U.S. NUCLEAR REGULATORY COMMISSION

DRAFT REGULATORY GUIDE DG-8061

Proposed Revision 2 to Regulatory Guide 8.39

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RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIAL

A. INTRODUCTION

Purpose

This regulatory guide (RG) provides methods that are acceptable to the U.S. Nuclear Regulatory Commission (NRC) staff for the release of individuals, referred to as patients in this regulatory guide, after a medical procedure involving the administration of unsealed byproduct material, such as radiopharmaceuticals, or implants that contain radioactive material. The RG includes tables of activity thresholds and dose rates that licensees may use to release patients in accordance with NRC regulatory requirements. This RG also provides licensees with a methodology to modify the activity and measured dose rate thresholds on a patient-specific basis.

In addition, Revision 2 includes activity thresholds for providing instructions to breastfeeding patients, guidance for before and after patients are administered radioactive material, and information on recordkeeping.

Applicability

This RG applies to all NRC medical licensees authorized to administer byproduct material subject to Title 10 of the *Code of Federal Regulations* (10 CFR) 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material" (Ref. 1).

Applicable Regulations

- 10 CFR Part 35, "Medical Use of Byproduct Material," includes requirements and provisions for the radiation safety of workers, the public, patients, and human research subjects.
    - 10 CFR 35.75(a) permits the licensee to authorize the release of any individual from its control who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (mSv) (0.5 rem). The 5 mSv release limit applies per administration to the patient and is not a yearly limit.

- 10 CFR 35.75(b) requires the licensee to provide the released individual or the individual's parent or guardian with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as reasonably achievable (ALARA) if the TEDE to any other individual is likely to exceed 1 mSv (0.1 rem). If the TEDE to a breastfeeding infant or child could exceed 1 mSv (0.1 rem) without the patient's interruption of breastfeeding, the instructions must also include (1) guidance on the interruption or discontinuation of breastfeeding and (2) information on the potential consequences of failure to follow the guidance.

- 10 CFR 35.75(c) and 10 CFR 35.2075(a) require the licensee to maintain a record of the basis for authorizing the release of an individual for 3 years after the date of release if the TEDE to any other individual from exposure to the released individual is calculated by using the retained activity rather than the activity administered, using an occupancy factor less than 0.25 at 1 meter (m), using the biological or effective half-life, or considering the shielding by tissue.

- 10 CFR 35.75(d) and 10 CFR 35.2075(b) require the licensee to maintain a record of instructions provided to a breastfeeding patient for 3 years after the date of release if the TEDE to a nursing infant or child is likely to exceed 5 mSv (0.5 rem) without breastfeeding interruption.

Related Guidance

- NUREG-1556, "Consolidated Guidance About Materials Licenses," Volume 9, Revision 3, "Program-Specific Guidance About Medical Use Licenses," issued September 2019 (Ref. 2), includes information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for materials licenses for the medical use of byproduct material.

Purpose of Regulatory Guides

The NRC issues RGs to describe methods that are acceptable to the staff for implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to provide guidance to licensees. Regulatory guides are not NRC regulations, and compliance with them is not required. Methods and solutions that differ from those set forth in RGs are acceptable if supported by a basis for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This RG provides voluntary guidance for implementing the mandatory information collections in 10 CFR Part 35 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), under control number 3150-0010. Send comments regarding this information collection to the FOIA, Library, and Information Collections Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, Office of Management and Budget, Washington, DC, 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

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B. DISCUSSION

Reason for Revision

This revision of RG 8.39 (Revision 2) provides updated guidance based on the available scientific information and data, which licensees can use for more accurate estimates of the timing, circumstances, and risks associated with patient release; public doses from the released patients; and when instructions or records are required.

Revision 2 specifically provides (1) information for the administered activity and measured dose rate thresholds to demonstrate compliance for commonly used radionuclides, (2) calculational methodologies to accommodate threshold modifications for patient-specific exposure situations with modifying factors for biokinetics, occupancy, geometry, and attenuation based on patient-specific information, (3) calculations assuming unity for the occupancy factor if patient-specific information is not known, to avoid underestimating exposure, (4) flexibility for emerging radiopharmaceuticals that could be used for diagnostic or therapeutic purposes, (5) radiopharmaceutical activity thresholds for patients who may continue breastfeeding an infant or child after administration of radioactive material, with recommendations for breastfeeding interruption times for many typical administered medical dosages, and (6) a new section on "Sources Separated from the Patient."

Background

In 1997, the NRC revised 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material" to clarify how the public dose limits in 10 CFR 20.1301 are related to the release of patients administered unsealed byproduct material or implants containing byproduct material. The NRC determined that while doses should be maintained as low as reasonably achievable (ALARA), the public dose limit in Part 20 did not apply to radiation exposure from a patient and a dose limit of 5 mSv (0.5 rem) provides adequate protection. The revised 10 CFR 35.75 allows a licensee to authorize the release of a patient from the licensee's control if the TEDE to any other individual, from exposure to the released patient, is not likely to exceed 5 mSv (0.5 rem). In addition, 10 CFR 35.75 requires that a licensee provide the released individual, or the patient's parent or guardian, with appropriate instructions, including written instructions, on recommended actions to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 1 mSv (0.1 rem).

In Staff Requirements Memorandum (SRM)-COMAMM-14-0001/COMWDM-14-0001, "Staff Requirements—COMAMM-14-00001/COMWDM-14-0001—Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance," dated April 28, 2014 (Ref. 4), the Commission directed staff to "Revise Regulatory Guide 8.39, and subsequently NUREG-1556, Volume 9, to specify guidelines for patient information and instructional guidance." The NRC staff responded to this SRM in SECY-18-0015, "Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release after Radioisotope Therapy," dated January 29, 2018 (Ref. 5). In SECY-18-0015, the staff concluded that the NRC's patient release regulations were protective of public health and safety and that rulemaking to change the patient release criteria was not warranted. However, the staff determined that a comprehensive update to the NRC's patient release guidance was warranted and should include guidance already published in the NRC's generic communications, as well as updated scientific methodologies for calculating the dose to the members of the public from released patients. Thereafter, the NRC staff updated NUREG-1556, Volume 9, "Consolidated Guidance About materials Licenses: Program-Specific Guidance About Medical Use Licenses," and RG 8.39. Most recently, the staff issued Revision 3 of NUREG-1550, Volume 9 in September 2019 and issued Revision 1 of RG 8.39 in April 2020.

In accordance with 10 CFR 35.75, licensees can authorize release of a patient from its control if the TEDE to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). To ensure compliance with 10 CFR 35.75, licensees must determine that the dose to all individuals other than the patient is likely to be below this limit, based on the amount of activity retained in the patient at the time of release and the expected patient interactions with others. This guidance refers to individuals being exposed to the released patient as bystanders.[1]

This revision implements the fundamentals outlined in the National Council on Radiation Protection and Measurements (NCRP) Report No. 155, "Management of Radionuclide Therapy Patients," issued December 2006 (Ref. 6), and NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," dated October 1, 1970 (Ref. 7). This RG is structured so that licensees can satisfy requirements related to patient release, patient instructions, and maintaining records. A simple comparison of the administered activity to conservative basic thresholds is sufficient to reach patient release conclusions, without invoking the patient-specific modifying factors, for most clinical procedures, particularly those involving diagnostic radiopharmaceuticals. When the administration activity is above these basic threshold values, methods are then provided to modify the threshold values using patient-specific factors. The patient-specific threshold is therefore more realistic when a licensee modifies these factors. If calculations show radiation doses could exceed the limits, the licensee can hold the patient in the medical facility for a specific hold time using the appropriate radiation controls to limit exposure. This guidance provides a methodology to calculate the hold time. NUREG-1556, Volume 9, also provides additional guidance on regulatory requirements and radiation safety considerations for patients who cannot be released in accordance with 10 CFR 35.75. In addition, this RG addresses instructions for the patient, for the unexpected death of the patient, for maintaining records, and for radioactive sources separated from the patient.

