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:	

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.

- 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

Table B-1. Uptake Fractions and Effective Half-Lives for I-131 Treatments

MEDICAL CONDITION	EXTRATHYROIDAL COMPONENT		THYROIDAL COMPONENT	
	Uptake Fraction F1	Effective Half-Life T_{1eff} (day)	Uptake Fraction F2	Effective Half-Life T_{2eff} (day)
Hyperthyroidism	0.20[a]	0.32[b]	0.80[a]	5.2[a]
Postthyroidectomy for Thyroid Cancer	0.95[c]	0.32[b]	0.05[c]	7.3[b]

a. See M.G. Stabin, C.S. Marcus, E.E. Watson, and R.D. Salk, "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine,* 32(5):808–813, issued June 1991. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this cited document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight line fit that accounts for about 75 percent of the data points shown in Figure 1 of this cited document (Ref. B-2).

b. See International Commission on Radiological Protection (ICRP) No. 53, "Radiation Dose to Patients from Radiopharmaceuticals," issued March 1987. The data in this ICRP document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. If other data are lacking, apply this value to hyperthyroid and thyroid cancer patients. For thyroid cancer, ICPR No. 53 suggests that the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid) (Ref. B-3).

c. Dr. M. Pollycove, M.D., a U.S. Nuclear Regulatory Commission (NRC) medical visiting fellow, recommended the thyroidal uptake fraction of 0.05 as an upper limit postthyroidectomy for thyroid cancer.

Substituting the appropriate values into Equation B-5, the dose to total decay is as follows:

$$D(\infty) = \frac{34.6\ (2.2)(200)}{(100\ \text{cm})^2}\left\{(0.75)(8.04)(0.8)\left(1 - e^{-\frac{0.693(0.33)}{8.04}}\right) + e^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.95)(0.32) + e^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.05)(7.3)\right\}$$

$$D(\infty) = 4.53\ \text{mSv}\ (0.453\ \text{rem})$$

Therefore, thyroid cancer patients administered 7,400 MBq (200 mCi) of I-131 or less would not have to remain under licensee control and could be released under 10 CFR 35.75, assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the dose to another individual is not likely to be greater than 5 mSv (0.5 rem).

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3, Hyperthyroidism: Calculate the maximum likely dose to an individual exposed to a patient who has been administered 2,035 MBq (55 mCi) of I-131 for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, calculate the dose using Equation B-5, Table A-1, and Table B-1 to account for the elimination of I-131 from the body by using the effective half-lives appropriate for hyperthyroidism. Use an occupancy factor, E, of 0.25 at 1 meter for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor (see Section B.1.2 of this appendix).

- 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.

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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

radioactive material, the treating authorized user and the radiation safety office (RSO), should be notified immediately. The RSO, or authorized user should perform an assessment of the type and amount of retained activity, based on the patient records.

If the death occurs in a hospital, access to the room occupied by the deceased should be controlled until the room has been surveyed and decontaminated if necessary. A specified form of patient identifier (e.g., bracelet, body tag) should be attached with relevant information to the radioactive body. A body bag may need to be used to contain the leakage of radioactive material. To minimize external radiation, the body may need to be retained in a secured area. Radiation safety procedures to be applied in practice for handling the body should be determined in close consultation with the RSO and an authorized user at the facility where the therapy was administered. If a patient is subsequently admitted to a different hospital or facility after release and then passes away, the local RSO should be involved.

Unsealed radioactive material may be present in a particular body cavity or organ, or it may have concentrated after systemic administration (e.g., I-131 in the thyroid gland). Drainage of the cavity or excision of the organ will reduce exposure if undertaken at the start of the autopsy. In addition, care should be given with respect to organs with significant activity. If the patient had received a dose of beta-emitting colloid or spheres (e.g., P-32 chromic phosphate into a body cavity, Y-90 microspheres into the liver), significant activity may be present in the cavity fluid or in the organ. Beta radiation sources may provide a significant dose to the hands because they will be in close contact with body tissues and fluids (Ref. 10).

Autopsy and pathology staff should wear standard protective clothing (i.e., gloves, laboratory coats, and eye protection), and personnel monitoring should be considered, if significant activity of photon emitting radionuclides are involved. For beta emitters, double surgical gloves may help reduce skin exposures. Wearing a face shield or eye protection and a face mask can prevent an intake of airborne material inadvertently released during the cutting or movement of radioactive tissue or organs.

