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.

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:	

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.

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.

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.

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"

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).

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

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.

- 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

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

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.

- 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.

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

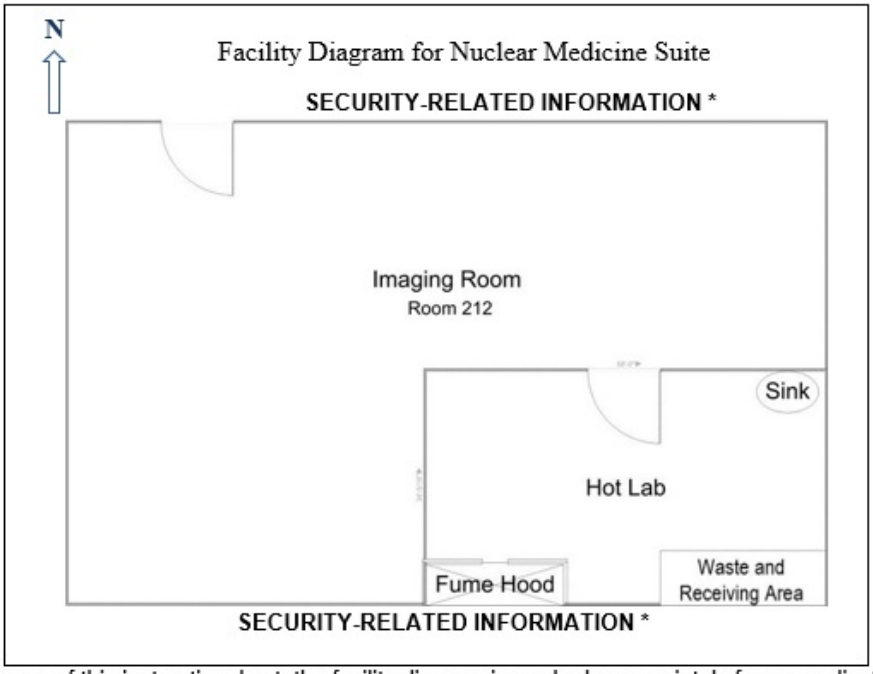
For all administrations requiring a written directive, commit to the establishment of procedures that meet all applicable requirements in 32 Ill. Adm. Code 335.1120. Appendix S of this instructional set provides guidance on developing these procedures.

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

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.

- 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.

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