The NRC staff has developed, for patients and their families, a printable brochure intended to foster a radiation-safety-oriented dialogue between patients and their health care team. In addition, the NRC staff developed a video, "Staying Safe While Getting Better, Protecting Yourself and Your Loved Ones While Taking Radioactive Drugs," to provide best practices for patients to keep exposure to others ALARA. The brochure and video can be found on the NRC website at https://www.nrc.gov/materials/miau/patient-release.html. The NRC provides foreign language versions of the brochure and video in Spanish, French, and Mandarin.

Consideration of International Standards

The International Atomic Energy Agency (IAEA) works with member states and other partners to promote the safe, secure, and peaceful use of nuclear technologies. The IAEA develops Safety Requirements and Safety Guides for protecting people and the environment from harmful effects of ionizing radiation. This system of safety fundamentals, safety requirements, safety guides, and other relevant reports, reflects an international perspective on what constitutes a high level of safety. To inform its development of this RG, the NRC considered IAEA Safety Requirements and Safety Guides pursuant to the Commission's International Policy Statement, dated July 10, 2014 (Ref. 8) and Management Directive and Handbook 6.6, "Regulatory Guides," dated May 2, 2016 (Ref. 9).

The following IAEA Safety Requirements and Guides were considered in the update of this RG:

- IAEA Safety Reports Series No. 63, "Release of Patients after Radionuclide Therapy," issued 2009 (Ref. 10), provides practical guidance and a framework for releasing patients after

1 Bystanders are all members of the public, including family members and caregivers.

unsealed radionuclide therapies. The IAEA recommends special considerations for patients who are or may become pregnant or patients who are breastfeeding children, as well as approaches to reducing exposure from deceased patients. While the essential elements of release programs included in the IAEA report are similar to the elements provided in this RG, the dose limits included in 10 CFR Part 35 differ from many other international dose requirements, including those of some IAEA member states.

C. STAFF REGULATORY GUIDANCE

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

Overview of Two-Tiered Approach

In accordance with 10 CFR 35.75, licensees may authorize release of an individual who has been administered unsealed byproduct material or implants containing byproduct material from its control if the TEDE to any other individual from exposure to the released patient is not likely to exceed 5 mSv (0.5 rem). In this RG, the individual who has been administered the byproduct material is referred to as a patient for simplicity, but in that individual may be human research subject as well, consistent with 10 CFR 35. To comply with 10 CFR 35.75, the licensee must ensure that each released patient is not likely to cause an exposure per release exceeding 5 mSv (0.5 rem) to a bystander. This document provides a two-tiered approach to demonstrate that the expected exposure to a bystander from the released patient is not likely to exceed 5 mSv (0.5 rem).

The first tier provides the basic activity (section 1.1) and dose rate (section 1.2) thresholds that licensees may use without detailed knowledge of patient-specific factors, such as the expected behavior of a patient following release. These thresholds may be used without patient-specific considerations because these thresholds were calculated using conservative assumptions such that it would be highly unlikely that patients released under these thresholds would cause exposures to bystanders in excess of the limits in 10 CFR 35.75 (5 mSv (0.5 rem)). Section 1.1 describes these assumptions. As the thresholds are appropriate for many clinical procedures, particularly those involving diagnostic radiopharmaceuticals, the basic activity and dose rate thresholds allow licensees to demonstrate compliance with 10 CFR 35.75 for many patient releases.

The second tier is for clinical procedures, activities, or dose rates that are expected to be above the first-tier basic activity and dose rate thresholds. In these cases, licensees may choose to: (1) hold the patient or (2) use the second-tier approach to demonstrate the patient can be released in accordance with 10 CFR 35.75. The second tier allows licensees to modify the conservative assumptions from the first tier using patient-specific information to demonstrate that the release is not likely to cause an exposure exceeding 5 mSv (0.5 rem) to a bystander. While the amount of patient-specific information will depend on the activity at the time of release, the second tier provides a method licensees can use to gather and use patient-specific information to determine an acceptable release activity (section 2.1) or measured dose rate (section 2.2) to demonstrate compliance with 10 CFR 35.75 for each patient release.

In some cases, licensees may find that a patient cannot be immediately released in accordance with 10 CFR 35.75. For these situations, sections 1.3 and 2.3 provide an acceptable methodology that licensees may use to calculate the amount of time to hold a patient to ensure compliance with 10 CFR 35.75. Licensees may use hold times without patient-specific information if the administered activity is expected to quickly decay below the thresholds provided in section 1.1. In many cases, licensees may use these methods before the procedure to inform patients of the amount of time they will likely need to stay at the licensees' facility so that patients can make appropriate plans.

1. Release Criteria (First-Tier Approach)

Fundamental Dose Equation for Patient Release

The fundamental dose equation for patient release was developed with updated parameters that implement fundamentals outlined in NCRP Report No. 155 and NCRP Report No. 37. In the first-tier, a basic dose assessment is performed using generic, conservative assumptions.

$$D = 1.44 \cdot T_r \cdot \Delta_{pr} \cdot A_0 \qquad \text{(equation 1)}$$

where

D = external dose equivalent, mSv
1.44 = constant for reciprocal of the natural logarithm of 2
T_r = radiological (physical) half-life, hours (h)
Δ_{pr} = dose rate constant for a point source at 1 m, $\frac{\text{mSv}}{\text{GBq h}}$
A_0 = activity of the radionuclide administered to the patient, gigabecquerels (GBq)

Equation 1 is used to calculate the maximum administered activity where the patients may be released without patient-specific information. This basic equation can demonstrate compliance with 10 CFR 35.75 for many low-activity procedures. These basic activity thresholds include the following assumptions:

- External dose equivalent to a point in tissue is calculated from the photon emissions (including electron bremsstrahlung) of a point source surrounded by an infinitely thin sphere of tissue.
- Dose rate is calculated at a distance of 1 m.
- Radionuclide loss from the patient only includes physical decay.
- External dose begins immediately after administration and lasts through infinity (i.e., total decay).
- An occupancy of 100 percent at 1 m is assumed.
- Implants are encapsulated in 50 micrometers (μm) of titanium (for manual brachytherapy applications).

Equation 1 does not account for patient-specific information. The assumptions listed above are meant to be overly conservative to ensure compliance by avoiding the underestimation of dose in likely situations. Conservative assumptions include assuming full occupancy and no excretion of activity. The second-tier approach described in section 2 allows for the consideration of patient-specific information to provide a basis for release and demonstrate compliance with 10 CFR 35.75 when desired.

The basic activity threshold Q is calculated by replacing A_0 with Q:

$$Q = \frac{D}{1.44 \cdot T_r \cdot \Delta_{pr}} \qquad \text{(equation 2)}$$

where

Q = basic activity threshold, GBq
D = TEDE limit, mSv

Licensees are authorized to release the patient when TEDE to the maximally exposed bystander is not likely to exceed 5 mSv (0.5 rem). Instructions to minimize dose to the bystander are required when TEDE is likely to exceed 1 mSv (0.1 rem). Basic activity thresholds for dose limits of 5 mSv (0.5 rem) for patient release and 1 mSv (0.1 rem) for issuing dose-minimizing instructions are denoted as Q_{rel} and Q_{ins}, respectively.