When an RSO has been notified that a patient has died shortly after administration of a therapeutic quantity of radioactive material, the RSO should notify the morgue or funeral home that the body contains residual quantities of radioactive material and provide precautions to minimize radiation exposures and radioactive contamination for embalming and burial or cremation. These include the use of gloves and protective clothing and proper cleaning of equipment.

If the body is to be cremated, the RSO should provide precautions on handling the body to crematorium employees who may receive external exposure from the radioactive body or from contamination of the crematorium or internal exposure from inhalation of radioactive particles while handling the ashes. A proportion of the activity retained will appear in cremated remains and may be a concern, particularly in the case of long-lived radionuclides, that will require specified controls. The main concern is in regard to the scattering of ashes, although contact dose rates with the container may have to be considered if cremation takes place shortly after administration of the treatment. Cremation may not be allowed based on local regulations and the RSO should consult with local authorities prior to making cremation arrangements.

Cremation of nonvolatile radionuclides might result in contamination of the furnace. Because workers could potentially inhale contaminated ash particles while cleaning the furnace, workers should wear dust masks and protective garments while cleaning the furnace. The most likely hazard to the general population near the crematorium is the inhalation of radioactive material emitted with the stack gases.

The RSO should be consulted to determine the amount of activity remaining in the deceased patient and a determination should be made if there are any state or municipal restrictions on cremation.

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).

An occupancy factor of 0.25 at 1 meter is not considered appropriate when the physical half-life is less than or equal to 1 day, and therefore, the dose is delivered over a short time. Specifically, the assumptions about patient behavior that led to an occupancy factor of 0.25 at 1 meter include the assumption that the patient will not be in close proximity to other individuals for several days. However, when the dose is from a short-lived radionuclide, the time that individuals spend in close proximity to the patient immediately following his or her release will be most significant because the dose to other individuals could be a large fraction of the total dose from the short-lived radionuclide. Therefore, to be conservative when providing generally applicable release quantities that may be used with little consideration of the specific details of a particular patient's release, the values calculated in Table 1 of this regulatory guide were based on an occupancy factor of 1 at 1 meter when the half-life is less than or equal to 1 day.

B-1.2 Occupancy Factors To Consider for Patient-Specific Calculations

The selection of an occupancy factor for patient-specific calculations will depend on whether the physical or effective half-life of the radionuclide is used and whether instructions are given to the patient before his or her release. Patient-specific calculations may use the following occupancy factors, E, at 1 meter:

a. E = 0.75 when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder-holding time) is less than or equal to 1 day.

b. E = 0.25 when an effective half-life is greater than 1 day if the patient has been given the following instructions:

   (1) Maintain a prudent distance from others for at least the first 2 days.
   (2) Sleep alone in a room for at least the first night.
   (3) Do not travel by airplane or public transportation for at least the first day.
   (4) Do not travel on a prolonged automobile trip with others for at least the first 2 days.
   (5) Have sole use of a bathroom for at least the first 2 days.
   (6) Drink plenty of fluids for at least the first 2 days.

c. E = 0.125 when an effective half-life is greater than 1 day if the patient has been given the following instructions:

   (1) Follow the instructions for E = 0.25 above.
   (2) Live alone for at least the first 2 days.
   (3) Have few visits by family or friends for at least the first 2 days.

d. In a two-component model (e.g., uptake of iodine (I)-131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to 1 day but is greater than 1 day for the other component, it is more justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1: Calculate the maximum likely dose to an individual exposed to a patient who has received 2,220 megabecquerels (MBq) (60 millicuries (mCi)) of I-131. The patient has been given instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

Table B-1. Uptake Fractions and Effective Half-Lives for I-131 Treatments

MEDICAL CONDITION	EXTRATHYROIDAL COMPONENT		THYROIDAL COMPONENT	
	Uptake Fraction F1	Effective Half-Life T_{1eff} (day)	Uptake Fraction F2	Effective Half-Life T_{2eff} (day)
Hyperthyroidism	0.20[a]	0.32[b]	0.80[a]	5.2[a]
Postthyroidectomy for Thyroid Cancer	0.95[c]	0.32[b]	0.05[c]	7.3[b]

a. See M.G. Stabin, C.S. Marcus, E.E. Watson, and R.D. Salk, "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine,* 32(5):808–813, issued June 1991. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this cited document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight line fit that accounts for about 75 percent of the data points shown in Figure 1 of this cited document (Ref. B-2).

b. See International Commission on Radiological Protection (ICRP) No. 53, "Radiation Dose to Patients from Radiopharmaceuticals," issued March 1987. The data in this ICRP document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. If other data are lacking, apply this value to hyperthyroid and thyroid cancer patients. For thyroid cancer, ICPR No. 53 suggests that the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid) (Ref. B-3).

c. Dr. M. Pollycove, M.D., a U.S. Nuclear Regulatory Commission (NRC) medical visiting fellow, recommended the thyroidal uptake fraction of 0.05 as an upper limit postthyroidectomy for thyroid cancer.

