procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients administered radioactive material.

3.2 Records of Instructions for Breastfeeding Patients

If a patient's failure to interrupt or discontinue breastfeeding could result in a dose to the infant or child in excess of 5 mSv (0.5 rem), 10 CFR 35.2075(b) requires a record that the licensee gave the patient instructions. For the radiopharmaceuticals commonly used in medical diagnosis and treatment, Column 2 of Table 3 lists the activities that require such records when administered to patients who are breastfeeding.

The record should include the patient's identifier, the radiopharmaceutical administered, the administered dosage, the date of the administration, and whether instructions were provided to the patient who could be breastfeeding an infant or child. The patient's identifier should be prepared in a way that would ensure that confidential information is not traceable or attributable to a specific patient.

4. Summary Table

Table 4 summarizes the criteria for releasing patients and the requirements for providing instructions and maintaining records.

Table 4. Summary of Release Criteria, Required Instructions to Patients, and Records To Be Maintained

PATIENT GROUP	BASIS FOR RELEASE	CRITERIA FOR RELEASE	INSTRUCTIONS NEEDED?	RELEASE RECORDS REQUIRED?
All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity ≤ Column 1 of Table 1	Yes, if administered activity > Column 1 of Table 2	No
	Retained activity	Retained activity ≤ Column 1 of Table 1	Yes, if retained activity > Column 1 of Table 2	Yes
	Measured dose rate	Measured dose rate ≤ Column 2 of Table 1	Yes, if dose rate > Column 2 of Table 2	Yes
	Patient-specific calculations	Calculated dose ≤ 5 mSv (0.5 rem)	Yes, if calculated dose > 1 mSv (0.1 rem)	Yes
Patients who are breast-feeding an infant or child	All the above bases for release	All of the above bases for release	Additional instructions required if administered dosage > Column 1 of Table 3 or licensee-calculated dose from breastfeeding > 1 mSv (0.1 rem) to the infant or child	Records that instructions were provided if administered dosage > Column 2 of Table 3 or licensee-calculated dose from continued breastfeeding > 5 mSv (0.5 rem) to the infant or child

NOTES FOR TABLE 1: The millicurie (mCi) values in Table 1 were calculated using Equation 2 or 3 and the physical half-life. The gigabecquerel (GBq) values were calculated based on the mCi values and the conversion factor from mCi to GBq. The dose rate values were calculated based on the mCi values and the exposure rate constants. In general, the values were rounded to two significant figures. However, values less than 0.37 GBq (10 mCi) or 0.1 mSv (10 millirem (mrem)) per hour were rounded to one significant figure. NUREG-1492 describes the calculations in detail. Agreement State regulations may vary. Agreement State licensees should check their State regulations before using these values.

If a licensee administers a radionuclide that is not listed in Table 1 and if it chooses to release a patient based on the measured dose rate, it should first calculate a dose rate that corresponds to the 5-mSv (0.5-rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. The regulations at 10 CFR 35.75(c) and 35.2075(a) require the licensee to maintain a record of the basis for authorizing release. The dose rate at 1 meter may be calculated from Equation 2 or 3, as appropriate, because the dose rate at 1 meter is equal to ΓQ per 10,000 square centimeters.

1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, in accordance with 10 CFR 35.75(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 mSv (0.5 rem), the licensee may release the patient. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table 1 by accounting for the effective half-life of the radioactive material and other factors that may be relevant to the particular case. If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, the effective half-life, or shielding by tissue, then 10 CFR 35.2075(a) requires the licensee to maintain a record of the basis for authorizing the patient's release.

Appendix B contains procedures for performing patient-specific dose calculations and describes how various factors may be considered in the calculations.

2. Instructions

2.1 Activities and Dose Rates That Require Instructions

In accordance with 10 CFR 35.75(b), for some administrations, licensees must give instructions to the released patients, including written instructions, on how to maintain doses to other individuals ALARA after they are released. Licensees may use Column 1 of Table 2 to determine the dosage above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter based on the activities in Column 1. If the patient is breastfeeding an infant or child, additional instructions may be required (see Section 2.2).