At the standard measurement distance of 1 m, the basic measurement threshold M is closely related to the basic activity threshold Q:

$$M = \Delta_{pr} \cdot Q \qquad \text{(equation 3)}$$

where

M = basic measurement threshold at 1 m, $\frac{\text{mSv}}{\text{h}}$

Denoted by M_{rel} and M_{ins}, basic measurement thresholds are computed from equation 3 for dose limits of 5 mSv (0.5 rem) for patient release and 1 mSv (0.1 rem) for issuing instructions, respectively. To avoid redundancy, equations in this section avoid the subscript notation.

Equations 1–3 consider external exposure from the patient and do not include internal dose contributions or exposure to material separated from the patient. Typically, doses from potential intakes by household members and members of the public have been shown to be negligible (less than a few percent) from current radiopharmaceuticals relative to external doses when instructions are followed as described in section 4 (Refs. 5, 10, 11, and 12). When internal dose pathways are negligible, licensees can assume TEDE equals the accumulated external dose equivalent, D. However, licensees must calculate the internal dose for infants or children who continue to breastfeed to determine whether instructions are needed in accordance with 10 CFR 35.75(b). Section 3 discusses guidance for breastfeeding patients. In addition, licensees may need to consider internal dose contributions or exposure to material separated from the patient from pathways to a bystander in unique patient-specific situations, such as when a patient is incontinent and needs caregiver support or is on dialysis.

1.1 Release of Patients Based on the Administered Activity

Licensees may demonstrate compliance with the dose limit in 10 CFR 35.75(a) for releasing patients from licensee control if the administered activity is not greater than the basic activity threshold listed in column 1 of table 1. Basic activity thresholds in column 1 of table 1 were calculated using equation 2 and are based on a TEDE to an individual of 5 mSv (0.5 rem) for the previously described conservative assumptions.

When the activity administered, A_0 (GBq), is not greater than Q_{rel} (GBq) in column 1 of table 1 $(A_0 \leq Q_{rel})$, dose limits in 10 CFR 35.75 are unlikely to be exceeded from exposure to released patients, and no record is required of the basis for authorizing the release of the patient, unless the patient is breastfeeding an infant or child, as explained in section 3.

Although the data listed in tables 1, 2, and 3 are applicable to all NRC licensees, Agreement State licensees should check with their individual State authority for applicability.

Table 1. Basic Activity Thresholds for Radionuclides

RADIONUCLIDE	COLUMN 1 Patient Release Threshold[d] Q_{rel}		COLUMN 2 Instruction Threshold[d] Q_{ins}	
	(GBq)	(mCi)	(GBq)	(mCi)
Ag-111	4.4	120	0.88	24
At-211	17	460	3.3	89
Au-198	0.88	24	0.18	4.9
Bi-213	210	5,700	41	1,100
C-11	68	1,800	14	380
C-14[a, b]	-	-	-	-
Cr-51	1.1	30	0.23	6.2
Cs-131	1.1	30	0.21	5.7
Cs-131 implant[c]	1.1	30	0.23	6.2
Cu-64	9.7	260	1.9	51
Cu-67	3.7	100	0.75	20
Dy-165	320	8,600	65	1,800
Er-169[b]	130	3,500	26	700
F-18	13	350	2.5	68
Ga-67	2.1	57	0.42	11
Ga-68	22	590	4.4	120
Ho-166[a]	26	700	5.2	140
I-123	6.7	180	1.3	35
I-124	0.20	5.4	0.041	1.1
I-125	0.074	2.0	0.015	0.41
I-125 implant[c]	0.084	2.3	0.017	0.46
I-131	0.32	8.6	0.063	1.7
In-111	0.64	17	0.13	3.5
Ir-192	0.015	0.41	0.0030	0.081
Ir-192 implant[c]	0.016	0.43	0.0033	0.089
Kr-81m[b]	-	-	-	-
Lu-177	4.1	110	0.82	22
N-13[b]	-	-	-	-
O-15[b]	-	-	-	-
P-32[a]	9.2	250	1.8	49
P-33[a]	64	1,700	13	350
Pd-103	0.27	7.3	0.055	1.5
Pd-103 implant[c]	0.39	11	0.077	2.1
Ra-223	0.27	7.3	0.054	1.5
Rb-82[b]	-	-	-	-
Re-186	6.2	170	1.2	32
Re-188[a]	16	430	3.1	84
Ru-106[a]	180	4,900	37	1,000
Ru-106[a] implant[c]	200	5,400	550	15,000
Sc-47	3.1	84	0.62	17
Se-75	0.0080	0.22	0.0016	0.043
Sm-153	6.8	180	1.4	38
Sn-117m	0.29	7.8	0.058	1.6
Sr-89[a]	3.3	89	0.66	18
Sr-90[a]	0.055	1.5	0.011	0.30

RADIONUCLIDE	COLUMN 1 Patient Release Threshold[d] Q_{rel} (GBq)	(mCi)	COLUMN 2 Instruction Threshold[d] Q_{ins} (GBq)	(mCi)
Tc-99m	30	810	6.1	160
Tl-201	1.2	32	0.23	6.2
Xe-127	0.073	2.0	0.015	0.41
Xe-133	2.1	57	0.42	11
Y-90[a]	34	920	6.8	180
Yb-169	0.094	2.5	0.019	0.51
Zr-89	0.21	5.7	0.042	1.1

a. More than 5 percent of Δ_{pr} is due to bremsstrahlung production.
b. Activity thresholds do not apply to these radionuclides because of the minimal exposures to bystanders resulting from dosages normally administered for diagnostic or therapeutic purposes. Table A-1 in appendix A contains more information.
c. Implants including eye plaques are assumed to be encapsulated in 50 μm of titanium.
d. This table does not include alpha-emitting radionuclides such as actinium (Ac)-225, thorium (Th)-227, lead (Pb)-212, and radium (Ra)-224 as activity, and dose limits are not applicable to these radionuclides because of the minimal external exposures to members of the public resulting from the microcurie (μCi) dosages normally administered for therapeutic purposes.

If the activity administered exceeds the activity in column 1 of table 1 $(A_0 > Q_{rel})$, the licensee should select one of the following options:

a. Consider releasing the patient according to measured dose rates as described in section 1.2.

b. Release the patient when the activity retained in the patient has decreased to Q_{rel} (GBq) in column 1 of table 1. In this case, 10 CFR 35.75(c) and 10 CFR 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.

c. Consider patient-specific modification of the activity threshold as described in section 2. In this case, 10 CFR 35.75(c) and 10 CFR 35.2075(a)(2)–(4) require the licensee to maintain a record of the basis for authorizing the release if the patient-specific modification of the activity threshold is such that the TEDE is calculated by using an occupancy factor less than 0.25 at 1 m, using the biological or effective half-life, or including shielding by tissue.

d. Calculate a hold time as described in section 1.3. In this case, 10 CFR 35.75(c) and 10 CFR 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.

Appendix A tabulates the radionuclide data used in the calculation of the basic thresholds. 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 by using the same methodology described to calculate basic thresholds for the radionuclide that corresponds to the dose limit of 5 mSv (0.5 rem). Licensees should maintain a record of the calculation for NRC inspection.

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. Section 3 includes more guidance for breastfeeding patients.

1.2 Release of Patients Based on the Measured Dose Rate

Licensees may release patients administered radionuclides in amounts greater than the activities listed in column 1 of table 1 ($A_0 > Q_{rel}$) if the measured dose rate from the patient is no greater than the M_{rel} value in column 1 of table 2 for that radionuclide. The dose rate is the highest measured exposure point taken at 1 m from the patient.