Substituting the appropriate values into Equation B-5, the dose to total decay is as follows:

$$D(\infty) = \frac{34.6\ (2.2)(200)}{(100\ \text{cm})^2}\left\{(0.75)(8.04)(0.8)\left(1 - e^{-\frac{0.693(0.33)}{8.04}}\right) + e^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.95)(0.32) + e^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.05)(7.3)\right\}$$

$$D(\infty) = 4.53\ \text{mSv}\ (0.453\ \text{rem})$$

Therefore, thyroid cancer patients administered 7,400 MBq (200 mCi) of I-131 or less would not have to remain under licensee control and could be released under 10 CFR 35.75, assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the dose to another individual is not likely to be greater than 5 mSv (0.5 rem).

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3, Hyperthyroidism: Calculate the maximum likely dose to an individual exposed to a patient who has been administered 2,035 MBq (55 mCi) of I-131 for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, calculate the dose using Equation B-5, Table A-1, and Table B-1 to account for the elimination of I-131 from the body by using the effective half-lives appropriate for hyperthyroidism. Use an occupancy factor, E, of 0.25 at 1 meter for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor (see Section B.1.2 of this appendix).

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

instructions under 10 CFR 35.75(b), the licensee should consider the patient's destination upon his or her release and the ability of the patient or caregiver to understand and follow the release instructions. The licensee should thoroughly ascertain the patient's posttreatment destination and the method by which he or she plans to travel to that destination to best estimate the likely cumulative radiation exposures to other members of the public (e.g., family and other caregivers) and, therefore, to direct appropriate protective measures to keep doses ALARA and ensure that the dose limit will likely be met.

I-131 is currently the medical radioisotope of highest concern, as it is the most commonly used radionuclide in radiopharmaceutical therapy and has the potential for a higher external exposure to members of the public because of its high-energy gamma emission and potential volatility (Ref. 8). However, the regulations in 10 CFR 35.75 apply to other medical radioisotope therapies such as yttrium (Y)-90, I-125, lutetium (Lu)-177, and radium (Ra)-223. Instructions should be specific to the type of treatment given and should include additional information for individual situations. Note that instructions should not interfere with or contradict the best medical judgment of the treating physician. The instructions should include a telephone number for the patient to contact with any questions.

2.3.1 Pretreatment Discussions on the Administration of Radiopharmaceuticals

Engaging the patient, and caregiver or family member, early in the treatment process (i.e., during treatment planning) may help the licensee better familiarize the patient and caregiver or family member with the treatment procedures, posttreatment radiation safety precautions, and protective measures to minimize radiation exposure to other individuals. This discussion should also include medical issues such as complications, side effects, and dietary and medication changes, as appropriate. Additionally, early engagement with the patient allows the patient to ask the licensee questions that will help him or her comply with the release instructions. It also helps the licensee to determine whether the patient will be able to follow the release instructions.

As soon as radiopharmaceutical or implant therapy is considered as a treatment option, the licensee should interview the patient or caregiver, or both, to fully assess the patient's specific circumstances. The licensee and patient or caregiver should discuss and consider the following topics during the pretreatment discussion:

a. What type of posttreatment lodging (e.g., single family home, group home, apartment, nursing home, hotel, detention facility) will the patient use?

b. What are the patient's plans for travel to his or her posttreatment recovery location?

    (1) Will the patient use a private vehicle, taxi service, ride-booking service, or public transportation (i.e., bus, train, or airplane)? The use of public transportation should be discouraged.

    (2) If the patient is traveling with other individuals, what is the duration of the trip? Based on the duration of the trip, can the patient keep an adequate distance from others? Emphasis should be made to minimize the number of traveling companions.

    (3) Will the patient be traveling internationally post treatment? Patients who travel via motor vehicles through international border checkpoints or on airplanes are subject to screening for radiation. Patients should be advised of this fact and provided appropriate documentation (procedure, isotope, date/time of release, treating facility and physician, contact information, etc.) to present to officials when alarms are triggered.