Licensees may use the activities or dose rates in Table 2 to determine when they must give instructions to patients. When the licensee uses patient-specific calculations (as described in Appendix B), it must give the patient instructions if the calculation indicates a dose that is greater than 1 mSv (0.1 rem).

If the licensee administers a radionuclide that is not listed in Table 2, it may calculate the activity or dose rate that corresponds to 1 mSv (0.1 rem) using Equation 2 or 3 or Appendix B, as appropriate.

To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign the treatment plan, indicating approval. The treatment plan should provide sufficient information and direction to meet the objectives of the WD.

For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, ophthalmic physicist, oncology physician, dosimetrist, or radiation therapist), preferably an individual who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:

1. for computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions)

2. for computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times)

3. for manually generated dose calculations, verifying

    a. no mathematical errors

    b. appropriate transfer of data from the WD, treatment plan, tables, and graphs

    c. appropriate use of nomograms (when applicable)

    d. appropriate use of all pertinent data in the calculations

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment-planning or dose-calculating computer program that could be used for dose calculations.

APPENDIX B

PROCEDURES FOR CALCULATING DOSES BASED ON PATIENT-SPECIFIC FACTORS

A licensee may release a patient who has been administered a dosage higher than the values listed in Column 1 of Table 1 of this regulatory guide if dose calculations using patient-specific parameters, which are less conservative than the conservative assumptions, show that the total effective dose equivalent to any individual is not likely to be greater than 5 millisieverts (mSv) (0.5 rem).

If the release of a patient is based on a patient-specific calculation that considered the retained activity, an occupancy factor of less than 0.25 at 1 meter, the effective half-life, or shielding by tissue, Title 10 of the *Code of Federal Regulations* (10 CFR) 35.2075(a) requires the licensee to maintain a record of the basis for authorizing the release.

The following equation can be used to calculate doses:

$$D(t) = \frac{34.6\,\Gamma\,Q_o\,T_p\,E\,(1-e^{-0.693t/T_p})}{r^2} \qquad \text{(Equation B-1)}$$

where D(t) = Accumulated exposure at time t, in rem

34.6 = conversion factor of 24 hours per day times total integration of decay (1.44)

Γ = exposure rate constant for a point source, R/mCi × hr at 1 centimeter (cm)

Q_0 = initial activity at the start of the time interval

T_p = physical half-life in days

E = occupancy factor that accounts for different occupancy times and distances when an individual is near a patient

r = distance in centimeters (this value is typically 100 cm)

t = exposure time in days

B-1. Occupancy Factor

B-1.1 Rationale for Occupancy Factors Used to Derive Table 1 of Regulatory Guide 8.39

In Table 1 of this regulatory guide, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members and considerations of normal human behavior (as discussed in the supporting regulatory analysis (Ref. B-1)) suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

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

$$D(\infty) = \frac{34.6\ (2.2)(55)}{(100\ \text{cm})^2}\left\{\begin{array}{c}(0.75)(8.04)(0.8)\left(1 - e^{-\frac{0.693(0.33)}{8.04}}\right) \\ + e^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.20)(0.32) + e^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.80)(5.2)\end{array}\right\}$$

$$D(\infty) = 4.86\text{mSv}\ (0.486\ \text{rem})$$

Therefore, hyperthyroid patients administered 2,035 MBq (55 mCi) of I-131 would not have to remain under the control of the licensee and could be released under 10 CFR 35.75 when the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction, $F_2 = 0.8$, is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B-3. Internal Dose

For some radionuclides, such as I-131, the concern is that the internal dose of an individual from exposure to a released patient could be significant. Equation B-6 can be used to calculate a rough estimate of the maximum likely committed effective dose equivalent from internal exposure.