Table 2. Basic Measurement Thresholds for Radionuclides[a]

RADIONUCLIDE	COLUMN 1 Patient Release Threshold[d] M_{rel}		COLUMN 2 Instruction Threshold[d] M_{ins}	
	(mSv/h)	(mrem/h)	(mSv/h)	(mrem/h)
Ag-111	0.019	1.9	0.0039	0.39
At-211	0.49	49	0.096	9.6
Au-198	0.054	5.4	0.011	1.1
Bi-213	4.6	460	0.90	90
C-11	10	1000	2.1	210
C-14[f]	-	-	-	-
Cr-51	0.0051	0.51	0.0011	0.11
Cs-131	0.015	1.5	0.0029	0.29
Cs-131 implant[b]	0.014	1.4	0.0030	0.30
Cu-64	0.27	27	0.053	5.3
Cu-67	0.056	5.6	0.011	1.1
Dy-165	1.5	150	0.30	30
Er-169[c]	0.016	1.6	0.0031	0.31
F-18	2.0	200	0.38	38
Ga-67	0.044	4.4	0.0088	0.88
Ga-68	3.1	310	0.62	62
Ho-166	0.13	13	0.026	2.6
I-123	0.26	26	0.051	5.1
I-124	0.034	3.4	0.0070	0.70
I-125	0.0024	0.24	0.00050	0.050
I-125 implant[b]	0.0024	0.24	0.00049	0.049
I-131	0.018	1.8	0.0036	0.36
In-111	0.051	5.1	0.010	1.0
Ir-192	0.0020	0.20	0.00039	0.039
Ir-192 implant[b]	0.0019	0.19	0.00040	0.040
Lu-177	0.022	2.2	0.0043	0.43
N-13[f]	21	2,100	4.2	420
O-15[f]	100	10,000	21	2,100
P-32[c]	0.010	1.0	0.0020	0.20
P-33[c]	0.0057	0.57	0.0012	0.12
Pd-103	0.0084	0.84	0.0017	0.17
Pd-103 implant[b]	0.0086	0.86	0.0017	0.17
Ra-223	0.013	1.3	0.0025	0.25
Rb-82[f]	160	16,000	32	3,200
Re-186	0.039	3.9	0.0076	0.76
Re-188	0.21	21	0.040	4.0
Ru-106	0.00038	0.038	0.000078	0.0078
Ru-106 implant[b]	0.00038	0.038	0.000077	0.0077

RADIONUCLIDE	COLUMN 1 Patient Release Threshold[d] M_{rel} (mSv/h)	(mrem/h)	COLUMN 2 Instruction Threshold[d] M_{ins} (mSv/h)	(mrem/h)
Sc-47	0.043	4.3	0.0087	0.87
Se-75	0.0012	0.12	0.00024	0.024
Sm-153	0.075	7.5	0.015	1.5
Sn-117m	0.010	1.0	0.0021	0.21
Sr-89[c]	0.0029	0.29	0.00057	0.057
Sr-90[c]	0.000014	0.0014	0.0000028	0.00028
Tc-99m	0.57	57	0.12	12
Tl-201	0.049	4.9	0.0094	0.94
Xe-127	0.0039	0.39	0.00081	0.081
Xe-133	0.027	2.7	0.0055	0.55
Y-90[c]	0.054	5.4	0.011	1.1
Yb-169	0.0045	0.45	0.00091	0.091
Zr-89	0.044	4.4	0.0088	0.88

a. Values listed in the table are calculated and shown for completeness. Values do not consider detection capabilities.
b. Implants including eye plaques are assumed to be encapsulated in 50 µm of titanium.
c. More than 5 percent of Δ_{pr} is due to bremsstrahlung production.
d. If the release is based on the dose rate at 1 m in column 2, the licensee must maintain a record as required by 10 CFR 35.75(c) and 10 CFR 35.2075(a)(4) because the measurement includes shielding by tissue. Section 5.1 contains information on records of release.
e. Dose rate thresholds do not apply to these radionuclides because of the minimal exposures to bystanders resulting from dosages normally administered for diagnostic or therapeutic purposes. Table A-1 in appendix A includes more information.
f. This table does not include alpha-emitting radionuclides such as Ac-225, Th-227, Pb-212, and Ra-224 as activity and dose rate limits are not applicable to these radionuclides because of the minimal external exposures to members of the public resulting from the µCi dosages normally administered for therapeutic purposes.

Unlike activity threshold (see Table 1), measured dose rates inherently account for biokinetic removal, geometric distribution of the radiopharmaceutical in the patient's body, and attenuation by the patient's body at the time of the measurement. As measured dose rates account for these items, licensees are required to maintain a record of the basis for release in accordance with 10 CFR 35.75(c) and 10 CFR 35.2075(a), as described in section 5.

If the measured dose rate at 1 m is greater than the M_{rel} value, licensees may choose to perform patient-specific release calculations as described in section 2, wait for decay until the measured dose rate is below M_{rel}, or hold the patient for release as described in section 1.3.

If a licensee administers a radionuclide not listed in table 1 and chooses to release a patient based on the measured dose rate, the licensee must calculate a dose rate that corresponds to the 5 mSv (0.5 rem) dose limit to determine when a patient can be released in accordance with 10 CFR 35.75. Dose rate constants are preferred over exposure-rate constants because dose rate constants are calculated for dose to tissue rather than exposure to air. For radionuclides not listed, the technical support document for this guide (Ref. 12) gives an approach to determine dose rate constants for new radionuclides. This technical support document includes a comparison of dose rate constants to exposure-rate constants published by other researchers (e.g., Refs. 13 and 14).

1.3 Release of a Patient After a Hold Time

When the administered activity or measured dose rate exceeds the basic activity or dose rate threshold for release, a licensee may choose to hold a patient until the threshold for release has been satisfied without needing to gather patient-specific information. NUREG-1556, Volume 9, Revision 3, provides guidance for NRC regulations associated with in-patient care. A licensee may also choose to perform a patient-specific calculation as described in section 2 to determine whether the threshold for release is satisfied after justifying more realistic values of the modifying factors for the patient.

A conservative hold time can be calculated based on radioactive decay:

$$t_{hold} = 1.44\, T_r \ln\left(\frac{A_0}{Q_{rel}}\right) \qquad \text{(equation 4)}$$

where hold times apply only when $A_0 > Q_{rel}$. This calculation can be done before administration to allow the licensee and patient to plan for the hold time.

2. Patient-Specific Dose Calculations (Second-Tier Approach)

The activity and dose rate thresholds provided in section 1 using the first-tier approach were calculated using highly conservative assumptions that provide confidence that dose limits in 10 CFR 35.75 would not likely be exceeded. If a licensee desires to release a patient with activity or dose rate measurements above the thresholds, the licensee could employ the second-tier approach using patient-specific information to release patients with activities or dose rates higher than those shown in tables 1 and 2.

Based on the same fundamentals in equation 1, the second-tier assessment includes four additional terms that can be modified using patient-specific information. These terms are referred to as modifying factors. The modifying factors account for patient-specific biokinetics, bystander occupancy, exposure geometry, and patient attenuation. When patient-specific details are considered, the basic dose assessment shown in equation 1 is modified as follows:

$$D = 1.44 \cdot T_r \cdot \Delta_{pr} \cdot A_0 \cdot F_B \cdot F_O \cdot F_G \cdot F_A \qquad \text{(equation 7)}$$

where

D	=	external dose equivalent, mSv
1.44	=	constant for reciprocal of the natural logarithm of 2
T_r	=	radiological (physical) half-life, h
Δ_{pr}	=	dose rate constant for a point source at 1 m, $\frac{\text{mSv}}{\text{GBq h}}$
A_0	=	activity of the radionuclide administered to the patient, GBq
F_B	=	biokinetic modifying factor, unitless
F_O	=	occupancy modifying factor, unitless
F_G	=	geometry modifying factor, unitless
F_A	=	attenuation modifying factor, unitless

Similar to the first-tier approach, the external dose pathway is considered to be dominant, and internal dose pathways are considered negligible compared to external exposure. Therefore, the external dose equivalent, D, in equation 7 is also the TEDE.