- 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

licensee should give the patient instructions on the discontinuation or interruption period for breastfeeding and the potential consequences of failing to follow the recommendation. The patient should also be informed if breastfeeding would not likely result in consequences for the infant or child. Table 3 also provides the recommended duration (Column 3) of interrupting or discontinuing breastfeeding to minimize the dose to below 1 mSv (0.1 rem) if the patient has received certain radiopharmaceutical doses (Column 1). Table 3 lists the radiopharmaceuticals that are commonly used in medical diagnosis and treatment.

If the licensee administers a radiopharmaceutical that is not listed in Table 3 to a patient who could be breastfeeding, it should evaluate whether instructions or records (or both) are required. The licensee can calculate the dose to the infant or child by using the dose conversion factors given for a newborn infant by M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine" (Ref. 6) and maintain a record of the calculation.

If additional instructions are required because the patient is breastfeeding, the instructions should include appropriate recommendations on whether to interrupt breastfeeding; the length of time to interrupt breastfeeding; or, if necessary, the discontinuation of breastfeeding. The instructions should inform the patient of the consequences of failure to follow the recommendation to interrupt or discontinue breastfeeding. The licensee should explain the consequences in a manner that will help the patient understand that, in some cases, breastfeeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving iodine (I)-131 is that continued breastfeeding could harm the infant's or child's thyroid.

Table 3. Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Could Breastfeed an Infant or Child After Release

	COLUMN 1 ACTIVITY ABOVE WHICH INSTRUCTIONS ARE REQUIRED		COLUMN 2 ACTIVITY ABOVE WHICH A RECORD IS REQUIRED		COLUMN 3 EXAMPLES OF RECOMMENDED DURATION OF INTERRUPTION OF BREASTFEEDING[a]
RADIOPHARMACEUTICAL	(MBq)	(mCi)	(MBq)	(mCi)	
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this infant or child)
I-123 NaI	20	0.5	100	3	3 days[b]
I-123 OIH	100	4	700	20	
I-123 MIBG	70	2	400	10	24 hours for 370 MBq (10 mCi)
I-125 OIH	3	0.08	15	0.4	
I-131 OIH	10	0.30	60	1.5	
Tc-99m DTPA	1,000	30	6,000	150	24 hours[b]
Tc-99m MAA	50	1.3	200	6	24 hours[b]
Tc-99m Pertechnetate	100	3	600	15	24 hours[b]
Tc-99m DISIDA	1,000	30	6,000	150	24 hours[b]
Tc-99m Glucoheptonate	1,000	30	6,000	150	24 hours[b]
Tc-99m HAM	400	10	2,000	50	24 hours[b]
Tc-99m MIBI	1,000	30	6,000	150	24 hours[b]
Tc-99m MDP	1,000	30	6,000	150	24 hours[b]
Tc-99m PYP	900	25	4,000	120	24 hours[b]
Tc-99m Red Blood Cell In Vivo Labeling	400	10	2,000	50	24 hours[b]

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

Table B-1. Uptake Fractions and Effective Half-Lives for I-131 Treatments

MEDICAL CONDITION	EXTRATHYROIDAL COMPONENT		THYROIDAL COMPONENT	
	Uptake Fraction F1	Effective Half-Life T_{1eff} (day)	Uptake Fraction F2	Effective Half-Life T_{2eff} (day)
Hyperthyroidism	0.20[a]	0.32[b]	0.80[a]	5.2[a]
Postthyroidectomy for Thyroid Cancer	0.95[c]	0.32[b]	0.05[c]	7.3[b]

a. See M.G. Stabin, C.S. Marcus, E.E. Watson, and R.D. Salk, "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine,* 32(5):808–813, issued June 1991. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this cited document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight line fit that accounts for about 75 percent of the data points shown in Figure 1 of this cited document (Ref. B-2).

b. See International Commission on Radiological Protection (ICRP) No. 53, "Radiation Dose to Patients from Radiopharmaceuticals," issued March 1987. The data in this ICRP document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. If other data are lacking, apply this value to hyperthyroid and thyroid cancer patients. For thyroid cancer, ICPR No. 53 suggests that the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid) (Ref. B-3).

c. Dr. M. Pollycove, M.D., a U.S. Nuclear Regulatory Commission (NRC) medical visiting fellow, recommended the thyroidal uptake fraction of 0.05 as an upper limit postthyroidectomy for thyroid cancer.