$$D_i = Q\ (10^{-5})\ (DCF) \qquad \text{(Equation B-6)}$$

where D_i = maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rem

Q = activity administered to the patient in millicuries

$1x10^{-5}$ = assumed fractional intake

DCF = dose conversion factor used to convert an intake in millicuries to an internal committed effective dose equivalent (such as tabulated in Ref. B-4)

Equation B-6 uses a value of $1x10^{-5}$ as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb was developed in Reference B-5 for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility; however, it does not specifically apply to cases of intake by an individual exposed to a patient. However, two studies (Refs. B-6 and B-7) of the intakes of individuals exposed to patients administered I-131 indicated that intakes were generally of the order of 1 millionth of the dosage administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of $1x10^{-5}$ has been assumed.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient who has been administered 1,110 MBq (33 mCi) of I-131. The ingestion

To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign the treatment plan, indicating approval. The treatment plan should provide sufficient information and direction to meet the objectives of the WD.

For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, ophthalmic physicist, oncology physician, dosimetrist, or radiation therapist), preferably an individual who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:

1. for computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions)

2. for computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times)

3. for manually generated dose calculations, verifying

    a. no mathematical errors

    b. appropriate transfer of data from the WD, treatment plan, tables, and graphs

    c. appropriate use of nomograms (when applicable)

    d. appropriate use of all pertinent data in the calculations

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment-planning or dose-calculating computer program that could be used for dose calculations.

NOTES FOR TABLE 1: The millicurie (mCi) values in Table 1 were calculated using Equation 2 or 3 and the physical half-life. The gigabecquerel (GBq) values were calculated based on the mCi values and the conversion factor from mCi to GBq. The dose rate values were calculated based on the mCi values and the exposure rate constants. In general, the values were rounded to two significant figures. However, values less than 0.37 GBq (10 mCi) or 0.1 mSv (10 millirem (mrem)) per hour were rounded to one significant figure. NUREG-1492 describes the calculations in detail. Agreement State regulations may vary. Agreement State licensees should check their State regulations before using these values.

If a licensee administers a radionuclide that is not listed in Table 1 and if it chooses to release a patient based on the measured dose rate, it should first calculate a dose rate that corresponds to the 5-mSv (0.5-rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. The regulations at 10 CFR 35.75(c) and 35.2075(a) require the licensee to maintain a record of the basis for authorizing release. The dose rate at 1 meter may be calculated from Equation 2 or 3, as appropriate, because the dose rate at 1 meter is equal to ΓQ per 10,000 square centimeters.

1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, in accordance with 10 CFR 35.75(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 mSv (0.5 rem), the licensee may release the patient. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table 1 by accounting for the effective half-life of the radioactive material and other factors that may be relevant to the particular case. If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, the effective half-life, or shielding by tissue, then 10 CFR 35.2075(a) requires the licensee to maintain a record of the basis for authorizing the patient's release.

Appendix B contains procedures for performing patient-specific dose calculations and describes how various factors may be considered in the calculations.

2. Instructions

2.1 Activities and Dose Rates That Require Instructions

In accordance with 10 CFR 35.75(b), for some administrations, licensees must give instructions to the released patients, including written instructions, on how to maintain doses to other individuals ALARA after they are released. Licensees may use Column 1 of Table 2 to determine the dosage above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter based on the activities in Column 1. If the patient is breastfeeding an infant or child, additional instructions may be required (see Section 2.2).

Licensees may use the activities or dose rates in Table 2 to determine when they must give instructions to patients. When the licensee uses patient-specific calculations (as described in Appendix B), it must give the patient instructions if the calculation indicates a dose that is greater than 1 mSv (0.1 rem).

If the licensee administers a radionuclide that is not listed in Table 2, it may calculate the activity or dose rate that corresponds to 1 mSv (0.1 rem) using Equation 2 or 3 or Appendix B, as appropriate.

To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign the treatment plan, indicating approval. The treatment plan should provide sufficient information and direction to meet the objectives of the WD.

