [32 Ill. Adm. Code 335.8190(b)(3)]?
        iv. Timer accuracy and linearity over the range of use [32 Ill. Adm. Code 335.8190(b)(4)]?
        v. On-off error [32 Ill. Adm. Code 335.8190(b)(5)]?
        vi. Trunnion centricity [32 Ill. Adm. Code 335.8190(b)(6)]?
        vii. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off [32 Ill. Adm. Code 335.8190(b)(7)]?
        viii. Helmet microswitches [32 Ill. Adm. Code 335.8190(b)(8)]?
        ix. Emergency timing circuit [32 Ill. Adm. Code 335.8190(b)(9)]?
        x. Stereotactic frames and localizing devices (trunnions) [32 Ill. Adm. Code 335.8190(b)(10)]?

8. Output corrected mathematically for decay [32 Ill. Adm. Code 335.8090(e), 32 Ill. Adm. Code 335.8160(g), 32 Ill. Adm. Code 335.8190(e)]?

9. Records maintained [32 Ill. Adm. Code 335.8090(g), 32 Ill. Adm. Code 335.8160(i), 32 Ill. Adm. Code 335.8190(g)]?

Periodic Spot-Checks for Therapeutic Devices

1. Performed at required frequency [32 Ill. Adm. Code 335.8100(a), 32 Ill. Adm. Code 335.8170(a), 32 Ill. Adm. Code 335.8200(a)]?

2. Procedures established by AMP [32 Ill. Adm. Code 335.8100(d), 32 Ill. Adm. Code 335.8170(b), 32 Ill. Adm. Code 335.8200(b)(1)]?

3. Procedures followed?

4. Medical physicist reviews results within 15 days [32 Ill. Adm. Code 335.8100(e), 32 Ill. Adm. Code 335.8170(c), 32 Ill. Adm. Code 335.8200(b)(2)]?

5. Performed with properly calibrated instrument [32 Ill. Adm. Code 335.8100(c), 32 Ill. Adm. Code 335.8200(c)(2)(A)]?

6. Output and safety spot-checks include:
    a. For teletherapy:
        i. Timer accuracy and linearity over the range of use [32 Ill. Adm. Code 335.8100(b)(1)]?
        ii. On-off error [32 Ill. Adm. Code 335.8100(b)(2)]?
        iii. Coincidence of radiation field and field light localizer [32 Ill. Adm. Code 335.8100(b)(3)]?
        iv. Accuracy of all measuring and localization devices [32 Ill. Adm. Code 335.8100(b)(4)]?
        v. The output for one typical set of operating conditions [32 Ill. Adm. Code 335.8100(b)(5)]?
        vi. Difference between measured and expected output [32 Ill. Adm. Code 335.8100(b)(6)]?
        vii. Interlock systems [32 Ill. Adm. Code 335.8100(f)(1)]?
        viii. Beam stops [32 Ill. Adm. Code 335.8100(f)(2)]?
        ix. Source exposure indicator lights [32 Ill. Adm. Code 335.8100(f)(3)]?
        x. Viewing and intercom systems [32 Ill. Adm. Code 335.8100(f)(4)]?
        xi. Treatment room doors, inside and out [32 Ill. Adm. Code 335.8100(f)(5)]?
        xii. Electrical treatment doors with power shut off [32 Ill. Adm. Code 335.8100(f)(6)]?
    b. For remote afterloaders:
        i. Interlock systems [32 Ill. Adm. Code 335.8170(d)(1)]?
        ii. Source exposure indicator lights [32 Ill. Adm. Code 335.8170(d)(2)]?
        iii. Viewing and intercom systems, except for LDR [32 Ill. Adm. Code 335.8170(d)(3)]?
        iv. Emergency response equipment [32 Ill. Adm. Code 335.8170(d)(4)]?
        v. Radiation monitors used to indicate source position [32 Ill. Adm. Code 335.8170(d)(5)]?
        vi. Timer accuracy [32 Ill. Adm. Code 335.8170 (d)(6)]?
        vii. Clock (date and time) in the unit's computer [32 Ill. Adm. Code 335.8170(d)(7)]?
        viii. Decayed source(s) activity in the unit's computer [32 Ill. Adm. Code 335.8170(d)(8)]?
    c. For gamma stereotactic radiosurgery:
        i. Treatment table retraction mechanism [32 Ill. Adm. Code 335.8200(c)(1)(A)]?
        ii. Helmet microswitches [32 Ill. Adm. Code 335.8200(c)(1)(B)]?
        iii. Emergency timing circuits [32 Ill. Adm. Code 335.8200(c)(1)(C)]?
        iv. Stereotactic frames and localizing devices [32 Ill. Adm. Code 335.8200(c)(1)(D)]?
        v. The output for one typical set of operating conditions [32 Ill. Adm. Code 335.8200(c)(2)(A)]?
        vi. Difference between measured and expected output [32 Ill. Adm. Code 335.8200(c)(2)(B)]?
        vii. Source output compared against computer calculation of output [32 Ill. Adm. Code 335.8200(c)(2)(C)]?
        viii. Timer accuracy and linearity over the range of use [32 Ill. Adm. Code 335.8200(c)(2)(D)]?
        ix. On-off error [32 Ill. Adm. Code 335.8200(c)(2)(E)]?
        x. Trunnion centricity [32 Ill. Adm. Code 335.8200(c)(2)(F)]?
        xi. Automatic positioning system?
        xii. Interlock systems [32 Ill. Adm. Code 335.8200(d)(1)]?

xiii. Source exposure indicator lights [32 Ill. Adm. Code 335.8200(d)(2)]?
xiv. Viewing and intercom systems [32 Ill. Adm. Code 335.8200(d)(3)]?
xv. Timer termination [32 Ill. Adm. Code 335.8200(d)(4)]?
xvi. Radiation monitors used to indicate room exposures [32 Ill. Adm. Code 335.8200(d)(5)]?
xvii. Emergency off buttons [32 Ill. Adm. Code 335.8200(d)(6)]?

7. Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required [32 Ill. Adm. Code 335.8100(g), 32 Ill. Adm. Code 335.8170(e), 32 Ill. Adm. Code 335.8200(f)]?

8. Records maintained [32 Ill. Adm. Code 335.8100(h), 32 Ill. Adm. Code 335.8170(f), 32 Ill. Adm. Code 335.8200(g)]?

Installation, Maintenance, and Repair of Therapy Devices

1. Only authorized individuals perform installation, maintenance, adjustment, repair, and inspection [32 Ill. Adm. Code 335.8020]? Name of organization/individual.

2. License verification?

3. Records maintained [32 Ill. Adm. Code 335.8020(d)]?

Emergency Procedures for Therapy Devices

1. Instructions on location of emergency procedures and emergency response telephone numbers posted at the device console [32 Ill. Adm. Code 335.8040(c)]?

2. Copy of the entire procedures physically located at the device console [32 Ill. Adm. Code 335.8040(b)]?

3. Procedures include:
   a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions [32 Ill. Adm. Code 335.8040(a)(4)(A)]?
   b. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure [32 Ill. Adm. Code 335.8040(a)(4)(B)]?
   c. The names and telephone numbers of the AUs, the AMP, and the RSO to be contacted if the unit or console operates abnormally [32 Ill. Adm. Code 335.8040(a)(4)(C)]?

4. AMP and AU:
   a. Physically present during initiation of patient treatment with remote afterloaders? [32 Ill. Adm. Code 335.8050(f)(1) and 32 Ill. Adm. Code 335.8050(f)(2)].

      NOTE: For MDR and PDR, an appropriately trained physician under the supervision of the AU may be physically present instead of the AU.

   b. Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device [32 Ill. Adm. Code 335.8050(f)(3)]?

Patient Surveys and Therapy Devices

1. Radiation survey of patient is performed to ensure source is returned to shielded position [32 Ill. Adm. Code 335.8180(a)]?

2. RSO and AU promptly notified if patient had a medical emergency or died [32 Ill. Adm. Code 335.8050(f)(4)]?

3. Records of radiation surveys maintained for 5 years [32 Ill. Adm. Code 335.8180(b)]?

Personnel Radiation Protection

1. Exposure evaluation performed [32 Ill. Adm. Code 340.510]?

2. As low as is reasonably achievable (ALARA) program implemented [32 Ill. Adm. Code 340.110(b)]?

3. External Dosimetry:
   a. Monitors workers per [32 Ill. Adm. Code 340.520(a)]?
   b. External exposures account for contributions from airborne activity [32 Ill. Adm. Code 340.230]?
   c. Supplier _____ Frequency
   d. Supplier is National Voluntary Laboratory Accreditation Program-approved [32 Ill. Adm. Code 340.510(d)(1)]?
   e. Dosimeters exchanged at required frequency?

4. Internal Dosimetry:
   a. Monitors workers per 32 Ill. Adm. Code 340.520?
   b. Program for monitoring and controlling internal exposures [32 Ill. Adm. Code 340.710, 32 Ill. Adm. Code 340.720] briefly described?
   c. Monitoring/controlling program implemented (includes bioassays)?
   d. Respiratory protection equipment [32 Ill. Adm. Code 340.730]?

5. Review of Records and Reports:
   a. Reviewed by _____ Frequency _____
   b. Reviewed personnel monitoring records for period _____ to _____.

   c. Prior dose determined for individuals likely to receive doses [32 Ill. Adm. Code 340.1140]?
   d. Maximum exposures TEDE Other
   e. Maximum committed dose equivalents (CDEs)
   f. Maximum CEDE _____ Organs _____
   g. Internal and external summed [32 Ill. Adm. Code 340.220]?
   h. Occupational limits met for adults [32 Ill. Adm. Code 340.210]?
   i. If applicable, occupational limits met for minors [32 Ill. Adm. Code 340.270]?
   j. Records of Occupational Dose [32 Ill. Adm. Code 340.1140 and 32 Ill. Adm. Code 340.1160]?
   k. If a worker declared her pregnancy during the audit period, was the dose in compliance [32 Ill. Adm. Code 340.280] and were the records maintained [32 Ill. Adm. Code 340.1160(d)]?

6. Any planned special exposures (number of people involved and doses received) [32 Ill. Adm. Code 340.260, 32 Ill. Adm. Code 340.1140, 32 Ill. Adm. Code 340.1150 and 32 Ill. Adm. Code 340.1240]?

7. Records of exposures, surveys, monitoring, and evaluations maintained [32 Ill. Adm. Code 340.1120, 32 Ill. Adm. Code 340.1130 and 32 Ill. Adm. Code 340.1160]?

Other Medical Uses of Byproduct Material or Radiation from Byproduct Material [32 Ill. Adm. Code 335.2140]

1. Use specific 32 Ill. Adm. Code 335.2140 licensing guidance and the above components, as applicable, to develop an audit of other medical uses licensed under 32 Ill. Adm. Code 335.2140.

Security Program for Category 1 and Category 2 Materials [32 Ill. Adm. Code Part 337]

1. Is access to the material controlled so that only authorized individuals can gain access to the material? Are personnel who have not been authorized escorted? [32 Ill. Adm. Code Part 337, Subpart B]

2. Have all personnel who have unescorted access to the material been deemed trustworthy and reliable, been fingerprinted, and been authorized in writing for access to the material? Is the list of authorized personnel up to date? [32 Ill. Adm. Code Part 337, Subpart B]

3. Is a system in place so that any unauthorized access to the material will be detected immediately? Are weekly verification checks conducted for Category 2 quantities of radioactive material? [32 Ill. Adm. Code 337.2050(a)]

4. Are procedures in place to ensure that any unauthorized access will be assessed to determine whether further response is required? If there have been any such accesses, was the procedure followed? [32 Ill. Adm. Code 337.2050(b)]

5. Is the security plan current? Is contact information for the local law enforcement agency current? [32 Ill. Adm. Code 337.2020(a)]

6. Is the security system operable? [32 Ill. Adm. Code 337.2060]

7. Does the security system have a dependable means of communication to notify assessment personnel? Do personnel have a dependable means of communication to notify response staff or local law enforcement? [32 Ill. Adm. Code 337.2050(c)]

8. Are all documents being retained as required? [32 Ill. Adm. Code 337.5020]

9. Is all sensitive information secured and protected in accordance with the procedure? Does the procedure address all required information? [32 Ill. Adm. Code 337.1060, 32 Ill. Adm. Code 337.2020(d)]

10. Have personnel with access to the material been trained on security procedures, including emergency response, notifications, and surveillance? [32 Ill. Adm. Code 337.2020(c)]

11. Are procedures in place to ensure the safe and secure transport of Category 1 and Category 2 radioactive sources or material? Were the procedures followed for preplanning, license verification, coordination, advance notification, physical protection, and reporting, as applicable? [32 Ill. Adm. Code 337.3010, 32 Ill. Adm. Code 337.3020, 32 Ill. Adm. Code 337.3030, 32 Ill. Adm. Code 337.3040, 32 Ill. Adm. Code 337.3050, and 32 Ill. Adm. Code 337.3060]

12. Is the security program content and implementation reviewed annually with records maintained for 3 years? [32 Ill. Adm. Code 337.2080]

Confirmatory Measurements

1. Detail location and results of confirmatory measurements.

Written Directive Review and Identification of Medical Events

1. Review a sampling of records for administrations requiring a WD. The number of patient cases to be sampled should be representative of each treatment modality performed in the institution.