Substituting the appropriate values into Equation B-5, the dose to total decay is as follows:

$$D(\infty) = \frac{34.6\ (2.2)(200)}{(100\ \text{cm})^2}\left\{(0.75)(8.04)(0.8)\left(1 - e^{-\frac{0.693(0.33)}{8.04}}\right) + e^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.95)(0.32) + e^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.05)(7.3)\right\}$$

$$D(\infty) = 4.53\ \text{mSv}\ (0.453\ \text{rem})$$

Therefore, thyroid cancer patients administered 7,400 MBq (200 mCi) of I-131 or less would not have to remain under licensee control and could be released under 10 CFR 35.75, assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the dose to another individual is not likely to be greater than 5 mSv (0.5 rem).

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3, Hyperthyroidism: Calculate the maximum likely dose to an individual exposed to a patient who has been administered 2,035 MBq (55 mCi) of I-131 for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, calculate the dose using Equation B-5, Table A-1, and Table B-1 to account for the elimination of I-131 from the body by using the effective half-lives appropriate for hyperthyroidism. Use an occupancy factor, E, of 0.25 at 1 meter for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor (see Section B.1.2 of this appendix).

An occupancy factor of 0.25 at 1 meter is not considered appropriate when the physical half-life is less than or equal to 1 day, and therefore, the dose is delivered over a short time. Specifically, the assumptions about patient behavior that led to an occupancy factor of 0.25 at 1 meter include the assumption that the patient will not be in close proximity to other individuals for several days. However, when the dose is from a short-lived radionuclide, the time that individuals spend in close proximity to the patient immediately following his or her release will be most significant because the dose to other individuals could be a large fraction of the total dose from the short-lived radionuclide. Therefore, to be conservative when providing generally applicable release quantities that may be used with little consideration of the specific details of a particular patient's release, the values calculated in Table 1 of this regulatory guide were based on an occupancy factor of 1 at 1 meter when the half-life is less than or equal to 1 day.

B-1.2 Occupancy Factors To Consider for Patient-Specific Calculations

The selection of an occupancy factor for patient-specific calculations will depend on whether the physical or effective half-life of the radionuclide is used and whether instructions are given to the patient before his or her release. Patient-specific calculations may use the following occupancy factors, E, at 1 meter:

a. E = 0.75 when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder-holding time) is less than or equal to 1 day.

b. E = 0.25 when an effective half-life is greater than 1 day if the patient has been given the following instructions:

   (1) Maintain a prudent distance from others for at least the first 2 days.
   (2) Sleep alone in a room for at least the first night.
   (3) Do not travel by airplane or public transportation for at least the first day.
   (4) Do not travel on a prolonged automobile trip with others for at least the first 2 days.
   (5) Have sole use of a bathroom for at least the first 2 days.
   (6) Drink plenty of fluids for at least the first 2 days.

c. E = 0.125 when an effective half-life is greater than 1 day if the patient has been given the following instructions:

   (1) Follow the instructions for E = 0.25 above.
   (2) Live alone for at least the first 2 days.
   (3) Have few visits by family or friends for at least the first 2 days.

d. In a two-component model (e.g., uptake of iodine (I)-131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to 1 day but is greater than 1 day for the other component, it is more justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1: Calculate the maximum likely dose to an individual exposed to a patient who has received 2,220 megabecquerels (MBq) (60 millicuries (mCi)) of I-131. The patient has been given instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

References for Appendix B[5]

B-1. U.S. Nuclear Regulatory Commission, NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," Washington, DC, February 1997.

B-2. M.G. Stabin, C.S. Marcus, E.E. Watson, and R.D. Salk, "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine,* 32(5):808–813, issued June 1991.

B-3. International Commission on Radiological Protection (ICRP) No. 53, "Radiation Dose to Patients from Radiopharmaceuticals," issued March 1987.

B-4. Eckerman, K.F., A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11: Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," U.S. Environmental Protection Agency, Washington, DC, September 1988.

B-5. Brodsky, A., "Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10^{-6} a Magic Number in Health Physics?')," *Health Physics,* 39(6):992–1000, January 1981.

B-6. Buchanan, R.C.T., and J.M. Brindle, "Radioiodine Therapy to Out-patients—The Contamination Hazard," *British Journal of Radiology,* 44(523):557, August 1971.

B-7. Jacobson, A.P., P.A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," *American Journal of Public Health,* 68(3):225–230, March 1978.

B-8. National Council on Radiation Protection and Measurements Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," Bethesda, MD, February 28, 1995.

[5] Publicly available NRC published documents are available electronically through the NRC Library on the NRC's public Web site at http://www.nrc.gov/reading-rm/doc-collections/ and through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html. The documents can also be viewed online or printed for a fee in the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD. For problems with ADAMS, contact the PDR staff at (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; or e-mail pdr.resource@nrc.gov.