For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, ophthalmic physicist, oncology physician, dosimetrist, or radiation therapist), preferably an individual who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:

1. for computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions)

2. for computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times)

3. for manually generated dose calculations, verifying

    a. no mathematical errors

    b. appropriate transfer of data from the WD, treatment plan, tables, and graphs

    c. appropriate use of nomograms (when applicable)

    d. appropriate use of all pertinent data in the calculations

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment-planning or dose-calculating computer program that could be used for dose calculations.

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

$$D(\infty) = \frac{34.6\ (2.2)(55)}{(100\ \text{cm})^2}\left\{\begin{array}{c}(0.75)(8.04)(0.8)\left(1 - e^{-\frac{0.693(0.33)}{8.04}}\right) \\ + e^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.20)(0.32) + e^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.80)(5.2)\end{array}\right\}$$

$$D(\infty) = 4.86\text{mSv}\ (0.486\ \text{rem})$$

Therefore, hyperthyroid patients administered 2,035 MBq (55 mCi) of I-131 would not have to remain under the control of the licensee and could be released under 10 CFR 35.75 when the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction, $F_2 = 0.8$, is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B-3. Internal Dose

For some radionuclides, such as I-131, the concern is that the internal dose of an individual from exposure to a released patient could be significant. Equation B-6 can be used to calculate a rough estimate of the maximum likely committed effective dose equivalent from internal exposure.

$$D_i = Q\ (10^{-5})\ (DCF) \qquad \text{(Equation B-6)}$$

where D_i = maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rem

Q = activity administered to the patient in millicuries

$1x10^{-5}$ = assumed fractional intake

DCF = dose conversion factor used to convert an intake in millicuries to an internal committed effective dose equivalent (such as tabulated in Ref. B-4)

Equation B-6 uses a value of $1x10^{-5}$ as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb was developed in Reference B-5 for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility; however, it does not specifically apply to cases of intake by an individual exposed to a patient. However, two studies (Refs. B-6 and B-7) of the intakes of individuals exposed to patients administered I-131 indicated that intakes were generally of the order of 1 millionth of the dosage administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of $1x10^{-5}$ has been assumed.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient who has been administered 1,110 MBq (33 mCi) of I-131. The ingestion

C. STAFF REGULATORY GUIDANCE

This section describes in detail the methods, approaches, or data that the NRC staff considers acceptable for meeting the requirements of the applicable regulations cited in the introduction.

1. Release Criteria

Licensees should use one of the following options to release a patient who has been administered radiopharmaceuticals or implants that contain radioactive material.

1.1 Release of Patients Based on the Administered Activity

One means that licensees may use to comply with the dose limit in 10 CFR 35.75(a) is to release patients from licensee control if the dosage administered is not greater than the activity in Column 1 of Table 1. The total effective dose equivalent is approximately equal to external dose because the portion of the internal dose that contributes to the total external dose exposure is small or negligible (see Appendix B, Section B-3). The activities in Table 1 are based on a total effective dose equivalent of 5 mSv (0.5 rem) to an individual using the following conservative assumptions:

a. administered activity;

b. physical half-life;

c. an occupancy factor of 0.25 at 1 meter for physical half-lives that are greater than 1 day and, for conservatism, an occupancy factor of 1 at 1 meter for physical half-lives that are less than or equal to 1 day; and

d. no shielding by tissue.

In this case, where the dosage administered is not greater than the activity in Column 1 of Table 1, no record of the instructions provided to the patient is required unless the patient is breastfeeding an infant or child, as discussed in Section 3.2 below.

If the activity administered exceeds the activity in Column 1 of Table 1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table 1. In this case, 10 CFR 35.75(c) and 35.2075(a)(1) require the licensee to maintain a record of the basis for authorizing the release because it is based on the retained activity instead of on the administered activity. The activities in Column 1 of Table 1 were calculated using either Equation 2 or 3 listed in section B. to this guide, depending on the physical half-life of the radionuclide.