2. Conduct a review of each applicable program area (e.g., radiopharmaceutical therapy, high dose-rate brachytherapy, implant brachytherapy, teletherapy, and emerging technologies). If feasible, the persons

conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work.

3. Review the procedures developed in accordance with 32 Ill. Adm. Code 335.1120 to ensure that the procedures for administrations requiring a WD are effective.

4. Determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable. Determine if a medical event, as described in 32 Ill. Adm. Code 335.1080, has occurred, and for permanent implant brachytherapy, that within 60 calendar days from the date the implant was performed the total source strength administered outside of the treatment site was compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented in accordance with 32 Ill. Adm. Code 335.1120. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified.

   If medical events meeting the criteria in 32 Ill. Adm. Code 335.1080 have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering WDs using the existing guidance.

   a. Event date _____ Information Source _____
   b. Notifications:
      i. IEMA Operations Center
      ii. Referring Physician
      iii. Patient
      iv. In writing
      v. By telephone
   c. If notification did not occur, why not?
   d. Written Reports [32 Ill. Adm. Code 335.1080(d)]: Submitted to IEMA within 15 days?
   e. Patient intervention that resulted in the total dose or dosage not being administered? Describe each intervention.

Notification and Reports

1. In compliance with 32 Ill. Adm. Code 400.130 (reports to individuals, public and occupational, monitored to show compliance with 10 CFR Part 20)?

2. In compliance with 32 Ill. Adm. Code 340.1210 (theft or loss)?

3. In compliance with 32 Ill. Adm. Code 340.1220(a) and (b) (overexposure and high radiation levels)?

4. Licensee in compliance with 32 Ill. Adm. Code 340.1220(c) (device defect)?

5. Aware of IEMA Operations Center telephone number [217-782-7860]?

6. In compliance with 32 Ill. Adm. Code 340.1230 (constraint on air emissions)?

Posting and Labeling

1. Agency Form KLA.001 "Notice to Employees" is posted [32 Ill. Adm. Code 400.110]?

2. 32 Ill. Adm. Code Parts 340 and 400, the license, the license conditions, any documents incorporated into the license by reference, amendments to these documents and operating procedures are posted, or a notice indicating where documents can be examined is posted [32 Ill. Adm. Code 400.110(a) and (b)]?

3. Other posting and labeling per 32 Ill. Adm. Code 340.920, 32 Ill. Adm. Code 340.940, and not exempted by 32 Ill. Adm. Code 340.930, 32 Ill. Adm. Code 340.950?

Recordkeeping for Decommissioning

1. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [32 Ill. Adm. Code 330.310(k)]?

2. Records include all information outlined in 32 Ill. Adm. Code 330.310(k)?

IEMA and U.S. NRC Correspondence

Bulletins, INs, Newsletters, etc., received and reviewed, as applicable? To receive these documents from the U.S. NRC electronically, subscribe to the Medical List Server by sending an e-mail to "Medical-GC.Resource@nrc.gov" with the word 'subscribe' in the subject line. Persons identified to IEMA as an individual authorized to speak and act on behalf of the license, are automatically included in email distributions. Appropriate action taken in response to Bulletins, Generic Letters, etc.?

Special License Conditions or Issues (L/C)

1. Special license condition or issues to be reviewed:
   a. If authorized for 32 Ill. Adm. Code 335.2140 medical uses, review the program for conformance with license application commitments, license conditions, and regulations.
   b. Other special license conditions.

Performance-Based Review

1. Conduct performance-based reviews of radiation workers performing licensed activities:
   a. to assess the capability of the radiation workers to maintain exposures ALARA;
   b. to assess that radiation workers follow the operating procedures;
   c. to assess the effectiveness of the operating procedures and compliance with the regulations, license conditions and the licensee commitments submitted in support of a license (and incorporated by "tie-down" conditions);
   d. to ensure the safe and secure use of radioactive material;
   e. to verify that radiation workers are cognizant of the emergency procedures and, if necessary, would be able to implement them and maintain exposures ALARA; and
   f. to ensure that emergency procedures have been developed for all likely scenarios.

2. Take the necessary actions to address programmatic and performance deficiencies with radiation workers and facilitate immediate corrective actions.

Evaluation of Other Factors

1. Senior licensee management is appropriately involved with the radiation safety program and/or RSO oversight?
2. RSO has sufficient time to perform radiation safety duties and is not too busy with other assignments?
3. Licensee has sufficient staff?

Audits and Findings

1. Summary of findings.
2. Corrective and preventive actions.
3. Amendment required?

Appendix V

RADIOACTIVE MATERIALS GUIDANCE FOR MOBILE MEDICAL SERVICES

Before submitting information to the IEMA, review Section II.C, "Identifying and Protecting Sensitive Information," of this document for guidance on identifying and protecting sensitive information. All security-related sensitive information in the application should be identified and properly marked.

Mobile medical service providers must comply with all applicable sections of 32 Ill. Adm. Code Parts 330 and 335 as well as U.S. Departmentof Transportation (DOT) regulations regarding approved source holders, placement of sources in approved containers prior to their transport, and hazardous materials training. For example, providers offering remote afterloaders must comply with 32 Ill. Adm. Code Part 335, Subpart I. The sections below describe the type of information that should be submitted when requesting to conduct mobile medical service provider activities.

Type and Location of Use

In general, there are two types of mobile medical service. One type is transportation and use of byproduct material within a transport vehicle (e.g., in-van or trailer use). A second type is transportation of byproduct material to a client's facility for use within a client's facility by either the mobile medical service's employees (i.e., transport and use) or the client's employees (i.e., transport only). Additionally, a licensee operating at a fixed location may contract for use of a mobile coach on a temporary (e.g., 3 months) or permanent basis under their own IEMA license. This is traditionally done when a licensee is in the process of constructing new nuclear medicine facilities or when the licensee starts a Positron Emission Tomography (PET) program. This is not a mobile medical service, since the mobile coach will be parked at the fixed location of use and operated by the non-mobile licensee. An amendment to add this additional area of use at their address of use should be requested as described in Section IV of this Instructional Set.

For mobile medical service, which includes use by the service provider, the service provider should apply for full-service authorization. Service providers who only transport and store a therapy device need only apply for authorization for possession and transport of the byproduct material. In this case, when the service provider is only transporting the therapy device for use,the client must possess a license for medical use of the byproduct material. Additionally, in thiscase, the client is authorized to provide the patient treatments and is responsible for all aspectsof the byproduct material use and patient treatments upon transfer of the byproduct material to the client's possession.

A PET mobile medical service provider that uses a "quiet room" and/or a patient waiting area in the client's facility may either be authorized for "in-van or trailer use only" or "transport and use," depending on whether the PET patients meet the criteria for release described in 32 Ill. Adm. Code 335.2110 while they are in the "quiet room." If they do not, then the "quiet room" is an area of use for the mobile medical service licensee and should be under their control while onsite. In addition, for mobile nuclear medicine and PET imaging, the licensee should take into account the possibility of using the client's bathroom dedicated for their use for PET patients and finding the bathroom with low levels of radioactive contamination during the end-of-day surveys. In this event, the mobile licensee must provide direction to the client for restricting access to the bathroom until follow up

surveys show the bathroom free of contamination (e.g., post and close off the patient bathroom for a designated period of time to allow for radioactive decay). The mobile medical service provider should also survey "quiet rooms," provided for their use at the client's site, for contamination and radiation levels, to ensure that public dose limits are not exceeded and that these areas are left free of contamination following use.

The locations of use for mobile medical services are of two basic types. One type of location is the base location where licensed material is received, stored, and sometimes used. The other type of location is the temporary jobsite at client facilities. The following two sections describe the type of information necessary for base locations and temporary jobsites.

Mobile Medical Service Agreement

Regulations in 32 Ill. Adm. Code 335.2120(a) require, in part, that a licensee providing mobile medical service obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client. This agreement must be applicable for the entire period of time over which the service is to be provided. The letter will be retained for 5 years after the last provision of service, as required by 32 Ill. Adm. Code 335.2120. Additionally, as required by 32 Ill. Adm. Code 335.2120(e), the licensee must survey all areas of use, to ensure compliance with the requirements in 32 Ill. Adm. Code Part 340 (e.g., ensure that all byproduct material, including radiopharmaceuticals, sealed sources, and all associated wastes, have been removed) before leaving a client's address.

The following is provided as an example of a PET mobile medical service agreement.

SAMPLE PET MOBILE MEDICAL SERVICE AGREEMENT

In accordance with 32 Ill. Adm. Code 335.2120(a), management designee, Sam Curie of ABC Hospital,Inc. acknowledges that mobile medical service provider, PET Mobile, Inc., will use byproduct material at client address 456 Rad Road, Somewhere, IL. Service will be provided every Monday beginning February 1, 2022. All radioactive material will be removed from the client facility prior to leaving the site. PET Mobile, Inc. will abide by all IEMA, U.S. NRC and Agreement State regulations while on-site.

The following authority and responsibilities are delegated to the client:

- Ordering of radioactive dosages

The following authority and responsibilities are delegated to the mobile medical service provider:

- Package receipt and return surveys.
- Quality control testing on equipment used to measure radioactive dosages (e.g., dose calibrator).
- Quality control testing and calibration of survey instrumentation (e.g., radiation survey meter, well counter).

- Sealed-source inventories and leak testing.
- Shipping papers.
- Radiation safety and hazardous materials training for mobile medical service personnel.
- Radiation safety training for client staff involved in: (i) controlling patient waiting areas used by the mobile medical service provider in the hospital; (ii) performing surveys to support release of the patient bathroom located in the hospital; and (iii) providing patient escort.
- Surveys of all interior PET trailer areas.
- Surveys of areas exterior to the PET trailer to ensure compliance with 32 Ill. Adm. Code 340.310 and roping off of any area (if necessary) to ensure that the dose rate is less than 0.01 mSv [2 millirem (mrem)] in any one hour.
- Surveys of patient waiting area in the hospital to ensure compliance with 32 Ill. Adm. Code 340.310 {0.02 mSv [2 mrem] in any one hour and 1 mSv [0.1 rem] in a year}since the patient has not yet been released under 32 Ill. Adm. Code 335.2110 and is awaiting scanning.
- Surveys of dedicated PET patient bathroom located within the hospital prior to leaving site.
- Decay in storage and disposal of radioactive material/waste. Radioactive waste will be removed to the PET trailer for storage. Non-radioactive waste that has been surveyed and shown to be at background may be disposed into the normal waste stream at the client's site.
- Confirming that AUs designated on the application are cognizant that they will be responsible for supervising the use of licensed material, including at the client's facility.
- Providing dosimetry to staff in accordance with 32 Ill. Adm. Code 340.520.
- Maintaining security of mobile PET trailer (e.g., keys, keypad codes).
- Ensuring that all radioactive material is accounted for and removed from the client at the end of the day of service.
- Radiation safety program audits, including use at client sites in accordance with 32 Ill. Adm. Code 340.110.

Note: In the event that bathroom contamination is found in the dedicated PET bathroom on hospital property and cannot be cleaned to below trigger levels for an unrestricted area, the mobile medical service provider will block off the bathroom and post it as a restricted area. In addition, the mobile medical service provider will post it as a radiation area, if necessary, in accordance with 32 Ill. Adm Code 340.920. The contamination will be reported to the client manager. The bathroom will be surveyed with a calibrated radiation survey meter the next day and released for unrestricted use, if radiation levels are below trigger levels for an unrestricted area described in the mobile medical service provider license.

This agreement will be retained by the licensee for 3 years after the last provision of service in accordance with 32 Ill. Adm. Code 335.2120(j).

Signed and Dated Vice President of Operations ABC Hospital, Inc.	Signed and Dated President PET Mobile, Inc.

Base Location

The base location (e.g., nuclear medicine hot lab or storage location for the remote afterloader) for the mobile medical service must be specified. A "base location" is one that is identified on the license, while a "temporary jobsite" (or client site) is a location that is other than a location ofuse identified on the license and where work is conducted for a limited period of time. The base location can be in a medical institution, noninstitutional medical practice, commercial facility, or mobile van or trailer. Applicants should specify in what type of facility the proposed base location is sited. A mobile licensee cannot provide a service to a private practice (non-licensee) located within a licensed medical institution (e.g., hospital). The medical institution's management (i.e., hospital management) must be consulted in this event. As required by 32 Ill. Adm. Code 330.240 and 32 Ill. Adm. Code 335.250, applicants must submit a description and diagram(s) of the proposed base location and associated equipment in accordance with Section IV of this Instructional Set. The description and diagram of the proposed base location should demonstrate that the building (or van or trailer) is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensures security of licensed material to prevent unauthorized access (e.g., control of keys), and ensures that radiation levels in unrestricted areas are in compliance with 32 Ill. Adm. Code 340.310 {e.g., shielding and roping off of areas greater than 0.02 mSv [2 mrem] in any one hour}. Include a diagram showing the location of the licensed material, receipt, and use areas, and identify all areas adjacent to restricted areas, including areas above and below the restricted areas. For storage locations within a van or trailer, the description of the van or trailer should address radiation levels in the van or trailer driver's compartment to demonstrate compliance with 32 Ill. Adm. Code 340.210, "Occupational dose limits for adults."

- Applicants may request multiple base locations. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered.