When the first-tier approach is used according to equation 2, the four modifying factors were not

shown because they were each assigned a value of unity (1) using the highly conservative assumptions described in section 1. Patient-specific information is needed when a licensee uses patient-specific modifying factors to demonstrate that the release will not result in a dose in excess of limits contained in 10 CFR 35.75. Use of all four modifying factors is not needed for release of a patient. When using patient-specific information to modify one factor, licensees may use conservative values for all other modifying factors. Conservative values can be determined without patient-specific information for biokinetic, occupancy, and attenuation modifying factors. The most conservative value for biokinetic and occupancy modifying factors is 1. Table A-1 lists conservative values for the attenuation modifying factor for administered radionuclides. As significant conservatism contained in the first-tier approach can be removed in patient-specific calculations, verification that the patient is not likely to have significant close contact with others at distances less than 1 m should be confirmed before using a value of unity for the geometry modifying factor.

Appendix B and data from RCD Radiation Protection Associates (Ref. 12) provide modifying factor definitions and methods to determine patient-specific values. The patient-specific activity threshold is determined by modifying the basic activity threshold as follows:

$$Q' = \frac{Q}{F_B \cdot F_O \cdot F_G \cdot F_A} \qquad \text{(equation 8)}$$

where

Q = basic activity threshold, GBq

Q' = patient-specific activity threshold at administration, GBq

Patient-specific activity thresholds for dose limits of 5 mSv (0.5 rem) for patient release and 1 mSv (0.1 rem) for issuing dose-minimizing instructions are denoted as Q'_{rel} and Q'_{ins}, respectively. Licensees must maintain a record of the basis for authorizing the patient release in accordance with the criteria in 10 CFR 35.2075(a) as described in section 5.1. As described in appendix B, patient instructions must match or be more limiting than patient-specific factors used to release patients to ensure that dose limits will not likely be exceeded after release in accordance with 10 CFR 35.75.

2.1 Release of Patients Based on the Administered Activity

When licensees calculate a patient-specific activity threshold, Q'_{rel} (GBq), according to equation 8, the patient can be released when the administered activity, A_0 (GBq), does not exceed Q'_{rel}. When the administered activity exceeds the patient-specific activity threshold ($A_0 > Q'_{rel}$), licensees can consider releasing patients based on the measured dose rate according to section 2.2 or can consider holding the patient for a period of time to allow exposure rates to decrease through radiological and biological decay. Section 2.3 provides a calculation that licensees may use to determine a hold time using patient-specific factors when a patient cannot be released in accordance with 10 CFR 35.75 immediately after treatment.

2.2 Release of Patients Based on the Measured Dose Rate

Instead of using administered activity, licensees may decide to release patients based on measuring the external dose rate at the highest measured exposure point taken at 1 m from the patient. As survey measurements are already affected by patient-specific biokinetics, attenuation, and geometry factors, these modifying factors cannot be applied to the measured dose rate, as that would result in an underestimate of dose. However, measured dose rates are independent of occupancy. Therefore, a patient-specific occupancy factor can be used to modify the measurement threshold. When a licensee

wants to release a patient using a measured dose rate that exceeds column 1 of table 2, the licensee should calculate a patient-specific measurement threshold using the following equation, which considers occupancy:

$$M'_{rel} = \frac{M_{rel}}{F_O} \quad \text{(equation 9)}$$

Appendix B (and Ref. 12) provides methods for determining the occupancy factor.

When the measured dose rate at 1 m exceeds the patient-specific measured dose rate threshold ($A_0 > M'_{rel}$), licensees should hold the patient for a period of time to allow exposure rates to decrease through radiological decay and biological removal unless they use another method to demonstrate release. Section 3.3 provides a calculation licensees may use to determine a hold time using patient-specific factors when a patient cannot be released in accordance with 10 CFR 35.75 immediately after treatment.

2.3 Release of a Patient After a Hold Time

When a patient cannot be released immediately, licensees should calculate a hold time, t_{hold}. Licensees may calculate a conservative hold time as discussed in section 1.3 without patient-specific information. However, the hold time can be reduced if licensees choose to use patient-specific information in place of conservative assumptions.

When calculating patient-specific hold times, licensees can use both patient-specific modifying factors and patient retention at time of release, which is based on radioactive decay and biological removal. If biological removal is not known, licensees can calculate the hold time conservatively, assuming no biological removal, as follows:

$$t_{hold} = 1.44\ T_r \ln\left(\frac{A_0}{Q'_{rel}}\right) \quad \text{(equation 10)}$$

where hold times apply only when $A_0 > Q'_{rel}$.

When biological removal is known, the hold time can be shortened using the following equation:

$$t_{hold} = \frac{t_n}{\ln(R_n)} \ln\left(\frac{Q'_{rel}}{A_0}\right) \quad \text{(equation 11)}$$

where

t_n = time after administration corresponding to the patient's radionuclide retention, h
R_n = retention fraction of radionuclide in the patient at time t_n, unitless

Similarly, if the effective half-life of the radiopharmaceutical for the patient is known, the hold time can be calculated as

$$t_{hold} = 1.44\ T_e \ln\left(\frac{A_0}{Q'_{rel}}\right) \quad \text{(equation 12)}$$

where hold times apply only when $A_0 > Q'_{rel}$. If patient-specific biokinetic information is unknown, the physical half-life can conservatively be used in place of the effective half-life in equation 12.

Appendix B, section B.3, discusses the determination of R_n and t_n, including how F_B is

calculated from these parameters. To confirm generic biological removal estimates, a dose rate should be measured before releasing the patient. The ratio of measured dose rate to the basic measurement threshold should be generally consistent with $\frac{A_0}{Q'_{rel}}$ (section 2.2). NUREG-1556, Volume 9, Revision 3, provides guidance for NRC regulations associated with in-patient care.

3. Breastfeeding Patients

The regulation in 10 CFR 35.75(b) requires licensees to provide additional written instructions to released patients that are breastfeeding if the TEDE to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there was no interruption of breastfeeding. Per 10 CFR 35.75(b), these instructions must include guidance on the interruption or discontinuation of breastfeeding; and information on the potential consequences, if any, of failure to follow the guidance. This requirement presumes that the licensee will determine a patient's breastfeeding status, as appropriate, before release if the dose to the infant or child could exceed 1 mSv (0.1 rem).

The breastfeeding activity thresholds list in table 3 were calculated for common radiopharmaceuticals that could lead to 5 mSv (0.5 rem) or 1 mSv (0.1 rem) to a nursing infant or child if there is no interruption in breastfeeding (Ref. 12). Column 2 of table 3 lists the thresholds for 1 mSv (0.1 rem). If the patient could be breastfeeding an infant or child after release and if the patient was administered a radiopharmaceutical with an activity above the value stated in column 2 of table 3, the TEDE to a nursing infant or child could exceed 1 mSv (0.1 rem) and thus licensees must provide additional breastfeeding instructions in accordance with 10 CFR 35.75(b). If a licensee decides to perform a patient-specific calculation for a breastfeeding infant or child, further information is available (Ref. B-1).

With respect to the requirement in 10 CFR 35.75(b) that licensees provide information on the potential consequences of failure to follow the guidance on the interruption or discontinuation of 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.

The requirement in 10 CFR 35.2075(b) also states that a licensee must retain a record of instructions provided to the patient if the radiation dose to the infant or child from continued breastfeeding would likely result in a TEDE exceeding 5 mSv (0.5 rem). The breastfeeding activity thresholds that could result in 5 mSv (0.5 rem) to a nursing infant or child are listed in column 1 of table 3 and are further described in supporting documentation (Ref. 12). If the administered activity is above this threshold, licensees should maintain a record of the instructions provided to the patient for 3 years after patient release.