If the licensee administers a radionuclide that is not listed in Table 1, it may demonstrate compliance with the regulation in 10 CFR 35.75, " Release of individuals containing unsealed byproduct material or implants containing byproduct material," by maintaining a record of the calculation (for NRC inspection) of the release activity that corresponds to the dose limit of 5 mSv (0.5 rem). Additional guidance can be found in Section C.3 of this guide. Equation 2 or 3 (listed above) may be used, as appropriate, to calculate the activity, Q, corresponding to 5 mSv (0.5 rem).

The release activities in Column 1 of Table 1 do not consider the dose to a breastfeeding infant or child from the ingestion of radiopharmaceuticals contained in a patient's breast milk. When the patient is breastfeeding an infant or child, the activities in Column 1 of Table 1 do not apply to the infant or child. In this case, it may be necessary to give instructions to the patient, as described in Section 2.2 below, as a

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.

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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.

This guide uses the NCRP equation (Equation 1) in the following manner to calculate the activities at which patients may be released:

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $\left(1 - e^{\frac{-0.693t}{T_p}}\right)$ is set equal to 1.

- It is assumed that 1 roentgen is equal to 10 mSv (1 rem).

- Appendix A to this guide provides the exposure rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures.

- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.

  When a patient's release is based on biological elimination (i.e., the effective half-life) instead of solely on the physical half-life of the radionuclide, Equation 1 is modified to account for the uptake and retention of the radionuclide by the patient, as discussed in Appendix B.

- For radionuclides with a physical half-life greater than 1 day and for cases in which biological elimination is not considered, the assumption is that the individual who is likely to receive the highest dose from exposure to the patient would receive a dose of 25 percent of the dose to total decay (0.25 in Equation 2) at a distance of 1 meter. The selection of 25 percent of the dose to total decay at 1 meter for estimating the dose is based on the measurements discussed in the supporting regulatory analysis in NUREG-1492 that indicate that the dose calculated using an occupancy factor, E, of 25 percent at 1 meter is conservative in most normal situations.

- For radionuclides with a physical half-life that is less than or equal to 1 day, justifying an occupancy factor of 0.25 is difficult because the relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life that is greater than 1 day, the following equation applies:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_o T_p (0.25)}{(100\ \text{cm})^2} \qquad \text{(Equation 2)}$$

For radionuclides with a physical half-life less than or equal to 1 day and if an occupancy factor of 1.0 is used:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_o T_p (1)}{(100\ \text{cm})^2} \qquad \text{(Equation 3)}$$

Equations 2 and 3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent) relative to the external gamma-ray dose (see Appendix B, Section B-3). Further, the equations above do not apply to the dose to breastfeeding infants or children who continue to breastfeed. Patients who are breastfeeding an infant or child must be considered separately, as discussed in Section 2.2 in Section C of this guide.

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

$$D(\infty) = \frac{34.6\ (2.2)(55)}{(100\ \text{cm})^2}\left\{\begin{array}{c}(0.75)(8.04)(0.8)\left(1 - e^{-\frac{0.693(0.33)}{8.04}}\right) \\ + e^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.20)(0.32) + e^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.80)(5.2)\end{array}\right\}$$

$$D(\infty) = 4.86\text{mSv}\ (0.486\ \text{rem})$$

Therefore, hyperthyroid patients administered 2,035 MBq (55 mCi) of I-131 would not have to remain under the control of the licensee and could be released under 10 CFR 35.75 when the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction, $F_2 = 0.8$, is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B-3. Internal Dose

For some radionuclides, such as I-131, the concern is that the internal dose of an individual from exposure to a released patient could be significant. Equation B-6 can be used to calculate a rough estimate of the maximum likely committed effective dose equivalent from internal exposure.