  — For diagnostic uses, the mobile medical service provider may list a portion of a client's site as a base location for which there is a clear, written agreement with the facility owner addressing security against unauthorized removal and establishing responsibility for the licensed material. This agreement should indicate the receipt and storage location and confirm that the mobile medical service provider will have sole access to the receipt/storage location and will be granted access to the facilities to remove any licensed material or decontaminatethe facility, as necessary. In this case, the mobile medical service provider may arrange to have licensed material delivered to the base location without their personnel present.

- Base locations can include the use of a mobile van or trailer. When the base location isin the van or trailer, and there is no permanent structure for the byproduct material storage, provide for the following:

— Secured off-street parking is under licensee control. Public rights-of-way are not considered part of the address of the client.

— Secured storage facilities are available for storage of byproduct material and radioactive waste, if the van or trailer is disabled.

- Byproduct material is delivered directly to the van or trailer parked at a site owned by the mobile medical service provider occupied by licensee personnel. In addition, for diagnostic uses only, the mobile medical service provider may arrange to have licensed material delivered to the van or trailer parked at a client site only if the mobile medical service provider submits information clearly demonstrating that they will have their personnel at the van or trailer to accept delivery and ensure the security and control of the licensed material.

- The mobile medical service provider may list a portion of a client's site as a base location for which there is a clear written agreement with the facility owner addressing security against unauthorized removal and establishing responsibility for the licensed material. This agreement should indicate the receipt and storage location and confirm that the mobile medical service provider will have sole access to the receipt/storage location and will be granted access to the facilities to remove any licensed material or decontaminate the facility, as necessary. In this case, the mobile medical service provider may arrange to have licensed material delivered to the base location without their personnel present.

- If a base location is in a residential area, provide the following information:

  — Justification of the need for a private residence location rather than for a commercial location.

  — Documentation of the agreement between the residence owner and the licensee. It is essential that the mobile medical service have access to the base location in the event of contamination. Provisions for decontamination of the mobile medical service van or trailer, etc., on the client property (if necessary) will be included. Documentation from both parties will illustrate the agreement between the clientand the mobile medical service.

  — A description of the program demonstrating compliance with 32 Ill. Adm. Code 340.310, "Dose limits for individual members of the public."

  — Verification that restricted areas do not contain residential quarters.

- Perform surveys necessary to show that exposure rates do not exceed 0.02 mSv [2 mrem] in any one hour nor 1 mSv/yr [100 mrem/yr].

Client Site for Diagnostic Uses

In general, client facility information does not need to be submitted; however, the mobile medical service provider may arrange to have licensed material delivered to the client site, only if the licensee submits information clearly demonstrating that the mobile medical service provider licensee will have its own personnel at the client site to accept delivery and ensure the security and control of the licensed material.

Alternatively, the mobile medical service provider may list a portion of a client's site as a base location for which there is a clear written agreement with the facility owner addressing security against unauthorized removal and establishing responsibility for the licensed material. This agreement should indicate the receipt and storage location and confirm that the mobile medical service provider will have sole access to the receipt/storage location and will be granted access to the facilities to remove any licensed material or decontaminate the facility, as necessary. In this case, the mobile medical service provider may arrange to have licensed material delivered to the base location without their personnel present and must provide an example contract that will be used with clients to designate these areas.

In addition, as described above, the client may designate "quiet rooms" for use by PET mobile medical service providers. These areas must also be described in the contract with the client and the applicant must provide an example contract that will be used with clients to designate these areas.

Client Site for Therapeutic Uses

This section applies only to therapeutic uses of byproduct material. For all types of therapy uses, the medical institutions, hospitals, or clinics and their addresses that comprise the client sites for mobile medical services must be listed.

For self-contained byproduct material services (e.g., in-van or trailer), the following additional facility information should be provided:

- For therapy treatments with byproduct material [e.g., high dose-rate (HDR) remote afterloader], provide a separate drawing for each client site showing the location of the treatment device and vehicle in relation to all nearby roads, sidewalks, structures, and any other locations accessible by members of the public.

- As delineated in the letter required by 32 Ill. Adm. Code 335.2120(a), a signed agreement that the location of the treatment device and vehicle will be on client-owned or controlled property.

- The protection from vehicular traffic that could adversely affect patient treatment(s), which could be accomplished either by locating the facility away from all vehicular traffic or by using barriers. Any protective measures must be shown on the facility or site drawings provided.

- A description of the emergency lighting system that automatically activates on detection

of the loss of primary power during patient remote afterloader treatments. The system must provide sufficient light to perform any possible emergency procedures, including the removal of a detached or stuck source that remains within the patient.

If transportable services will be provided to the client's site for use within the client's facility by the mobile medical service's employees, the following client facility information and commitment should be provided:

- A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment. The description and diagram of the proposed use facility must demonstrate that the facility isof adequate construction and design to protect its contents from the elements (e.g., highwinds, rain), ensure security of licensed material to prevent unauthorized access, and ensure that radiation levels in unrestricted areas are in compliance with 32 Ill. Adm. Code 340.310. Include a diagram showing the location of the equipment, receipt, anduse areas, and identify all areas adjacent to restricted areas.

- A commitment, as delineated in the letter required by 32 Ill. Adm. Code 335.2120(a), that the mobile medical service licensee has full control of the treatment room during byproduct materialuse for each client.

- The initial installation records and function checks of a remote afterloader device for each site of use, as required by 32 Ill. Adm. Code 335.8160, "Full calibration measurements on remote afterloader units;" 32 Ill. Adm. Code 335.8170, "Periodic spot-checks for remote afterloader units;" and 32 Ill. Adm. Code 335.8210, "Additional technical requirements for mobile remote afterloader units."

For a transport-only mobile medical service for therapy devices that are transported to the client's facility, used by the client's staff (under their own license), and removed by the service provider, ensure the following:

- Each client is properly licensed for medical use of byproduct material (which also includes accelerator-produced radioactive materials and discrete sources of radium-226). If applicable, licensees should ensure that each client has received the necessary initial and, if appropriate, recurrent training for the specific make and model ofthe remote afterloader device being provided. If the above applicable conditions are not met, the mobile medical service licensee must not transfer the remote afterloader deviceto the client.

- No signed agreement with a client may state or imply any assumption of responsibility on the part of the mobile medical service for the use of byproduct material for patient treatments. This includes such activities as dosage measurements, source calibrations, and remote afterloader device operational checks. Although these and other services may be provided to the client by the mobile medical service, if the mobile medical service is specifically licensed to provide such services, the client (licensee) retains all ofthe responsibilities related to the use of the byproduct material for patient treatments. The responsibilities for supervising individuals who use the byproduct material, set forth in 32 Ill. Adm. Code 335.1050, "Supervision," transfer to the client's authorized users (AU) upon transfer of the device to the client by the mobile medical service provider.

- The initial installation of a remote afterloader device at the client site may be performed by either the mobile medical service provider or the client, but all device function checks are the responsibility of the client (i.e., the licensee authorized to provide patient treatments at the client site).
- As required by 32 Ill. Adm. Code 310.40, "Records," a formal record of the transfer of control of the byproduct material from the mobile medical service provider to the client, and from the client back to the mobile medical service provider, must be made for each transfer of byproduct material.

Supervision

In addition to the requirements in 32 Ill. Adm. Code 400.120, 32 Ill. Adm. Code 335.1050 requires that instructions be given to supervised individuals in written radiation protection procedures, written directive procedures, regulations, and license conditions with respect to the use of byproduct material. Additionally, 32 Ill. Adm. Code 335.1050 requires the supervised individual to:

- Follow the instructions of the supervising AU for medical uses of byproduct material.
- Follow the instructions of the supervising AU for preparation of byproduct material for medical uses.
- Follow the written radiation protection procedures and written directive procedures established by the licensee.
- Comply with the provisions of 32 Ill. Adm. Code Part 335 [e.g., 32 Ill. Adm. Code 335.2120 and 32 Ill. Adm. Code 335.8210 (if applicable)], and the license conditions with respect to the mobile medical use of byproduct material.

Training for Individuals Working in or Frequenting Restricted Areas

Drivers and technologists (or therapists) will be properly trained in applicable transportation regulations and emergency procedures, in addition to the training requirements of 32 Ill. Adm. Code 400.120, 32 Ill. Adm. Code 335.1050, 32 Ill. Adm. Code 335.5020, 32 Ill. Adm. Code 335.7020, and 32 Ill. Adm. Code 335.8040 (as applicable). The training for these individuals will include, at a minimum, DOT regulations, shielding, as low as is reasonably achievable (ALARA), basic radiation protection, and emergency response.

Survey Instrument and Dose Measurement Instrument Checks

As required by 32 Ill. Adm. Code 335.2120, instruments should be checked for proper operation before use at each address of use. Dosage measurement instruments should be checked before medical use at each address of use or on each day of use, whichever is more frequent. Additionally, all other transported equipment (e.g., cameras) should be checked for proper function before medical use at each address of use.

Order and Receipt of Byproduct Material

Byproduct material will be delivered by a supplier to the base location or to the client's address, if the client is licensed to receive the type of byproduct material ordered. Additionally, if the mobile medical service provider is specifically licensed for receipt and storage in the client's facility, byproduct material may be delivered to the client's address. Delivery of byproduct material to a van or trailer that is not occupied by the mobile medical service personnel will not be permitted.

Alternatively, licensees may pick up the byproduct material (e.g., radiopharmaceuticals) from the supplier (e.g., nuclear pharmacy) en route to client facilities.

Emergency Procedures

The mobile medical service provider applicant should commit to develop, implement, and maintain emergency procedures in accordance with the radiation protection program required by 32 Ill. Adm. Code 340.110. Indicate typical response times of the radiation safety officer (RSO) and AU in the event of an incident and develop and implement procedures that include emergency response regarding an accident scenario. An accident is defined as a vehicle collision or other event, such as wind, water, or fire that results in damage to exterior or interior portions of the vehicle or the byproduct material used in the mobile medical service. The transportation emergency response plan should cover both the actions to be taken by the mobile medical service provider's headquarters emergency response personnel and the "on-scene" hazardous-material (HAZMAT)-trained personnel, and it will be readily available to both transport vehicle personnel and headquarters emergency-response contacts. The plan should include the following:

- A 24-hour emergency contact telephone number for the mobile medical service provider's emergency response personnel.
- The emergency contact number for IEMA's Operation Center.
- Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist.
- Procedures for retrieving and securing any byproduct material, including a sealed source that may become detached or dislodged to the extent that a radiological hazard is created, which may require one or more emergency shielded source containers.
- Predetermined (calculated) exposure rates for an unshielded therapy source (if applicable) as a function of distance for use in controlling the exposures of emergency response personnel to the maximum extent possible under various emergency response scenarios.
- Preplanned decontamination procedures, including ready access to all necessary materials.
- A calibrated, operational radiation survey meter maintained in the cab of the transporting vehicle, which may be used at an accident scene for conducting surveys.

- Security of the transport vehicle against unauthorized access, including the driver's compartment.

- Procedures to ensure that following any accident, no patient treatments with remote afterloaders will occur until all systems pertaining to radiation safety have been tested and confirmed to be operational by the RSO or authorized medical physicist. If any problem is found, including remote afterloader device interlocks and operation, the remote afterloader device or facility will be repaired and re-certified by the device vendor prior to return to service. In addition, a copy of the report, generated in accordance with 32 Ill. Adm. Code 340.1230 will be provided to clients following any accident in which there is actual or possible damage to the client's facility or the device.

Note: The type of response should be consistent with the level of the incident. The response may range from telephone contact for minor spills to prompt onsite response (less than 3 hours) to events such as a medical event or lost radioactive material.

Transportation

The mobile medical service provider applicant should commit to develop, document, and implement procedures to assure that the following takes place:

- Radioactive material is transported in accordance with 49 CFR Parts 171–177, "Transportation." Procedures will include:

  — use of approved packages
  — use of approved labeling
  — conduct of proper surveys
  — complete and accurate shipping papers
  — bracing of packages
  — security provisions
  — written emergency instructions

- Management (or management's designee) will perform audits, at least annually, of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities.

- Licensed material is secured during transport and use at the client's facilities.

- Radioactive waste is handled properly during transport. Describe the method of storage and final disposal.

- The transport vehicle, including the driver's compartment, if separate, will be secured at all times from any unauthorized access when the vehicle is unattended.

Note: The necessary DOT Type 7A package certification for remote afterloader devices is established by prior approval of the appropriate sealed source and device sheets; however, if the remote afterloader device is damaged in any way during use or transport, then the integrity of the DOT Type 7A packaging may be compromised, and the device must not be used or transported until

checked by the vendor and certified as retaining its integrity as a Type 7A package.

Appendix Y of this Instructional Set summarizes DOT requirements for Transportation of Licensed Material.

Radioactive Waste Management

If waste will be stored in vans or trailers, they must be properly secured and posted as byproduct material storage locations. Ensure that the van or trailer will be secured against unauthorized access and that the waste storage location will be posted as a byproduct material storage area. Develop, document, and implement final waste disposal procedures in accordance with Section III. Item 15 of this Instructional Set.

Excreta from individuals undergoing medical diagnosis or therapy with radioactive material maybe disposed of without regard to radioactivity, if it is discharged into the sanitary sewer system in accordance with 32 Ill. Adm. Code 340.1030. However, collecting excreta from patients in a van or trailer restroom with a holding tank is not considered direct disposal into the sanitary sewer system. If restroom facilities are provided in the van or trailer for patient use, submit the following information for IEMA review:

- A description of the structure of the tank holding facility and the location of the tank in relation to members of the public, workers in the van or trailer, and the driver of the van or trailer; a description of procedures to assess the tank for possible leakage; and a description of any restroom ventilation if any iodine-131 will be held in the tank.