Table 4 provides the recommended duration of the interruption (or discontinuation) of breastfeeding to minimize the dose to below 5 mSv (0.5 rem) and 1 mSv (0.1 rem) for typical administrations of certain radiopharmaceuticals (Ref. 12). When the biological half-time, T_b (h), of a radiopharmaceutical is known, the effective half-life, T_e (h), can be calculated as:

$$T_e = \frac{T_r \cdot T_b}{T_r + T_b} \qquad \text{(equation 5)}$$

When breastmilk is pumped and discarded during interruption, the interruption time, τ (h), equals:

$$\tau = 1.44 \cdot T_e \cdot \ln\left(\frac{A_0}{Q_{B|ins}}\right) \quad \text{(equation 6)}$$

where

$Q_{B|ins}$ = breastfeeding activity threshold for instructions shown in table 3

For administrations of radiopharmaceuticals that are not listed in tables 3 or 4 to a patient who could be breastfeeding, the licensee should evaluate whether instructions or records (or both) are required. A method for calculating dose to the infant or child is documented separately (Ref. 12). Records of the calculation must be maintained, consistent with 10 CFR 35.2075(a). Further, as required by 10 CFR 35.2075(b), the licensee must maintain a record that the instructions required by § 35.75(b) were provided to a breastfeeding patient if the dose to the nursing child or infant is likely to exceed 5 mSv (0.5 rem) without breastfeeding interruption.

Table 3. Breastfeeding Activity Thresholds Assuming No Breastfeeding Interruption

RADIO-NUCLIDE	PHARMA-CEUTICAL	COLUMN 1 5 mSv (0.5 rem) Breastfeeding Activity Requiring a Record $Q_{B\|rec}$		COLUMN 2 1 mSv (0.1 rem) Breastfeeding Activity Threshold for Instructions $Q_{B\|ins}$	
		(GBq)	(mCi)	(GBq)	(mCi)
C-11	choline	2	60	0.5	10
Cr-51	EDTA	30	800	6	200
F-18	FDG	1	30	0.2	6
Ga-67	citrate	0.08	2	0.02	0.4
Ga-68	octreotate	9	200	2	50
I-123	MIBG	1	40	0.3	8
	OIH	2	40	0.3	8
	NaI[a,]	0.002	0.05	0.0004	0.01
I-124	NaI[a,b]	<1 μCi	<1 μCi	<1 μCi	<1 μCi
I-125	OIH	0.1	3	0.02	0.6
	NaI[a,b]	<1 μCi	0.002	<1 μCi	<1 μCi
I-131	OIH	0.08	2	0.02	0.4
	NaI[a,b]	<1 μCi	<1 μCi	<1 μCi	<1 μCi
In-111	octreotate	0.9	30	0.2	5
	WBC	0.08	2	0.02	0.4
Lu-177	octreotate	0.4	10	0.08	2
N-13	Any	10	400	3	70
O-15	water	10	300	2	60
Ra-223	Dichloride[b]	<1 μCi	<1 μCi	<1 μCi	<1 μCi
Rb-82	chloride	10	300	2	60
Tc-99m	DISIDA	0.2	6	0.05	1
	DTPA	50	1000	10	300
	DTPA aerosol	100	4000	30	700
	glucoheptonate	20	600	5	100
	HAM	0.2	7	0.05	1
	MAA	2	60	0.4	10
	MAG3	40	1000	8	200
	MDP	40	1000	9	200
	MIBI	30	800	6	200
	pertechnetate	0.5	10	0.1	3
	PYP	0.7	20	0.1	4
	RBC in vitro	50	1000	10	300
	RBC in vivo	40	1000	8	200
	sulfur colloid	0.5	10	0.1	3
	WBC	0.8	20	0.2	4
Tl-201	chloride	2	50	0.4	10
Zr-89	panitumumab	0.01	0.3	0.002	0.07

a. $Q_{B|rec}$ and $Q_{B|ins}$ are based on thyroid dose equivalent to nursing child or infant after patient release.

b. The calculated activity is less than 1 μCi. For these radionuclides, breastfeeding record retention is required, and instructions must be given.

Table 4. Recommended Breastfeeding Interruption Times for Radiopharmaceutical Administrations

RADIO-NUCLIDE	PHARMA-CEUTICAL	Example Administered Activity		Interruption Time (h)	
		(GBq)	(mCi)	for 5 mSv (0.5 rem)	for 1 mSv (0.1 rem)
C-11	any	0.925	25	-	-
Cr-51	EDTA	0.00185	0.05	-	-
F-18	FDG	0.74	20	-	3
Ga-67	citrate	0.333	9	120	250
Ga-68	octreotate	0.185	5	-	-
I-123	MIBG	0.37	10	-	4
	OIH	0.074	2	-	-
	NaI*(HYP)	0.185	0.01	78	110
I-124	NaI*(HYP)	0.074	2	620	750
I-125	OIH	0.00037	0.01	-	-
	NaI*(CA)	0.0185†	0.05	1,100	1,400
I-131	OIH	0.011	0.3	-	-
	NaI*(CA)	5.55	150	1,700	1,900
In-111	octreotate	0.185	5	-	-
	WBC	0.037	1	-	50
Lu-177	octreotate	7.8	210	350	540
N-13	any	0.925	25	-	-
O-15	water	1.85	50	-	-
Ra-223	dichloride	0.00385	0.1	1,400	1,700
Rb-82	chloride	1.85	50	-	-
Tc-99m^{+}	DISIDA	0.296	8	1	10
	DTPA	1.11	30	-	-
	DTPA aerosol	0.04	1	-	-
	glucoheptonate	0.74	20	-	-
	HAM	0.296	8	-	8
	MAA	0.151	4	-	-
	MAG3	0.37	10	-	-
	MDP	1.11	30	-	-
	MIBI	1.48	40	-	-
	pertechnetate	0.37	10	-	6
	PYP	0.555	15	-	7
	RBC in vitro	1.11	30	-	-
	RBC in vivo	1.11	30	-	-
	sulfur colloid	0.222	6	-	5
	WBC	0.37	10	-	5
Tl-201	chloride	0.148	4	-	-
Zr-89	panitumumab	0.075	2	140	270

* Interruption time is based on most restrictive infant thyroid dose equivalent for mothers with hyperthyroidism (HYP) or thyroid cancer (CA).

† 10 percent of the activity is administered as I-123 (to consider nuclide contamination).

$^{+}$ 24-hour interruption is generally applied to technetium (Tc)-99m pharmaceuticals.

A dash (-) indicates that no interruption of breastfeeding is required.

4. Instructions

4.1 Activities and Dose Rates that Require Instructions

In accordance with 10 CFR 35.75(b), licensees must give instructions to released patients, including written instructions, on how to maintain doses to bystanders ALARA if the TEDE to any other individual is likely to exceed 1 mSv (0.1 rem). Licensees may always choose to provide instructions to keep radiation dose ALARA even if the dose limit is not likely to be exceeded. Licensees should use column 2 of table 1 to determine the administered activity or column 2 of table 2 for the corresponding dose rates at 1 m because above these thresholds instructions must be given in accordance with 10 CFR 35.75(b).