$$D_i = Q\ (10^{-5})\ (DCF) \qquad \text{(Equation B-6)}$$

where D_i = maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rem

Q = activity administered to the patient in millicuries

$1x10^{-5}$ = assumed fractional intake

DCF = dose conversion factor used to convert an intake in millicuries to an internal committed effective dose equivalent (such as tabulated in Ref. B-4)

Equation B-6 uses a value of $1x10^{-5}$ as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb was developed in Reference B-5 for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility; however, it does not specifically apply to cases of intake by an individual exposed to a patient. However, two studies (Refs. B-6 and B-7) of the intakes of individuals exposed to patients administered I-131 indicated that intakes were generally of the order of 1 millionth of the dosage administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of $1x10^{-5}$ has been assumed.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient who has been administered 1,110 MBq (33 mCi) of I-131. The ingestion

Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this guide makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80 percent of the I-131 administered is removed from the body at a rate determined only by the physical half-life of I-131.

Thus, an equation to calculate the dose from a patient administered I-131 may have three components. The first component is the dose for the first 8 hours (0.33 day) after administration. This component comes directly from Equation B-1 using the physical half-life and a factor of 80 percent. The second component is the dose from the extrathyroidal component from 8 hours to total decay. In this component, the first exponential factor represents the activity at t = 8 hours based on the physical half-life of I-131. The second exponential factor represents the activity from t = 8 hours to total decay based on the effective half-life of the extrathyroidal component. The third component, the dose from the thyroidal component for 8 hours to total decay, is calculated in the same manner as the second component. Equation B-5 shows the full equation.

$$D(\infty) = \frac{34.6\,\Gamma\,Q_o}{(100\text{ cm})^2}\left\{\begin{array}{c} E_1 T_p (0.8)\left(1 - e^{-\frac{0.693(0.33)}{T_p}}\right) + \\ e^{-0.693(0.33)/T_p} E_2 F_1 T_{1eff} + e^{-0.693(0.33)/T_p} E_2 F_2 T_{2eff} \end{array}\right\} \qquad \text{(Equation B-5)}$$

where F_1 = extrathyroidal uptake fraction
F_2 = thyroidal uptake fraction
E_1 = occupancy factor for the first 8 hours
E_2 = occupancy factor from 8 hours to total decay

Equations B-1, B-3, and B-4 define all the other parameters. Table B-1 lists acceptable values for F_1, T_{1eff}, F_2, and T_{2eff} for thyroid ablation and treatment of thyroid remnants after surgical removal of the thyroid for thyroid cancer. If these values have been measured for a specific individual, the measured values may be used.

Section 3.1 in this regulatory guide describes the record of the patient's release as required by 10 CFR 35.2075(a).

Example 2, Thyroid Cancer: Calculate the maximum likely dose to an individual exposed to a patient who has been administered 7,400 MBq (200 mCi) of I-131 for the treatment of thyroid remnants and metastases.

Solution: In this example, calculate the dose using Equation B-5 to account for the elimination of I-131 from the body based on the effective half-lives appropriate for thyroid cancer. The physical half-life and the exposure rate constant are from Table A-1 in Appendix A to this document. The uptake fractions and effective half-lives are from Table B-1. An occupancy factor, E, of 0.75 at 1 meter will be used for the first component because the time period under consideration is less than 1 day. However, for the second and third components, an occupancy factor of 0.25 will be used because (1) the effective half-life associated with the dominant component is greater than 1 day and (2) the patient was asked patient-specific questions to justify the occupancy factor (see Section B.1.2 of this appendix).

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.

This guide uses the NCRP equation (Equation 1) in the following manner to calculate the activities at which patients may be released:

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $\left(1 - e^{\frac{-0.693t}{T_p}}\right)$ is set equal to 1.

- It is assumed that 1 roentgen is equal to 10 mSv (1 rem).

- Appendix A to this guide provides the exposure rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures.

- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.