- A description of procedures to ensure doses to occupational workers and members of the public will not exceed the exposure limits in 32 Ill. Adm. Code 340.210 and 32 Ill. Adm. Code 340.310; that the external surfaces of the van or trailer do not exceed 0.02 mSv/h [2 mrem/h]; and that doses to members of the public and workers are maintained ALARA, including considerations of external dose rates in the restroom caused by the proximity of the holding tank to the toilet.

- A description of procedures for emptying and disposing of the contents of the holding tank, including the frequency of disposal, who empties the tank into the sanitary sewer system, and the location of disposal into the sanitary sewer, including precautions taken to minimize contamination in this process.

Mobile Medical Services with Remote Afterloader Devices

Because the movement of the remote afterloader device from one location to another increases the risk of electro-mechanical component failures or misalignments, it is important that the proper operation of the device be fully checked after each such relocation. Therefore, develop, document, and implement the following procedures to determine if a device is operating properly before the commencement of patient treatments:

- Conduct safety checks on a remote afterloader device and facility. The procedure will include the periodic spot-checks required by 32 Ill. Adm. Code 335.8170 and the

additional spot-checks required by 32 Ill. Adm. Code 335.8210 before use at each address of use. Additionally, the procedure should include provisions for prompt repair of any system not operating properly.

- The pretreatment operational function checks after each device move should include a review of any device alarm or error message and, if necessary, a resolution of problems indicated by such messages.

- Such tests should be performed in accordance with written procedures.

- As required by 32 Ill. Adm. Code 335.8170 and 32 Ill. Adm. Code 335.8210, records showing the results of the above safety checks must be maintained for IEMA inspection and review for a period of 5 years.

- Perform surveys of the source housing and areas adjacent to the treatment room following relocation of an HDR unit. These surveys should include the source housing with the source in the shielded position and all areas adjacent to the treatment room with the source in the treatment position.

Appendix W

MODEL RADIATION SAFETY COMMITTEE PROCEDURES

U.S. NRC NUREG 1516, "Management of Radioactive Material Safety Programs at Medical Facilities", May 1997, describes a systematic approach for effectively managing radiation safety programs at medical facilities. Various aspects of program management are discussed, and guidance is offered on selecting the radiation safety officer, determining adequate resources for the program, using such contractual services as consultants and service companies, conducting audits, and establishing the roles of authorized users and supervised individuals. Although some of the referenced material has been superseded, Chapters 1 and 2 as well as select appendices may assist applicants in formulating RSC procedures. Chapter 1 discusses the selection and roles of management within the RSC. Chapter 2 outlines common responsibilities and duties of an RSC. The appendices provide a model RSC meeting agenda (Appendix B), template RSC meeting minutes (Appendix C), and a listing of required procedures (Appendix D). A licensee may utilize the applicable portions of this document as detailed below for their Radiation Safety Committee procedures or submit equivalent procedures for Agency evaluation.

- The applicant's management has established and empowered the Radiation Safety Committee (RSC) to conduct their official duties and responsibilities and exercise authority in accordance with regulatory requirements, including those described in the license application. Management has delegated an appropriate level of authority to the RSC to enable the committee to fulfill its role as part of the management team. The RSC shall serve as a collegial consensus and resource for executive management and is responsible for the oversight of all uses of radioactive material permitted by the license.

  Signed: _____

  Printed Name: _____

  Title: _____

- We will utilize the list of duties and responsibilities for the radiation safety committee specified in Chapter 2 of NUREG 1516, May 1997, in addition to those specific requirements in 32 Ill. Adm. Code 335.1040 and 32 Ill. Adm. Code 340.110. This includes, at a minimum,

  - Review and approval of requests for a license application, renewal or amendment before submittal to the Agency.
  - Review and approval of any individual before allowing that individual to work as an authorized user or authorized medical physicist.
  - Review and approval of user permits.
  - Review of consultant's reports and findings
  - Oversee the conduct of required annual program audits and program reviews which include, at a minimum, the topics discussed in Section 2.5.3 of NUREG 1516.
  - Maintain documentation of RSC meeting minutes and a record of actions taken by the licensee's management for 5 years as specified in 32 Ill. Adm. Code 335.1040, and

- The RSC will hold regularly scheduled meetings at least quarterly.

- To establish a quorum, at least half of the members must be present (physically or virtually), including the RSO and executive management representative. If the designated executive management representative is unable to attend or to send an alternate, the meeting may be held, but it will not be counted as one of the required periodic meetings.

- RSC membership will meet the requirements specified in 32 Ill. Adm. Code 335.1040(f). Specifically, the Committee shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

- A member of management has been selected to represent executive management and oversee the radiation safety program. This individual represents the highest level of facility management and has the authority to delegate resources for the radiation safety program as identified by the RSC. The executive manager has sufficient authority to appropriate funds in a timely manner to the radiation safety program and has broad responsibilities and authority over the involved departments. In this capacity, the member of management on the RSC is able to effect change or allocate resources for the Radiation Protection Program, without having to consult with higher management officials.

- RSC members must, at a minimum, attend meetings annually to retain membership on the RSC. Executive management will monitor attendance of required RSC members and recommend to the RSC replacement of members that are routinely absent.

Appendix X

REPORTING REQUIREMENTS

NOTE: The following list of notification and reporting requirements is provided to inform licensees about typical notification and reporting requirements that apply to their licensed activities. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, notification and reporting requirements change; therefore, licensees should consult the regulations for definitive information about current requirements.

Typical IEMA Notifications and/or Reports			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Reports to individual workers	None	annually	32 IAC 400.130(b)
Reports to former individual workers	None	upon request	32 IAC 400.130(c)
Notification of special circumstances to individuals	None	30 days	32 IAC 400.130(d)
Reports to worker terminating employment	None	upon request	32 IAC 400.130(e)
Package received with removable radioactive surface contamination exceeding the limits of 32 IAC 341.10 (49 CFR 173.443); or external radiation levels exceeding the limits of 32 IAC 341.10 (49 CFR 173.443).	immediate [(IEMA) and final delivery carrier must be notified]	none	32 IAC 340.960(d)
Theft or loss of material	immediate	30 days	32 IAC 340.1210(a) and (b)
Whole body dose greater than 0.25 Sieverts (Sv) [25 rem]	immediate	30 days	32 IAC 340.1220(a)(1)(A), 32 IAC 340.1230(a)
Extremity dose greater than 2.5 Gray [250 rads]	immediate	30 days	32 IAC 340.1220(a)(1)(C), 32 IAC 340.1230(a)
Whole body dose greater than 0.05 Sv [5 rem] in 24 hours	24 hours	30 days	32 IAC 340.1220(b)(1)(A), 32 IAC 340.1230(a)
Extremity dose greater than 0.5 Sv [50 rem] in 24 hours	24 hours	30 days	32 IAC 340.1220(b)(1)(C), 32 IAC 340.1230(a)
Doses in excess of specified criteria	None	30 days	32 IAC 340.1230(a)(2)
Levels of radiation or concentrations of radioactive material in excess of specified criteria	None	30 days	32 IAC 340.1230(a)(3) 32 IAC 340.1230(a)
Planned special exposures	None	30 days	32 IAC 340.1240
Report to individuals of exceeding dose limits	None	30 days	32 IAC 340.1250
Report of individual monitoring	None	annually	32 IAC 400.130
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i) 10 CFR 21.21(d)(3)(ii)
Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits	Immediate (not morethan 4 hours after discovery)	30 days	32 IAC 340.1220(a) 32 IAC 340.1230

Typical IEMA Notifications and/or Reports (Continued)			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	32 IAC 340.1220(c)(2) 32 IAC 340.1230
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	32 IAC 340.1220(c)(4) 32 IAC 340.1230
Generally licensed devices	None	30 days	32 IAC 330.220(a)(3) 32 IAC 330.220(a)(4) 32 IAC 330.220(a)(9)
Licensee permits individual to work as authorized users (AU), authorized medical physicist (AMP) or ophthalmic physicist	None	30 days	32 IAC 335.45(a)
RSO, AU, ARSO, or AMP discontinues performance of duties under license or has a name change	None	30 days	32 IAC 335.45(b)(1)
Temporary Radiation Safety Officer	None	30 days	32 IAC 335.45(b)(2)
Licensee's mailing address changes	None	30 days	32 IAC 335.45(b)(3)
Licensee's name changes without constituting a transfer of control	None	30 days	32 IAC 335.45(b)(4)
Licensee adds or changes areas of32 IAC 335.3010 or 335.4010 use of byproduct material identified in application or license if the change does not include an area where PET radionuclides are used, administered, produced, or stored	None	30 days	32 IAC 335.45(b)(5)
The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment	None	30 days	32 IAC 335.45(b)(6)
Medical event	1 day	15 days	32 IAC 335.1080(c) 32 IAC 335.1080(d)
Dose to an embryo/fetus that is greater than 50 millisieverts (mSv) [5 rem] dose equivalent	1 day	15 days	10 CFR 35.3047(c) 10 CFR 35.3047(d)
Dose to a nursing child that is greater than 50 mSv [5 rem] or resulted in unintended permanent functional damage	1 day	15 days	32 IAC 335.1100(c) 32 IAC 335.1100(d)
Leaking source	none	5 days	32 IAC 340.1260 32 IAC 330.220(a)(3)(E)
Eluate exceeding permissible molybdenum-99, strontium-82, or strontium-85 concentrations	7 days	30 days	32 IAC 335.4020(d)

Typical IEMA Notifications and/or Reports (Continued)			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Determination that any licensee that has not previously implemented the security requirements or been subject to the provisions of 32 IAC Part 337, Subpart C will aggregate radioactive material to a quantity that equals or exceeds the Category 2 threshold	None	90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold	32 IAC 337.2010(a)(3)
Coordination with local law enforcement agency (LLEA) has failed, either because the LLEA has not responded or because the LLEA does not plan to participate	3 business days	Submittal of a written report concerning failures of coordination with LLEA as described in 32 IAC 337.2030(b) is not required; however, licensees must document their efforts to coordinate with the LLEA and keep this documentation for 3 years	32 IAC 337.2030(b)
Determination that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantity of radioactive material	As soon as possible (but not at the expense of causing delay or interfering with the LLEA response), but no later than 4 hours after discovery	30 days	32 IAC 337.2090(a) 32 IAC 337.2090(c)
Assessment of any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material	As soon as possible, but no later than 4 hours after notifying the LLEA	none	32 IAC 337.2090(b)
Determination that a shipment containing a Category 1 quantity of material is lost or missing in transport	Within 1 hour of the determination. Also, notify LLEA within 1 hour of determination	30 days and periodic updates (if subsequent substantive information)	32 IAC 337.3060(a) 32 IAC 337.3060(g) 32 IAC 337.3060(h)
Determination that a shipment containing a Category 2 quantity of material is lost or missing in transport	Within 4 hours of the determination and again within 24 hours if the material has not yet been located and secured	30 days and periodic updates (if subsequent substantive information)	32 IAC 337.3060(b) 32 IAC 337.3060(g) 32 IAC 337.3060(h)

Typical IEMA Notifications and/or Reports (Continued)			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Discovery along the route of any actual or attempted theft or diversion, or suspicious activity, related to a Category 1 quantity of material in transport	As soon as possible upon discovery. Also notify LLEA as soon as possible upon discovery	30 days (except no report for suspicious activity) and periodic updates after report (if subsequent substantive information)	32 IAC 337.3060(c) 32 IAC 337.3060(g) 32 IAC 337.3060(h)
Discovery of any actual or attempted theft or diversion, or suspicious activity, related to a Category 2 quantity of material in transport	As soon as possible	30 days (except no report for suspicious activity) and periodic updates after report (if subsequent substantive information)	32 IAC 337.3060(d) 32 IAC 337.3060(g) 32 IAC 337.3060(h)
Upon recovery of any lost or missing Category 1 quantity of material	As soon as possible. Also notify the LLEA as soon as possible	To be included in the 30-day report of an event described in 32 IAC 337.3060(g), if recovered during that time or in a subsequent update	32 IAC 337.3060(e) 32 IAC 337.3060(h)
Upon recovery of any lost or missing Category 2 quantity of material	As soon as possible	To be included in the 30-day report of an event described in 32 IAC 337.3060(g), if recovered during that time or in a subsequent update	32 IAC 337.3060(f) 32 IAC 337.3060(h)

Note: Telephone notifications shall be made to the IEMA Operations Center at 217-782-7860, except as noted. The Center is staffed 24 hours a day.

APPENDIX Y

SUMMARY OF DOT REQUIREMENTS FOR TRANSPORTATION OF TYPE A,TYPE B, OR LIMITED QUANTITIES OF LICENSED MATERIAL

NOTE: The charts included at the end of this Appendix are for reference only and are not a substitute for U.S. Department of Transportation (DOT) and IEMA transportation regulations.