Licensees should do the following to determine whether dose-minimizing instructions are required based on activity thresholds:

a. Compare the administered radionuclide activity, A_0 (GBq), to the basic activity threshold for issuing instructions shown in column 2 of table 1, Q_{ins} (GBq).

b. If the administered radionuclide activity does not exceed the basic activity threshold for instructions ($A_0 \leq Q_{ins}$), the patient can be released without dose-minimizing instructions. Licensees may choose to give instructions whether or not they are required.

c. When patient-specific calculations are performed as described in section 2, the administered radionuclide activity can be compared to the patient-specific activity threshold for issuing instructions, Q'_{ins} (GBq). Appendix B provides details on determining the modifying factors.

d. If the administered radionuclide activity does not exceed the patient-specific activity threshold for issuing instructions ($A_0 \leq Q'_{ins}$), the patient can be released without dose-minimizing instructions when the patient-specific activity threshold calculation is not relying on instructions in the calculation of Q'_{ins}.

e. Dose-minimizing instructions are required for cases when neither criterion b nor d is met.

Figure 1 summarizes the decision process for providing instructions based on activity thresholds.

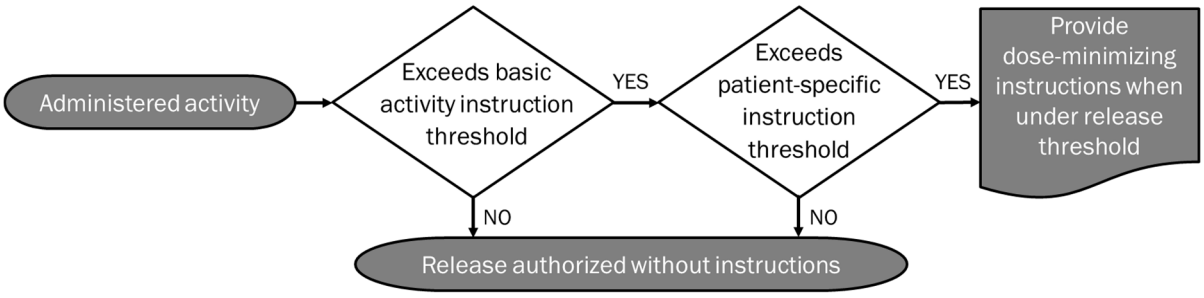

Figure 1. Patient instruction decision based on activity thresholds

Alternatively, licensees can use the dose rate measured at 1 m to determine whether the instructions are required under 10 CFR 35.75(b). Given that measured dose rates are already affected by patient-specific biokinetics, attenuation, and geometry factors, these modifying factors cannot be applied to the measured dose rate, as that would result in an underestimate of dose. However, a patient-specific

occupancy factor can be used to modify the measurement threshold measured dose rates are independent of occupancy. For these reasons, the measured dose rate after administration can be compared to the basic measurement threshold divided by the occupancy modifying factor, F_0 (unitless). Appendix B contains details on determining the occupancy modifying factor.

Licensees should do the following to determine whether dose-minimizing instructions are required based on measurement thresholds:

a. Compare the measured dose rate at 1 m at administration, d_0 (mSv/h), to the basic measurement threshold for issuing instructions shown in column 2 of table 2, M_{ins} (mSv/h).

b. If the dose rate at administration does not exceed the basic measurement threshold for instructions ($d_0 \leq M_{ins}$), the patient can be released without dose-minimizing instructions.

c. If the dose rate at 1 m at the time of release, d_{rel} (mSv/h), does not exceed the basic measurement threshold divided by the occupancy modifying factor $\left(d_{rel} \leq \frac{M_{ins}}{F_O}\right)$, the patient can be released without dose-minimizing instructions.

d. Dose-minimizing instructions are required for cases when neither criterion b nor c is met.

Figure 2 summarizes the decision process for providing instructions based on measurement thresholds.

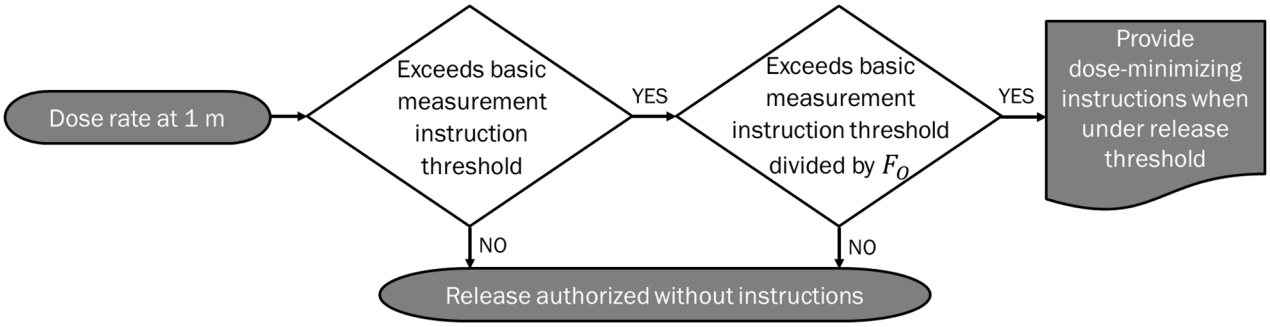

Figure 2. Patient instruction decision based on measured dose rates at 1 m

If the patient is breastfeeding an infant or child, additional instructions may be required (refer to sections 2 and 5.2).

4.2 Content of Instructions

This section describes different aspects that the licensee should consider when developing patient release instructions before and after a patient's treatment, based on discussions with the patient or caregiver. Generally, when a licensee releases a patient, it is to the patient's home where family or other caregivers may be present. To provide adequate release instructions under 10 CFR 35.75(b), the licensee should confirm the patient's or caregiver's ability to understand and follow the release instructions. The licensee should thoroughly ascertain the patient's posttreatment destination(s), including means of travel, to provide instructions to maintain doses ALARA and ensure that the dose limit will not likely be exceeded. Licensees should verify pretreatment plans on the day of treatment. If the proposed pretreatment plans made before the day of the treatment change, then the instructions that were developed based on those plans should be changed to reflect the actual arrangements made on the day of the administration.

The regulations in 10 CFR 35.75 apply to all medical radioisotope therapies, such as I-131, yttrium (Y)-90, I-125, lutetium (Lu)-177, Ra-223, and Ac-225. Instructions should be specific to the type of treatment given and should include additional information for the patient's posttreatment situations. Also, the instructions that are needed to meet the requirements for release should not interfere with or contradict the best medical judgment of the treating physician. The instructions should include the licensee's telephone number for the patient to contact with any questions.

4.2.1 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 bystanders. In addition, prerelease discussions are necessary if licensees intend to use patient-specific modifying factors, such as occupancy, as part of their release basis. The prerelease discussion also lets the licensee make appropriate arrangements if the patient cannot be released immediately (i.e., arrange a temporary hold or hospitalization if necessary). Early engagement helps to identify any patient-specific aspects that may prohibit release after treatment due to the potential of exceeding the 10 CFR 35.75 dose limit, determine whether the patient will be able to follow necessary release instructions, and allow time for the patient or caregivers to ask questions on following instructions to keep doses ALARA. If the licensee determines that the patient's posttreatment plans—including planned mode of transportation, posttreatment destination(s), or any instructions that it believes the patient cannot follow—are likely to cause a dose to bystanders that will exceed 5 mSv (0.5 rem), the licensee must not release the patient until the dose to bystanders is not likely to exceed 5 mSv (0.5 rem). This discussion should include medical issues such as complications, side effects, and dietary and medication changes, as appropriate.

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, especially if the licensee intends to use patient-specific occupancy factors. 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 bystanders, what is the duration of the trip? Based on the duration of the trip, can the patient keep an adequate distance from others? Emphasize the importance of minimizing the number of traveling companions.