  When a patient's release is based on biological elimination (i.e., the effective half-life) instead of solely on the physical half-life of the radionuclide, Equation 1 is modified to account for the uptake and retention of the radionuclide by the patient, as discussed in Appendix B.

- For radionuclides with a physical half-life greater than 1 day and for cases in which biological elimination is not considered, the assumption is that the individual who is likely to receive the highest dose from exposure to the patient would receive a dose of 25 percent of the dose to total decay (0.25 in Equation 2) at a distance of 1 meter. The selection of 25 percent of the dose to total decay at 1 meter for estimating the dose is based on the measurements discussed in the supporting regulatory analysis in NUREG-1492 that indicate that the dose calculated using an occupancy factor, E, of 25 percent at 1 meter is conservative in most normal situations.

- For radionuclides with a physical half-life that is less than or equal to 1 day, justifying an occupancy factor of 0.25 is difficult because the relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life that is greater than 1 day, the following equation applies:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_o T_p (0.25)}{(100\ \text{cm})^2} \qquad \text{(Equation 2)}$$

For radionuclides with a physical half-life less than or equal to 1 day and if an occupancy factor of 1.0 is used:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_o T_p (1)}{(100\ \text{cm})^2} \qquad \text{(Equation 3)}$$

Equations 2 and 3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent) relative to the external gamma-ray dose (see Appendix B, Section B-3). Further, the equations above do not apply to the dose to breastfeeding infants or children who continue to breastfeed. Patients who are breastfeeding an infant or child must be considered separately, as discussed in Section 2.2 in Section C of this guide.

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).

NOTES FOR TABLE 1: The millicurie (mCi) values in Table 1 were calculated using Equation 2 or 3 and the physical half-life. The gigabecquerel (GBq) values were calculated based on the mCi values and the conversion factor from mCi to GBq. The dose rate values were calculated based on the mCi values and the exposure rate constants. In general, the values were rounded to two significant figures. However, values less than 0.37 GBq (10 mCi) or 0.1 mSv (10 millirem (mrem)) per hour were rounded to one significant figure. NUREG-1492 describes the calculations in detail. Agreement State regulations may vary. Agreement State licensees should check their State regulations before using these values.

If a licensee administers a radionuclide that is not listed in Table 1 and if it chooses to release a patient based on the measured dose rate, it should first calculate a dose rate that corresponds to the 5-mSv (0.5-rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. The regulations at 10 CFR 35.75(c) and 35.2075(a) require the licensee to maintain a record of the basis for authorizing release. The dose rate at 1 meter may be calculated from Equation 2 or 3, as appropriate, because the dose rate at 1 meter is equal to ΓQ per 10,000 square centimeters.

1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, in accordance with 10 CFR 35.75(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 mSv (0.5 rem), the licensee may release the patient. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table 1 by accounting for the effective half-life of the radioactive material and other factors that may be relevant to the particular case. If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, the effective half-life, or shielding by tissue, then 10 CFR 35.2075(a) requires the licensee to maintain a record of the basis for authorizing the patient's release.

Appendix B contains procedures for performing patient-specific dose calculations and describes how various factors may be considered in the calculations.

2. Instructions

2.1 Activities and Dose Rates That Require Instructions

In accordance with 10 CFR 35.75(b), for some administrations, licensees must give instructions to the released patients, including written instructions, on how to maintain doses to other individuals ALARA after they are released. Licensees may use Column 1 of Table 2 to determine the dosage above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter based on the activities in Column 1. If the patient is breastfeeding an infant or child, additional instructions may be required (see Section 2.2).

Licensees may use the activities or dose rates in Table 2 to determine when they must give instructions to patients. When the licensee uses patient-specific calculations (as described in Appendix B), it must give the patient instructions if the calculation indicates a dose that is greater than 1 mSv (0.1 rem).

If the licensee administers a radionuclide that is not listed in Table 2, it may calculate the activity or dose rate that corresponds to 1 mSv (0.1 rem) using Equation 2 or 3 or Appendix B, as appropriate.