Licensed material must be transported in accordance with DOT regulations. Applicants and licensees should review the most recent regulations in Title 49 of the *Code of Federal Regulations* (49 CFR). Licensees should note that the list is incomplete, in that not all potentially applicable requirements have been included. Also, transportation requirements change; therefore, licensees should consult the regulations for definitive information about current requirements. The following are the major areas in DOT regulations most relevant for medical use licensees transporting licensed material:

- Table of Hazardous Materials and Special Provisions—Subpart B
  - 49 CFR 172.101—Purpose and Use of Hazardous Materials Table [proper shipping name, hazard class, identification number]
  - Table 2, Appendix A to 49 CFR 172.101—List of Hazardous Substances and Reportable Quantities [for radionuclides]
- Shipping Papers—Subpart C
  - 49 CFR 172.201—Preparation and retention of shipping papers
  - 49 CFR 172.202—Description of hazardous material on shipping papers
  - 49 CFR 172.203—Additional description requirements
  - 49 CFR 172.204—Shipper's certification [if applicable]
- Markings—Subpart D
  - 49 CFR 172.301—General marking requirements for non-bulk packaging
  - 49 CFR 172.304—Marking requirements
  - 49 CFR 172.310—Class 7 (radioactive) materials
  - 49 CFR 172.324—Hazardous substances in non-bulk packaging [designation of "reportable quantities" with the letters "RQ"]
- Labeling—Subpart E
  - 49 CFR 172.400—General labeling requirements

- 49 CFR 172.400(a)—Exceptions from labeling
- 49 CFR 172.403—Class 7 (radioactive) material
- 49 CFR 172.406—Placement of labels
- 49 CFR 172.436, 172.438, 172.440, 172.450—Labels [White-1, Yellow-2, Yellow-3, Empty]

- Placarding—Subpart F
  - 49 CFR 172.504—General placarding requirements
  - 49 CFR 172.516—Visibility and display of placards
  - 49 CFR 172.556—RADIOACTIVE placard
- Emergency Response Information—Subpart G
  - 49 CFR 172.600—Applicability and general requirements
  - 49 CFR 172.602—Emergency response information
  - 49 CFR 172.604—Emergency response telephone number
- Training—Subpart H
  - 49 CFR 172.702—Applicability and responsibility for training and testing
  - 49 CFR 172.704—Training requirements [types of training, frequency, recordkeeping]
- Safety and Security Plans – Subpart I
  - 49 CFR 172.800—Purpose and applicability
  - 49 CFR 172.802—Components of a security plan
- Shippers—General Requirements for Shipments and Packaging—49 CFR Part 173
  - Class 7 (Radioactive Materials) – Subpart I.
    - 49 CFR 173.25—Authorized packaging and overpacks
    - 49 CFR 173.403—Definitions
    - 49 CFR 173.410—General design requirements
    - 49 CFR 173.412—Additional design requirements for Type A packages

- 49 CFR 173.413—Requirements for Type B packages
- 49 CFR 173.415—Authorized Type A packages
- 49 CFR 173.416—Authorized Type B packages [includes packaging certification requirements]
- 49 CFR 173.421—Excepted packages for limited quantities of Class 7 (radioactive) materials
- 49 CFR 173.422—Additional requirements for excepted packages containing Class 7 (radioactive) materials
- 49 CFR 173.425—Table of activity limits—excepted quantities and articles [limited quantity]
- 49 CFR 173.431—Activity limits for Type A and Type B packages
- 49 CFR 173.435—Table of A_1 and A_2 values for radionuclides [fordetermination of package type]
- 49 CFR 173.441—Radiation level limitations and exclusive use provisions
- 49 CFR 173.443—Contamination control
- 49 CFR 173.471—Requirements for U.S. Nuclear Regulatory Commission approved packages
- 49 CFR 173.476—Approval of special form Class 7 (radioactive) materials [includes requirement for documentation of special form status]

- Carriage by Public Highway—49 CFR Part 177
  - General Information and Regulations-Subpart A
    - 49 CFR 177.817—Shipping papers [location of shipping papers during transport]
- Loading and Unloading—Subpart B
  - 49 CFR 177.842—Class 7 (radioactive) material [includes requirement for blocking and bracing during transport]

Applicants should visit the DOT Web site for additional information on transportation requirements: https://www.dot.gov/.

1. Minimum Required Packaging for Class 7 (Radioactive) Material:[1] (49 CFR 173 and 32 IAC Part 341)[2]

These are basic reference charts; refer to current U.S. DOT and IEMA regulations for complete requirements.

Minimum Packaging Required for Radioactive Materials other than Low Specific Activity (LSA) Material and Surface Contaminated Objects (SCO) based on Activity of Package Contents

Radioactive Material Quantity[3]		Limited Quantities and Articles	Type A[4] [9]	Type B
Activity Restrictions		≤ the limits specified in Table 4 of § 173.425	≤ A_1 for special form ≤ A_2 for normal form	> A_1 for special form > A_2 for normal form
Contents of Package	Non-fissile and Fissile Excepted	Excepted Package	Type A Package	Type B(U) or Type B(M) package
	Fissile	N/A	Type AF[10] package	Type B(U)F or Type B(M)F package

Minimum Packaging Required for LSA Material and SCO[5,6]

Type(s) of LSA and/or SCO	LSA-I	LSA-II	LSA-III	SCO-I	SCO-II
Category of Package for Domestic or International Transport[7,8]	Unpackaged[8] **IP-1:** solids or liquids/exclusive use **IP-2:** liquids/non-exclusive use **Specification tank cars or cargo tank motor vehicles:** liquids/exclusive use	- - **IP-2:** exclusive use[9] **IP-3:** liquids or gases/non-exclusive use[9]	- - **IP-2:** exclusive use **IP-3:** non-exclusive use	Unpackaged[8] IP-1 - -	- - IP-2 -
Alternative Provisions for Domestic only Transport[8]	Packaging shall meet the requirements of §§ 173.24, 24a, and 173.410. Transportation shall be an exclusive use shipment. Activity per shipment must be less than an A_2 quantity (see § 173.427(b)(4)).				

[1] Additional provisions may apply for radioactive materials that are pyrophoric, oxidizing, fissile excepted, or uranium hexafluoride.

[2] Each IEMA licensee shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180,and 390 through 397 (see § 71.5).

[3] Materials that contain radionuclides, where both the activity concentration and the total activity in the consignment exceed either thevalues specified in the table in § 173.436 or the values derived according to the instructions in § 173.433, must be regulated in transport as Class 7 (radioactive) material.

[4] Except for LSA material and SCO, a Type A package may not contain a quantity of Class 7 (radioactive) material greater than A_1 orA_2 (see § 173.431(a)). See A_1 and A_2 definitions in § 173.403.

[5] The external dose rate from LSA material or SCO in a single package may not exceed 10 mSv/h (1 rem/h) at 3 meters from theunshielded material or objects (see §§ 173.427(a)(1) and (d)).

[6] LSA material and SCOs that are or contain fissile material in quantities that are not fissile excepted must be packaged in appropriateType AF or Type BF packages, and not classified as LSA material or SCO. For alternate domestic transport provisions, see § 173.427(b)(4). For comprehensive guidance on packaging and transportation of LSA material and SCO, see NUREG-1608.

[7] For the quantity of LSA material and SCO transported in a single conveyance, see the limits specified in § 173.427(a)(2).

[8] LSA material or SCO shall be appropriately packaged in accordance with § 173.427(b) or (d). Certain LSA-I material and SCO-I maybe transported unpackaged under the conditions in § 173.427(c).

[9] See §§ 173.411(c) and 173.415(a) for requirements related to package record retention (2 years) and associated documentation of physical tests.

[10] See §§ 71.22(a), 71.23(a) and 173.417(a) for regulations regarding the use of non-AF packages for fissile materials.

2. Radiation Level, TI and CSI Limits for Transportation by Mode:[1] (49 CFR 173 - 177, and 32 Ill. Adm. Code Part 341)[10]

Type of Transport	Non-exclusive use	Exclusive use		
Mode of Transport	**Road, Rail, Vessel and Air[9]**	**Road and Rail**	**Vessel**	**Air (cargo only)**
Radiation Level Limits[2]				
Package Surface	**2 mSv/h (200 mrem/h)**	**2 mSv/h (200 mrem/h):** other than closed vehicles **10 mSv/h (1000 mrem/h):** closed vehicles	**2 mSv/h[11] (200 mrem/h)**	**2 mSv/h (200 mrem/h)[3]**
Conveyance[4]	**N/A**	**2 mSv/h (200 mrem/h):** outer surfaces (sides, top and underside) of vehicle[5]	**N/A**	**N/A**
		0.1 mSv/h (10 mrem/h): at any point two (2) m (6.6 ft) from sides of the vehicle[5]	**N/A**	**N/A**
Occupied position	**N/A**	**0.02 mSv/h (2 mrem/h):** in any normally occupied area[6]	**Requirements of § 176.708 apply**	**N/A**
Transport Index (TI) Limits[2]				
Package[7]	**3:** passenger aircraft **10:** road, rail, vessels and cargo aircraft	**No limit**		**10**
Conveyance[4]	**50:** road, rail and passenger aircraft **50 to No limit:** vessels[8] **200:** cargo aircraft	**No limit**		**200**
Overpack	**N/A:** for road, rail **50 to 200:** vessel[8] **3:** passenger aircraft; **10:** cargo aircraft	**N/A**	**No limit[8]**	**N/A**
Criticality Safety Index (CSI) Limit for fissile material[2]				
Package[7]	**50**	**100**	**100**	**100**
Conveyance[4]	**50:** road, rail and air **50:** for holds, compartments or defined deck areas of vessels[8] **200 to No limit:** for a total vessel[8]	**100**	**200 to No limit:** for a total vessel[8]	**100**
Overpack	**50:** road, rail, vessels[8] and air	**N/A**		

[1] Radiation level, TI, and CSI are defined in § 173.403.

[2] In addition to any applicable radiation level, TI and CSI limits, separation distance requirements apply to packages, conveyances, freight containers and overpacks; to occupied positions; and to materials stored in transit. Separation distancesare based on the sum of the TIs and, for fissile materials, the sum of the CSIs. [see applicable 49 CFR references for: Rail - § 174.700; Air – §§ 175.700 through 175.703; Vessel - §§ 176.700 through 176.708; and Highway - § 177.842].

[3] Higher package surface radiation levels may be allowed through an approved special arrangement.

[4] Conveyance is, for transport by public highway or rail, any transport vehicle or large freight container; and for transport by air,any aircraft. See definitions in § 173.403.

[5] The outer surfaces (sides, top and underside) of vehicles are specified for road and rail vehicles in § 173.441.

[6] For rail, normally occupied areas include the transport vehicle and adjacent rail cars. The 0.02 mSv/h (2 mrem/h) limit does not apply to carriers operating under a State or federally regulated radiation protection program where personnel wear radiation dosimetry devices.

[7] Additional TI and CSI limits apply for individual packages when non-fissile radioactive material packages are mixed with fissilematerial packages (see § 173.459).

[8] For details on TI and CSI limits for transport by vessel, see § 176.708.

[9] Only excepted packages and packages intended for use in research, medical diagnosis, and treatment are permitted onpassenger aircraft (see §§ 173.448(f) and 175.700).

[10] The limits in this table do not apply to excepted packages. See the following references for the radiation level limits for: limitedquantities, § 173.421; instruments and articles, § 173.424; articles containing natural uranium or thorium, § 173.426; or empty packaging, § 173.428.

[11] 2 mSv/h (200 mrem/h) other than intermodal transport of closed transport vehicles or exclusive use vessel.

3. Contamination Limits and Quality Control for Class 7 (Radioactive) Materials: (49 CFR 173.443 and 173.475, and 10 CFR 71)

These are basic reference charts; refer to current U.S. DOT and IEMA regulations for complete requirements.

Maximum Permissible Limits for Non-fixed Radioactive Contamination on Packages When Offered for Transport

The level of non-fixed (removable) radioactive contamination on the external surface of each package, conveyance, freight container, and overpack offered for transport must be kept as low as reasonably achievable, and shall not exceed the values shown in the following table:

Contaminant	Maximum permissible limits (§ 173.443(a), Table 9)		
	Bq/cm^2	µCi/cm^2	dpm/cm^2
Beta and gamma emitters and low toxicity alpha emitters	4	10^{-4}	240
All other alpha emitting radionuclides	0.4	10^{-5}	24

The non-fixed contamination shall be determined by:

(a) wiping, with an absorbent material using moderate pressure, sufficient areas on the package to obtain a representative sampling of the non-fixed contamination;
(b) ensuring each wipe area is 300 cm^2 in size;
(c) measuring the activity on each single wiping material and dividing that value by the surface area wiped and the efficiency of the wipe procedure, where an actual wipe efficiency may be used, or it may be assumed to be 0.10.

Alternatively, the contamination level may be determined using alternative methods of equal or greater efficiency.
A conveyance used for non-exclusive use shipments is not required to be surveyed unless there is reason to suspect that it exhibits contamination (see § 173.443(a)(2)).

Provisions for Control of Contamination on Radioactive Material Packages Offered for Transport and at the Time of Receipt

- When offered for transport, the non-fixed contamination on each package of radioactive material must be kept as low as reasonably achievable and may not exceed the limits set forth in § 173.443(a), Table 9 (as shown above).
- During transport, non-fixed contamination levels on packages transported as exclusive use by rail or highway may not exceed 10 times the limits in § 173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination on Excepted and Empty Radioactive Material Packages

- The non-fixed radioactive surface contamination on the external surface of excepted and empty packages shall not exceed the limits specified in § 173.443(a), Table 9 (as shown above).
- The internal contamination of an empty package must not exceed 100 times the limits in § 173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination on Packages and in Rail and Road Vehicles used for Exclusive Use Shipments of Radioactive Material

- The levels of non-fixed radioactive contamination on the packages (a) at the beginning of transport, may not exceed the levels prescribed in the above table, and (b) at any time during transport, may not exceed ten times the levels prescribed in § 173.443(a), Table 9 (as shown above) [see § 173.443(b)].
- Each conveyance, overpack, freight container, or tank used for transporting Class 7 (radioactive) material as an exclusive use shipment that utilizes the provisions of § 173.443(b) must be surveyed with appropriate radiation detection instruments after each exclusive use transport. If contamination values exceed acceptable levels, the transport vehicle may not be returned to exclusive use transport service, and then only for subsequent exclusive use shipment, unless the radiation dose rate at each accessible surface is demonstrated to be 0.005 mSv/h (0.5 mrem/h) or less, and that there is no significant non-fixed radioactive surface contamination as specified in § 173.443(a), Table 9 (as shown above) [see § 173.443(c)].

Provisions for Non-fixed (Removable) Contamination in Closed Rail and Road Vehicles that are used Solely for the Transportation of Radioactive Material (§ 173.443(d))

- The contamination levels must not exceed 10 times the levels prescribed in § 173.443(a), Table 9 (as shown above).
- Each vehicle is marked with the words "*For Radioactive Materials Use Only*" in letters at least 76 mm (3 in) high in a conspicuous place on both sides of the exterior of the vehicle.
- The vehicle must meet the placard requirements of Subpart F of Part 172.
- A survey of the interior surfaces of the empty closed vehicle must show that the radiation dose rate at any point does not exceed 0.1 mSv/h (10 mrem/h) at the surface or 0.02 mSv/h (2 mrem/h) at 1 m (3.3 feet) from the surfaces.
- Each vehicle shall be kept closed except for loading or unloading.

Provisions for Quality Control Prior to Each Shipment of Radioactive Material (§ 173.475)

- Before each shipment of any radioactive materials package, the offeror must ensure, by examination or appropriate tests, that:
  (a) the packaging is proper for the contents to be shipped;
  (b) the packaging is in unimpaired physical condition, except for superficial marks;
  (c) each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;
  (d) for fissile material, each moderator and neutron absorber, if required, is present and in proper condition;
  (e) each special instruction for filling, closing, and preparation of the packaging for shipment has been followed;
  (f) each closure, valve, or other opening of the containment system is properly closed and sealed;
  (g) each packaging containing liquid in excess of an A_2 quantity and intended for air shipment has been tested to show that it will not leak under an ambient atmospheric pressure of not more than 25 kPa, absolute (3.6 psia), where the test must be conducted on the entire containment system, or on any receptacle or vessel within the containment system, to determine compliance with this requirement;
  (h) the internal pressure of the containment system will not exceed the design pressure during transportation; and
  (i) the external radiation and contamination levels are within the allowable limits specified in §§ 173.441 and 173.443.

4. Hazard Communications for Class 7 (Radioactive) Materials: Shipping Papers (49 CFR 172, Subpart C)

These are basic reference charts; refer to current U.S. DOT and IEMA regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information. [1]

Shipping Paper Entries

Always Required

Basic description (in sequence):

- **UN Identification number**
- **Proper Shipping Name**
- **Hazard Class (7)**
- **Maximum activity contained in each package in SI units** (e.g., Bq, TBq), or in both SI and customary units (e.g., Ci, mCi) with customary units in parentheses following the SI units
- **Number and type of packages**

Additional description:

- **Name of each radionuclide**[2]
- **Description of physical and chemical form** (unless special form)
- **"Special form" when not in the proper shipping name**
- **Category of label** used
- **Transport index (TI)** of each package bearing a Yellow-II or Yellow-III label

Additional entry requirements:

- 24 hour **emergency telephone number**
- **Shipper's Certification** shall be provided by each person offering radioactive material for transportation[3]
- Proper page numbering (e.g., Page 1 of 4)

Sometimes Required

Materials-based Requirements:

- The criticality safety index (CSI) or "Fissile Excepted" for fissile material
- "Highway route controlled quantity" or "HRCQ" for highway route controlled quantities
- The letters "RQ" entered either before or after the basic description for each hazardous substance [see § 171.8]
- Enter applicable subsidiary hazard class(es) in parentheses immediately following the primary hazard class when a subsidiary hazard label is required
- A hazardous waste manifest and the word "Waste" preceding the proper shipping name is required for radioactive material that is hazardous waste

Package-based Requirements:

- The applicable DOE or NRC package approval identification marking for each Type B(U), Type B(M), or fissile material package
- The International Atomic Energy Agency (IAEA) Certificate of Competent Authority identification marking for export shipment or shipment in a foreign made package

Shipment- and Administrative-based Requirements:

- Specify "exclusive use shipment" as required
- Specify instructions for maintaining exclusive use controls for shipments of LSA material or SCO under exclusive use
- Specify the notation "DOT–SP" followed by the special permit number for a special permit shipment

Optional Entries

- The weight in grams or kilograms may be inserted instead of activity units for fissile radionuclides, except for Pu-239 and Pu-241
- The weight in grams of Pu-239 and Pu-241 may be inserted in addition to the activity units
- Other information is permitted provided it does not confuse or detract from the proper shipping name or other required information

Special Considerations/Exceptions for Shipping Papers

- For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, or be entered in a color that readily contrasts with any description on the shipping papers or highlighted on the shipping papers in a contrasting color, or be designated by an "X" (or "RQ" if appropriate).
- Emergency response information consistent with §§ 172.600 – 172.606 shall be readily available on the transport vehicle.
- Shipments of excepted radioactive material in excepted packages, under UN2908, UN2909, UN2910, and UN2911, are excepted from shipping paper requirements if (a) the material is not a hazardous substance or hazardous waste and (b) the package does not contain fissile material or contain fissile material that is excepted by § 173.453.
- For road transport, the shipping papers shall be (a) readily available to authorities in the event of accident or inspection, (b) stored within the driver's immediate reach while he is restrained by the lap belt, (c) readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle, and (d) either in a holder mounted to the inside of the door on the driver's side of the vehicle or on the driver's seat [see § 177.817(e)].

[1] International Atomic Energy Agency (IAEA); International Air Transportation Association (IATA); International Civil Aviation Organization (ICAO); International Maritime Organization (IMO).

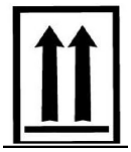
[2] For mixtures of radionuclides, the radionuclides to be shown must be determined in accordance with § 173.433(g), which is commonlyknown as the 95% rule; abbreviations (symbols) are authorized.

[3] The Shipper's certification shall satisfy the requirements of § 172.204.

5. Hazard Communication for Class 7 (Radioactive) Materials:
Marking of Packages:(49 CFR 172, Subpart D; and 49 CFR 173.471, 178.3 and 178.350)

These are basic reference charts; refer to current U.S. DOT and IEMA regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Markings on Packages

Markings Always Required Unless Excepted[1]	Additional Markings Sometimes Required	Optional Markings
For Non-bulk Packages: • Proper shipping name • Identification number (preceded by "UN" or "NA," as appropriate) • Name and address of consignor or consignee, unless the package is: ▪ highway only and no motor carrier transfers; or ▪ part of a rail carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee **For Bulk Packages:** • Identification number on orange panel or white square-on-point display [see §§ 172.332 or 172.336]: ▪ on each side and each end, if the packaging has a capacity of 3,785 L (1,000 gallons) or more[2], or ▪ on two opposing sides, if the packaging has a capacity of less than 3,785 L (1,000 gallons)[2]	**Package-based marking requirements:** • Gross mass, including the unit of measurement (which may be abbreviated) for each package with gross mass greater than 50 kg (110 lb) • Package type as appropriate, i.e., "TYPE IP–1," "TYPE IP–2," "TYPE IP–3," "TYPE A," "TYPE B(U)" or "TYPE B(M)"[1] • Marked with international vehicle registration code of country of origin for IP–1, IP–2, IP–3 or Type A package design (e.g., "USA") • Radiation (trefoil) symbol[3] on outside of outermost receptacle of each Type B(U) or Type B(M) packaging design  • Each NRC-approved package (e.g., Type AF, Type B(U), Type B(M), Type B(U)F, and Type B(M)F) must be marked with the identification marking indicated in the package approval • For Specification 7A packaging, mark on the outside with "USA DOT 7A Type A", and the name and address or symbol of the manufacturer satisfying §§ 178.3 and 178.350 **Materials-based requirements:** • For a non-bulk IP–1 package containing a liquid, use underlined double arrow symbol indicating upright orientation[4], where the symbol is placed on two opposite sides of the packaging [see § 172.312]  • For a non-bulk package containing a hazardous substance, mark the outside of each package with the letters "RQ" in association with the proper shipping name **Administrative-based requirements:** • For each Type B(U), Type B(M) or fissile material package destined for export shipment, mark "USA" in conjunction with specification marking, or certificate identification; and package identification indicated in the U.S. Competent Authority Certificate • Mark "DOT–SP" followed by the special permit number assigned for each package authorized by special permit • Competent authority identification marking and revalidation for foreign made Type B(U), Type B(M), Type H(U), Type H(M), or fissile material package for which a Competent Authority Certificate is required	• Both the name and address of consignor and consignee is recommended. • Other markings on packages such as advertising are permitted, but must be located away from required markings and labeling. For marking exceptions for LSA material and SCO, [see § 173.427(a)(6)(vi)] (e.g., RADIOACTIVE-LSA, RADIOACTIVE-SCO, or RQ, as appropriate). For an overpack, the marking "OVERPACK" in lettering 12 mm (0.5 inches) high. This marking is not required if the package type contained in the overpack is visible from the outside [see § 173.25].

Special Considerations for Marking Requirements

- All markings are to be (a) on the outside of each package, (b) durable and legible, (c) in English, (d) printed on or affixed to the surface of a package or on a label, tag, or sign, (e) displayed on a background of sharply contrasting color, and (f) unobscured by labels or attachments.
- When an overpack is used, see §§ 173.25 and 173.448(g) for marking requirements.

[1] Some marking exceptions exist for excepted packages, as specified in §§ 173.421, 173.422, 173.424, 173.426 and 173.428.

[2] If the identification number marking on a bulk package is not visible, the transport vehicle or freight container must be marked on each side and each end [see § 172.331].

[3] The radiation symbol shall be resistant to the effects of fire and water, plainly marked by embossing, stamping or other means resistant to the effects of fire and water and conform to the size requirements of Appendix B to Part 172.

[4] The arrows must be either black or red on white or other suitable contrasting background and commensurate with the size of the package; depicting a rectangular border around the arrows is optional.

6. Hazard Communications for Class 7 (Radioactive) Materials:
Labeling of Packages (49 CFR 172.400-450)

These are basic reference charts; refer to current U.S. DOT and IEMA regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Requirements for Labels[1]

- Label each package, except for (a) excepted packages of radioactive material; and (b) Low Specific Activity (LSA) material and Surface Contaminated Objects (SCO), packaged or unpackaged, when transported under exclusive use controls domestically and when the material or object contains less than an A_2 quantity.
- Labels are required to be (a) printed or affixed to a surface other than the bottom of the package, (b) placed near the proper shipping name marking, (c) printed or affixed to a background of contrasting color or have a dotted or solid line outer border, (d) clearly visible, (e) not obscured by markings or other attachments, (f) representative of the hazardous material content, and (g) in conformance with the label specifications of § 172.407.
- The appropriate radioactive label must be affixed to opposite sides or two ends (other than the bottom) of all non-bulk packages of radioactive material.

Category of Radioactive Labels [3]

White-I

Yellow-II

Yellow-III

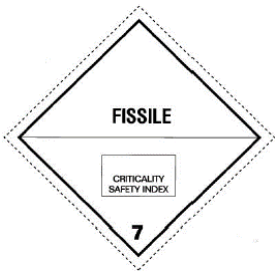
Maximum Radiation Surface Level (RSL)

mSv/h	**RSL** ≤ 0.005	0.005 < **RSL** ≤ 0.5	0.5 < **RSL** ≤ 2[5]
mrem/h	**RSL** ≤ 0.5	0.5 < **RSL** ≤ 50	50 < **RSL** ≤ 200[5]

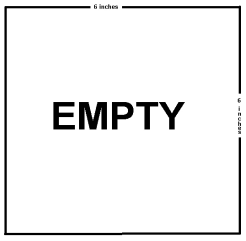
Transport Index (TI):[4]

TI = 0	0 < **TI** ≤ 1	1 < **TI** ≤ 10[5]

Other Radioactive Labels[2]



Fissile



Empty

Fissile labels required for each package containing fissile material, other than fissile-excepted material; and labels must be affixed adjacent to radioactive category labels.

Empty labels required for empty Class 7 (radioactive) packages satisfying § 173.428; and any previously-used labels must not be visible.

Contents on Labels

- Each radioactive category label must contain: (a) Except for LSA-I material, the names of the radionuclides in the package where, for mixtures of radionuclides, the names listed must be in accordance with the 95% rule specified in § 173.433(g); and, for LSA-I material, the term "LSA-I"; (b) maximum activity in appropriate SI units (e.g., Bq, TBq), or appropriate customary units (e.g., Ci, mCi) in parentheses following SI units; and (c) for Yellow-II or Yellow-III labels the Transport Index (TI). Abbreviations and symbols may be used. Except for Pu-239 and Pu-241, the weight in g or kg of fissile radionuclides may be inserted instead of activity units; for Pu-239 and Pu-241, the weight in g of fissile radionuclides may be inserted in addition to the activity units [see § 173.403 for fissile material definition].
- Each fissile label must contain the relevant Criticality Safety Index (CSI) [see § 172.403(e)].

[1] Additional labels may be required if the contents of a package contains material that also meets the definition of one or more other hazard class. See §§ 172.402 and 406(c) for details on additional labeling requirements. [See §§ 172.400a, 173.421 through 173.427for details when labels are not required, and see § 172.407 for details on label durability, design, size, color, form identification, exceptions, and the trefoil symbol size].

[2] A "Cargo Aircraft Only" label is required for each package containing a hazardous material which is authorized for cargo aircraft only[see § 172.402(c)].

[3] The category of the label must be the higher of the two values specified for RSL and TI [see § 172.403(b)].

[4] The TI is determined from the radiation level 1 meter from the package surface [see TI definition in § 173.403]. If the measured TI is notgreater than 0.05, the value may be considered to be zero. When an overpack is used, it must be labeled in accordance with § 72.403(h).

[5] Packages with a TI > 10 or an RSL > 2 mSv/h (200 mrem/h) must be transported under exclusive use provisions [see § 173.441(b)].Any package containing a Highway Route Controlled Quantity (HRCQ) must be labelled as RADIOACTIVE YELLOW-III.

7. Hazard Communications for Class 7 (Radioactive) Materials: Placarding (49 CFR 172, Subpart F)

These are basic reference charts; refer to current U.S. DOT and IEMA regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

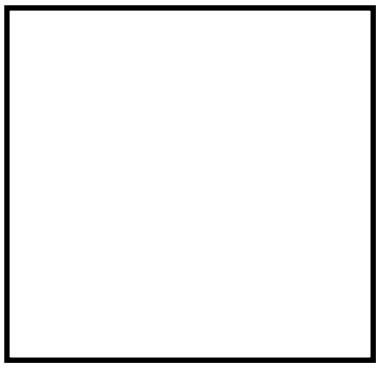
Conditions when Display of Placards is Required [§§ 172.504, 172.507(a), 172.508, and 172.512]

- Each bulk package, freight container, unit load device[1], transport vehicle, or rail car containing any quantity of hazardous material must be placarded on each side and each end with the placards specified in § 172.504(e).
- Radioactive placards are required for: shipments that contain a package labeled as Radioactive Yellow-III; unpackaged LSA-I or SCO-I when transported under exclusive use provisions; shipments required by §§ 173.427, 173.441, and 173.457 to be operated under exclusive use; and closed vehicles marked "For Radioactive Materials Use Only" transported under § 173.443(d).
- The Radioactive placard is placed on a square background on any motor vehicle used to transport a package containing a Highway Route Controlled Quantity (HRCQ) Class 7 (radioactive) material[2].

Visibility and Display of Radioactive Placards [§ 172.516]

- Placards are required to:
  - be clearly visible, on a motor vehicle and rail car, from the direction they face, except from the direction of another transport vehicle or rail car to which the motor vehicle or rail car is coupled[3]
  - be securely attached or affixed thereto or placed in a holder thereon
  - be located clear of appurtenances and devices such as ladders, pipes, doors, and tarpaulins
  - be located, so far as practical, so dirt or water is not directed to it from the transport vehicle wheels
  - be located at least 3 inches (76.0 mm) away from any marking (e.g. advertising) that could reduce its effectiveness
  - have "RADIOACTIVE" printed on it displayed horizontally, reading from left to right
  - be maintained by the carrier so format, legibility, color, and visibility of the placard will not be substantially reduced due to damage, deterioration, or obscurement by dirt or other matter
  - be affixed to a background of contrasting color, or have a dotted or solid line outer border which contrasts with the background color.

Radioactive Placards

PLACARD (FOR OTHER THAN HRCQ)	PLACARD FOR HRCQ
	
White triangular background color in the lower portion with yellow triangle in the upper portion; trefoil symbol, text, class number and inner and outer borders in black. [see § 172.556 and Appendix B of Part 172]	Square background must consist of a white square surrounded by one-inch black border. The placard inside the square is identical to that for other than HRCQ. [see § 172.527]

General Specifications for Placards and Subsidiary Hazard Placarding

- Placards must conform to the specifications in § 172.519.
- A CORROSIVE placard is also required for each transport vehicle that contains 454 kg (1001 pounds) or more gross weight of non-fissile, fissile-excepted, or fissile uranium hexafluoride [see § 172.505(b)].
- Placards are also required for subsidiary hazards of POISON INHALATION HAZARD, POISON GAS, or DANGEROUS WHEN WET [see § 172.505].

[1] See § 172.512 for exceptions and variations to the placarding requirements for freight containers and aircraft unit load devices.
[2] See § 173.403 for the definition of Highway Route Controlled Quantity (HRCQ). A package containing an HRCQ must be labeled with RADIOACTIVE Yellow-III labels [see §§ 172.403(c) and 172.507(a)].
[3] Required placarding of the front of a motor vehicle may be on the front of a truck-tractor instead of or in addition to the placarding on thefront of the cargo body to which a truck-tractor is attached § 172.516(b).

8. Requirements/Guidance for Registration, Emergency Response and Action for Class 7 (Radioactive) Materials: (49CFR 107, Subpart G; 49 CFR 171.15; 49 CFR 172, Subparts F and G)

These are basic reference charts; refer to current U.S. DOT and IEMA regulations for complete requirements.

Provisions for Persons Who Offer or Transport Class 7 (Radioactive) Materials (49 CFR 107, Subpart G)

- Any person, other than those excepted by § 107.606, who offers for transportation, or transports, in foreign, interstate or intrastate commerce any of the following Class 7 (radioactive) materials must satisfy registration and fee requirements of Part 107, Subpart G:
  - a highway route-controlled quantity of radioactive material;
  - a shipment in a bulk packaging with a capacity ≥ 13,248 L (3,500 gallons) for liquids or gases, or > 13.24 cubic meters (468 cubic feet) for solids; or
  - any quantity of radioactive material that requires placarding, under provisions of Part 172, Subpart F.
- Any person required to register must submit a complete and accurate registration statement on DOT Form F 5800.2 by June 30th for each registration year, or in time to have on file a current Certificate of Registration in accordance with § 107.620.
- Each registrant or designee must maintain for a period of 3 years from the date of issuance a copy of the registration statement and Certificate of Registration issued by PHMSA and must furnish its Certificate of Registration (or a copy thereof) and related records to an authorized representative or special agent of DOT upon request.
- Each motor carrier subject to registration requirements of this subpart must carry a copy of its current Certificate of Registration or another document bearing the registration number on board each truck and truck tractor, and the Certificate of Registration or document must be made available, upon request, to enforcement personnel.
- The amount of fees to be paid and procedures to be followed are found at §§ 107.612 and 107.616.

Provisions for Providing and Maintaining Emergency Response Information (49 CFR 172, Subpart G)

- When shipping papers for the transportation of radioactive materials are required [see Part 172, Subpart C], emergency response information shall
  - be provided and maintained during transportation and at facilities where materials are loaded for transportation, stored incidental to transportation, or otherwise handled during any phase of transportation;
  - be provided by persons who offer for transportation, accept for transportation, transfer or otherwise handle hazardous materials during transportation;
  - be immediately available for use at all times the hazardous material is present; and
  - include and make available the emergency response telephone number [see § 172.604] to any person, representing a Federal, State or local government agency, who responds to an incident involving the material or is conducting an investigation which involves the material.
- Emergency response information is information that can be used in mitigating an incident involving radioactive materials. It must contain at least the information specified in §§ 172.602 and 172.604; and includes an emergency response telephone number that is monitored at all times the material is in transportation by (a) knowledgeable person, or (b) a person who has immediate access to a knowledgeable person, or (c) an organization capable of accepting responsibility for providing the necessary detailed information concerning the material.
- Each carrier who transports or accepts for transportation radioactive material for which a shipping paper is required shall instruct, according to the requirements of § 172.606, the operator of a conveyance to contact the carrier in the event of an incident involving the material.

Actions to be Taken in the Event of Spillage, Breakage, or Suspected Contamination by Radioactive Material

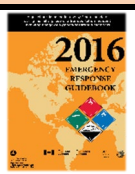
- If there is evidence of a leaking package or conveyance, access to the package or conveyance must be restricted, the area impacted and the extent of the contamination must be determined, and appropriate measures must be taken to minimize impact to persons and the environment [see § 173.443(e)].
- Except for a road vehicle used solely for transporting Class 7 (radioactive) material [see § 173.443(d)], each aircraft used routinely, and each motor vehicle used for transporting radioactive materials under exclusive use, must be (a) periodically checked for radioactive contamination, (b) taken out of service if contamination levels are above acceptable limits, and (c) remain out of service until the radiation dose rates at accessible surfaces are less than 0.005 mSv/h (0.5 mrem/h) and non-fixed radioactive surface contamination levels are below the limits in §§ 173.443(a), Table 9; and 173.443(c) for exclusive use vehicle provisions [see Chart 3].
- Following any breakage, spillage, release or suspected radioactive contamination incident, any rail or air carrier shall notify, as soon as possible, the offeror (i.e. the consignor); special provisions apply for buildings, areas, and equipment that might become contaminated during rail transport. Alternative provisions may apply for motor vehicles transporting radioactive materials under exclusive use [see §§ 174.750(a), 175.705(e), and 177.843(b)].

Provisions for Immediate Notification for Reportable Incidents Involving Radioactive Materials (§§ 171.15 and 171.16)

- Each person in physical possession of radioactive material must provide notice in the event of a reportable incident (see § 171.15(b)) as soon as practical, but no later than 12 hours after the occurrence of the reportable incident, to the National Response Center (NRC) by telephone at 800–424–8802 (toll free) or 202–267–2675 (toll call) or online at https://www.nrc.uscg.mil. Thereafter, notify the IEMA Operations Center by telephone at 217-782-7860.
- Each notice must include the information specified in § 171.15(a)(1) – (a)(7).
- A detailed incident report must also submitted as required by § 171.16.

Guidance on Responding to Emergencies (Emergency Response Guidebook)

- The DOT issues guidance to aid first responders in quickly identifying the hazards of the dangerous goods involved in an accident or incident, and for protecting themselves and the general public during the initial response to the accident or incident. For each proper shipping name or UN ID Number, the user is led to a specific guide that provides insight into potential hazards and steps to be taken for public safety and emergency response.
- The current edition of the Emergency Response Guidebook is available at https://phmsa.dot.gov/hazmat/outreach-training/erg.



9. Requirements for Training and Safety and Security Plans for Class 7 (Radioactive) Materials: (49 CFR 172, Subparts H and I, 49 CFR 173, and 32 Ill. Adm. Code Part 337)

These are basic reference charts; refer to current U.S. DOT and IEMA regulations for complete requirements.

Training (49 CFR 172, Subpart H)

- For any person who is employed by an employer or is self-employed, and who directly affects hazardous materials transportation safety, a systematic program shall be established to ensure that the person:
  - has familiarity with the general provisions of Part 172, Subpart H;
  - is able to recognize and identify radioactive materials;
  - has knowledge of specific requirements of Part 172 that are applicable to functions performed by the employee;
  - has knowledge of emergency response information, self-protection measures and accident prevention methods and procedures; and
  - does not perform any function related to the requirements of Part 172 unless instructed in the requirements that apply to that function.
- The person shall be trained pursuant to the requirements of § 172.704(a) and (b), may be trained by the employer or by other public or private sources, and shall be tested by appropriate means. The training must include the following:
  (a) general awareness training providing familiarity with applicable regulatory requirements;
  (b) function-specific training applicable to functions the employee performs;
  (c) safety training concerning emergency response information, measures to protect the employee from hazards, and methods and procedures for avoiding accidents;
  (d) security awareness training providing awareness of security risks and methods designed to enhance transportation security; and
  (e) in-depth security training if a security plan is required for the shipment(s) involved.
- Initial and recurrent training shall comply with the requirements of § 172.704(c).
- Records of training shall be created and retained in compliance with the requirements of § 172.704(d).

Security (49 CFR 172, Subpart I, 49 CFR 173, and 32 Ill. Adm. Code Part 337)

- A security plan for hazardous materials that conforms to the requirements of Part 172, Subpart I must be developed and adhered to by each person who offers for transportation in commerce or transports in commerce in a motor vehicle, rail car, or freight container any of the following radioactive materials:
  (a) IAEA Code of Conduct Category 1 and 2 materials (see §§ 172.800(b)(15) and 32 Ill. Adm. Code Part 337);
  (b) a highway route controlled quantity (HRCQ) of radioactive material as defined in § 173.403 [see § 172.800(b)(15)];
  (c) known radionuclides in forms listed as radioactive material quantities of concern (RAM–QC) by IEMA [see §§ 172.800(b)(15)and 32 Ill. Adm. Code Part 337]; or
  (d) a quantity of uranium hexafluoride requiring placarding under § 172.505(b) [see § 172.800(b)(14)].
- The security plan must include an assessment of possible transportation security risks and appropriate measures to address the assessed risks.
- Specific measures put into place by the plan may vary commensurate with the level of threat at a particular time.
- At a minimum, a security plan must address personnel security, unauthorized access, and enroute security.
- The security plan must be
  (a) in writing;
  (b) retained for as long as it remains in effect;
  (c) available as copies or portions thereof to the employees who are responsible for implementing it, consistent with personnel security clearance or background investigation restrictions and a demonstrated need to know;
  (d) revised and updated as necessary to reflect changing circumstances; and
  (e) maintained (all copies) as of the date of the most recent revision, when it is updated or revised.
- Security plans that conform to regulations, standards, protocols, or guidelines issued by other Federal agencies, international organizations, or industry organizations may be used to satisfy the requirements in Part 172, provided such security plans address the requirements specified in Part 172, Subpart I.
- Additional security planning requirements may apply for rail transport of a highway route-controlled quantity of radioactive material[see §§ 172.820 and 173.403].

EXHIBITS

Exhibit A

RELEASE AND AUTHORIZATION
FULL DUE DILIGENCE INVESTIGATION

I authorize and grant my consent to any authorized representative of IEMA to conduct a background investigation to obtain any information related to my activities from individuals, schools, residential management agents, previous employers, criminal justice agencies, or other sources of information. This information may include, but is not limited to, my academic, residential, achievement, or performance information and information about my attendance, disciplinary, employment, and criminal history records. I understand that the purpose of the background investigation is so IEMA has a basis of confidence to approve me as an agent authorized to speak and act on behalf, or to be an authorized user on a radioactive material license.

I understand that, for previous employers and other sources of information, separate specific releases may be needed and that I may be contacted for such releases at a later date. I authorize custodians of records and other sources of information pertaining to me to release such information upon request of the investigator or other duly authorized representative of IEMA regardless of any previous agreement to the contrary.

I understand that photocopies of this authorization and consent document with my signature are valid and that this authorization will remain in effect as long as I am authorized to speak and/or act on behalf of the radioactive material licensee.

Applications for a radioactive materials license and other documents submitted to the Agency pursuant to 32 Ill. Adm. Code 330 are subject to disclosure under the Illinois Freedom of Information Act. However, the Agency takes the protection of personal information seriously and will only release such information in accordance with Illinois law or only as needed for official State of Illinois business. Any information obtained by the Agency during the background investigation will either be redacted or destroyed to prevent unauthorized use.

_____ _____
Applicant Full Legal Name (Printed) Other Names Used (Printed)

_____
Street and Physical Address

_____
City, State and Zip Code

_____ _____
Contact Email Contact Phone

_____ _____
Social Security Number Date of Birth

I certify that all information provided on this questionnaire is correct. I understand that any misstatement, misrepresentation, or omission may be cause for disapproval by the Illinois Emergency Management Agency – Division of Nuclear Safety.

_____ _____
Applicant Signature Date

EXHIBIT B

INSTRUMENTATION FORM

NOTE: A licensee reserves the right to upgrade survey instruments as necessary, as long as they are adequate to measure the type and level of radiation for which they are used.

1. **LOW-RANGE RADIATION DETECTION SURVEY INSTRUMENTS**
(Typically, 1 μSv/hr to 500 μSv/hr [0.1 mrem/hr to 50 mrem/hr])

See Section III. Item 8A - The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low-energy or low-activity seeds [e.g., iodine-125, palladium-103], (e.g., NaI instruments).

Manufacturer: _____

Model: _____

Available: _____

Range:_____ Units: _____

Detector Type (G-M, Ion, etc.): _____

Window Thickness (mg/cm^2), if applicable: _____

2. **HIGH-RANGE RADIATION DETECTION SURVEY INSTRUMENTS**
(Typically, 10 μSv/hr to 10 mSv/hr [1.0 mrem/hr - 1000 mrem/hr])

See Section III. Item 8A - Applicants requesting authorization to use radioactive material for radiopharmaceutical therapy, brachytherapy, low and high dose rate afterloader therapy, gamma stereotactic radiosurgery or imaging and localization studies originating from an in-house generator program will require an instrument capable of measuring higher exposure rates to meet the regulatory requirements in the applicable Subparts.

Manufacturer: _____

Model: _____

Available: _____

Range:_____ Units: _____

Detector Type (G-M, Ion, etc.): _____

Window Thickness (mg/cm^2), if applicable: _____

3. **INSTRUMENT USED TO DETECT REMOVABLE CONTAMINATION**
(Typically, units of counts per minute (cpm) or disintegrations per minute (dpm))

See Section III. Item 8A - Licensees that wish to be able to release a restricted area for unrestricted use may require further detection sensitivity to adequately demonstrate compliance with Appendix A to 32 Ill. Adm. Code Part 340.

Manufacturer: _____

Model: _____

Available: _____

Range(s):_____ Units: _____

Minimum Detectable Activity[1]: _____
[1] If applicable, specify the action levels utilized to declare an area of use as an 'unrestricted area'

4. **FIXED AREA MONITOR**
(See 32 Ill. Adm. Code 340.610 and 32 Ill. Adm. Code 335.8060)

Manufacturer: _____

Model: _____

Available: _____

Range:_____ Units: _____

5. **LIQUID SCINTILLATION COUNTER**

Manufacturer: _____

Model: _____

Minimum Detectable Activity[2]: _____
[2] If used to analyze wipes, submit MDA calculations as described in Appendix D.

6. **WELL COUNTER**

Manufacturer: _____

Model: _____

Minimum Detectable Activity[2]: _____
[2] If used to analyze wipes, submit MDA calculations as described in Appendix D.

7. **INSTRUMENT USED FOR ANALYSIS OF LEAK TESTS**
(Submit MDA calculations as described in Appendix D.)

Generic Description: _____

Manufacturer: _____

Model: _____

Minimum Detectable Activity: _____

8. **THYROID BIOASSAY PROBE**
(Submit MDA calculations as described in Appendix D. See discussion in Appendix O.)

Manufacturer: _____

Model: _____

Range/Minimum Detectable Activity *(i.e., 1.48 kBq (0.04 μCi) of I-131)*: _____

9. **OTHER INSTRUMENTS**
(Continue on separate sheet if necessary.)

See Section III. Item 8C – For example, measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, identify specialized measurement equipment and the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer's instructions to calibrate the instrument.

Generic Description: _____

Manufacturer: _____

Model: _____

Range: _____

Nationally Recognized Standard or Manufacturer's Instructions for Calibration (attached) ____

10. **DOSIMETRY EQUIPMENT**
(As detailed in 32 Ill. Adm. Code 335.8080)

Manufacturer: _____

Model: _____

EXHIBIT C

State of Illinois
Illinois Emergency Management Agency

Division of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704

IEMA is requesting disclosure of information that is necessary to accomplish the statutory purpose as outlined under 420 ILCS 40/1-40/44. Disclosure of this information is required. Failure to provide any information will result in delay of termination of license.

CERTIFICATE
TERMINATION AND DISPOSITION OF RADIOACTIVE MATERIAL

LICENSEE:	**LICENSE NUMBER:**
ADDRESS:	
	TELEPHONE NUMBER:

The following information is provided in accordance with 32 Ill. Adm. Code 330.325, "Termination Requirements for Specific Licenses and Locations of Use."
This regulation appears on the back of this form. Check all that apply below.

☐ 1. All use of radioactive material authorized under the above referenced license has been terminated.

☐ 2. Radioactive contamination has been removed to the level outlined in 32 Ill. Adm. Code 340.Appendix A, to the extent practicable.

☐ 3. All radioactive material previously procured and/or possessed under the authorization granted by the above referenced license has been disposed of as follows:

- ☐ Transferred to (Name and Address): _____
  _____
  _____
  _____
  who is authorized to possess such material under License Number _____
  issued by (Licensing Agency): _____
- ☐ Decayed, surveyed and disposed of as non-radioactive waste.
- ☐ Licensed under License Number: _____
  issued by (Licensing Agency): _____
- ☐ No radioactive material has ever been procured and/or possessed by the licensee under the authorization granted by the above referenced license.
- ☐ Other (Attach additional pages).

☐ 4. Attached are radiation surveys or the equivalent as specified in 32 Ill. Adm. Code 330.325(b)(1)(F).

☐ 5. Records required to be maintained for the license requested to be terminated are available at the following location:

Name: _____
Address: _____
_____
_____
Telephone No.: _____ Contact Person: _____

☐ 6. Additional remarks. (Attach additional pages.)

THE UNDERSIGNED, ON BEHALF OF THE LICENSEE, HEREBY CERTIFIES THAT LICENSABLE QUANTITIES OF RADIOACTIVE MATERIAL UNDER THE JURISDICTION OF THE ILLINOIS EMERGENCY MANAGEMENT AGENCY ARE NOT POSSESSED BY THE LICENSEE. IT IS THEREFORE REQUESTED THAT THE ABOVE REFERENCED LICENSE BE TERMINATED.

SIGNATURE: _____ DATE: _____

NAME: _____ TITLE: _____
(print or type)

Section 330.325 Termination Requirements for Specific Licenses and Locations of Use

a) To lawfully obtain termination of a specific license or a location of use, each licensee shall meet the requirements of this Section no later than the end of the expiration date on the specific license or on any applicable amendment to the specific license unless the licensee has filed an application for renewal in accordance with Section 330.320(a) of this Part prior to the expiration date.

AGENCY NOTE: If the licensee has filed a renewal application in accordance with Section 330.320(a) of this Part and the Agency subsequently denies the application, the Agency shall, in an order issued to the licensee in accordance with the Act, the Illinois Administrative Procedure Act [5 ILCS 100] and 32 Ill. Adm. Code 200, specify the time by which the licensee must meet the requirements of this Section.

b) Requirements for Obtaining Termination of a Specific License, Removal of a Site or Location of Use from a Specific License

1) The licensee shall:

A) Cease use of radioactive material;

B) Remove radioactive contamination to levels considered acceptable for unrestricted use. A site will be considered acceptable for unrestricted use when:

i) Radioactive contamination is removed to levels outlined in 32 Ill. Adm. Code 340.Appendix A; or

ii) The residual radioactivity, excluding radon, thoron and their progeny, that is distinguishable from background radiation does not result in a total effective dose equivalent (TDE) to an average member of the critical group that exceeds 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels that are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal;

C) Properly transfer and/or dispose of radioactive material;

D) Submit a completed Agency Form KLM.007 (Certificate Termination and Disposition of Radioactive Material) or provide equivalent information;

E) For licensees authorized to possess sealed sources, submit evidence of transfer and/or disposal of all sealed sources authorized on the license and a copy of the most recent leak test; and

F) For licensees authorized to possess radioactive material in forms other than sealed sources, submit a radiation survey report to confirm the absence of radioactive materials or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The radiation survey report shall specify the date of the survey and the instrumentation used and shall certify that each instrument was properly calibrated and tested. The licensee shall, as applicable, report levels or quantities of:

i) Beta and gamma radiation at 1 centimeter from surfaces in units, multiples, or subunits of Sieverts or rem per hour;

ii) Gamma radiation at 1 meter from surfaces in units, multiples, or subunits of Sieverts or rem per hour;

iii) Removable radioactivity on surfaces in units, multiples, or subunits of Becquerels or Curies per 100 square centimeters of surface area, or in disintegrations (transformations) per minute per 100 square centimeters of surface area;

iv) Fixed radioactivity on surfaces in units, multiples, or subunits of Becquerels or Curies per 100 square centimeters of surface areas or in disintegrations (transformations) per minute per 100 square centimeters of surface area;

v) Radioactivity in contaminated liquids, such as water, oils or solvents, in units, multiples, or subunits of Becquerels or Curies per milliliter of volume; and

vi) Radioactivity in contaminated solids, such as soils or concrete, in units, multiples, or subunits of Becquerels or Curies per gram of solid.

2) If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found.

3) If detectable levels or residual radioactive contamination attributable to activities conducted under the license are found, the licensee shall:

A) In addition to the information submitted under subsections (b)(1)(D) and (b)(1)(F) of this Section, submit for Agency approval a plan for reclaiming the facility, including decontamination and removal of residual radioactive contamination;

B) Limit actions involving radioactive material to those approved under the decontamination plan in subsection (b)(3)(A) of this Section;

C) Continue to control entry to restricted areas until they are suitable for release for unrestricted use; and

D) Implement and complete the plan approved under subsection (b)(3)(A) of this Section.

c) When a licensee ends activities authorized under a specific license and has met the termination requirements of subsection (b) of this Section, the licensee shall immediately notify the Agency in writing and request that the license be terminated. This notification and request for termination shall include the documents required by subsection (b) of this Section and shall otherwise substantiate that the licensee has met all of the requirements in subsection (b) of this Section.

d) After receiving a request for license termination pursuant to subsection (c) of this Section, the Agency shall confirm, through such inspections and record reviews as may be necessary, that the licensee has met the requirements of subsection (b) of this Section. Upon confirmation, the Agency shall issue an amendment to terminate the licensee. Until issued the termination amendment, the licensee shall maintain a valid specific license in accordance with Section 330.320 of this Part.

e) A licensee who fails to comply with the pertinent requirements of this Section shall be subject to such civil penalties and sanctions as may be appropriate in accordance with the Act and 32 Ill. Adm. Code 310. The passing of the expiration date shall not relieve the licensee of the duties and responsibilities of applying for and maintaining a valid specific license in accordance with Section 330.320 of this Part, decommissioning, reclaiming, and meeting the license termination requirements of this Section. Immediately upon the passing of the expiration date, a licensee that fails to comply with subsection (a) of this Section shall comply with the requirements of Section 330.320(c) of this Part.

(Source: Added at 30 Ill. Reg. 8928, effective April 28, 2006)