    (3) Will the patient be traveling internationally after treatment? Patients who travel by motor vehicle, boat, or airplane through international border checkpoints are subject to screening for radiation. Patients should be advised of this fact, and the physician should provide the patient with appropriate documentation (e.g., procedure, isotope, date and time of release, treating facility and physician, contact information) to present to officials

when alarms are triggered.

c. Which household members, if any, will be present at the patient's posttreatment recovery location? Consider their age or other factors which could increase exposure and whether there is a nursing infant or pregnant woman in the household.

d. Can the patient be appropriately isolated from others in the household after treatment?

e. Can the patient take care of themselves, and is the patient capable of complying with the release instructions?

f. Can the patient sleep alone in a separate bedroom or area?

g. Is the patient incontinent?

h. Are there any necessary household or dietary changes, or fluid intake restrictions (e.g., preexisting medical conditions)?

i. Are there any factors that might prevent treatment (e.g., breastfeeding, pregnancy)?

j. Can the patient delay the return to work? What kind of work does the person do (e.g., daycare provider)?

k. What are the potential restrictions on burial or cremation if the patient should pass away within a certain period of time following treatment?

By gathering this information before the treatment (i.e., during the treatment planning stage) when the activity to be administered is expected to exceed the basic activity threshold for release, the licensee can begin to estimate patient-specific modifying factors for use in the release calculations. This information can be used to (1) provide a patient-specific estimate of the likely cumulative dose to other members of the public, (2) direct appropriate protective measures, (3) allow the licensee to make arrangements if the patient cannot be immediately released (i.e., arrangements to temporarily hold the patient or hospitalize the patient), (4) allow the patient time to plan for his or her potential isolation after release, and (5) allow the licensee to assess the patient's capacity to understand the procedure and precautions to ensure the dose limits in 10 CFR 35.75 will not likely be exceeded. In addition, immediately before treatment, licensees should verify that the patient's plans did not change in a way that would alter the patient-specific factors used in release calculations, which might require a different plan (i.e., need for instructions or inability to release at the planned time) or content of the final release instructions.

4.2.2 Patient Precautions

The licensee should consider the following precautions or measures for most patients to minimize exposures to others and to keep radiation exposures to others at or below the 5 mSv (0.5 rem) limit. These patient precautions can be considered by the licensee but are not NRC requirements. The licensee should use judgment with the instructions needed for the patient on a case-by-case basis, based on the treatment. The licensee should discuss the following precautions and measures with the patient as appropriate. This list of precautions is not all inclusive and should be modified for each treatment or radioactive material administered.

a. The greatest radiation dose potential to bystanders from the released patient is from external

exposure. Therefore, the most important precautions to take are measures to reduce or avoid the radiation exposure emanating from the patient, especially in the early time period after the administration.

(1) Emphasize the importance of keeping an adequate distance from others, especially children and pregnant women, and to minimize the time spent near others.

(2) If the patient is traveling with a bystander to a posttreatment lodging location, emphasize the importance of minimizing the number of traveling companions and maximizing the distance from the patient.

(3) Emphasize that the patient should sleep separately and abstain from all forms of intimate contact.

b. The release instructions may include measures that are necessary to limit the transfer of radioactive contamination to others. The licensee should provide specific instructions on how to limit direct contact with others and on measures necessary to limit the contamination of objects and surfaces and the spread of radioactive contamination. Patient education and awareness of how to minimize, isolate, and clean radioactive contamination are important in reducing intake by others.

(1) Encourage the use of a bathroom reserved exclusively for the patient, if possible.

(2) Encourage the patient not to prepare or share food with others.

(3) Encourage the use of kitchen utensils that are dedicated solely to the patient (i.e., not shared with other household members) and that are washed separately from other dishes. Alternately, encourage patients to use disposable eating utensils.

(4) Encourage the use of disposable gloves and wipes and frequent hand washing.

(5) Encourage the laundering of a patient's clothing and linens separately from another household member's clothing.

(6) Discuss how to clean up an area contaminated with body fluids (e.g., urine, vomit) and how to dispose of cleaning materials.

(7) Evaluate the need to dispose of patient-related trash in a separate strong plastic bag that is not mixed with other household members' trash, holding the patient's trash to allow for radioactive decay and implementing ways to reduce radiation exposure from this trash. Holding trash to allow for radioactive decay will be important, as most landfills can detect the radiation and will not accept the trash.

(8) Advise the patient on the recommended length of time he or she should wait before becoming pregnant to minimize radiation exposures to a developing fetus.

(9) Discuss how the patient may contact the licensee if needed. Provide information to a family member or caregiver to contact the treatment medical facility if the patient has a medical emergency or dies.

(10) Explain that, in case of a medical emergency, the patient, or a caregiver or family

member, should inform the ambulance or the emergency care location of the recentness of the radioactive therapy treatment.

(11) Provide posttreatment release instructions to the patient verbally and in writing, including how long he or she should follow the release instructions.

The licensee may encourage patients to have available plastic bags, disposable gloves, and wipes before treatment. The licensee should provide specific information on how to limit direct contact with others and on measures necessary to limit the contamination of objects and surfaces and the spread of radioactive contamination. Patient education and awareness of how to minimize, isolate, and clean radioactive contamination are important in minimizing exposure to others.

The NRC recognizes that pregnancy tests have limited ability to detect early pregnancies. The NRC encourages licensees to advise patients who could become pregnant to contact the licensee immediately if a patient subsequently discovers that the patient was pregnant at the time the medical treatment was administered. Licensees must report any dose to an embryo or fetus that is greater than the 50 mSv (5 rem) dose equivalent resulting from the treatment to a pregnant individual unless the authorized user specifically approved the dose to the embryo or fetus in advance in accordance with 10 CFR 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child."

Patients receiving radiopharmaceutical treatment need to be aware that they might trigger the alarms of radiation detectors at national borders, at airports, at cruise ports, within cities, or at their place of employment for several weeks or months following treatment. Consequently, the licensee should consider issuing the patient a letter or card that contains appropriate information about the treatment in case any officials need to verify that information.

4.2.3 Patient Instructions

Consistent with 10 CFR 35.75, before releasing the patient, the licensee must ensure that the radiation dose to bystanders is not likely to exceed 5 mSv (0.5 rem) from the released patient who has been administered radiopharmaceuticals or implants that contain radioactive material. It is understood that once a patient is released, the licensee has no control over the patient. However, licensees may rely on discussions with the patients where they or their caregivers demonstrate they are able and willing to take the necessary precautions described in instructions to ensure a dose to the maximum bystander is not likely to exceed 5 mSv (0.5 rem) from the released patient. In addition, patient instructions must be given to keep exposures ALARA in accordance with 10 CFR 35.75(b).

The Advisory Committee on the Medical Uses of Isotopes recommended that instructions should be appropriate and easy to follow to enable the patient to understand how to minimize radiation exposure to bystanders (Ref. 10). Consideration should be given to providing instructions in the patient's native or primary language. For most therapies, experience shows that radiation exposure from patients can be safely controlled through appropriate treatment-specific release instructions provided by licensees and followed by patients. Pursuant to 10 CFR 35.75, the licensee cannot authorize release of a patient if it is likely that exposure could exceed 5 mSv (0.5 rem) following a release and the patient is unable to or will not follow instructions. Therefore, if the patient or caregiver is mentally or physically unable, does not have the resources, or is not willing to agree to comply with release instructions necessary to ensure that exposure is not likely to exceed 5 mSv (0.5 rem), the licensee will have to hold the patient as an in-patient following treatment until the patient can be released without having to follow these instructions.

The list below provides some basic posttreatment instructions that may be given to the patient following release to minimize bystander radiation exposure and keep exposures ALARA. The instructions

should always be tailored to the specific patient situation and type and amount of radioactive material administered or implanted. Instruction should also be realistic and state how long the precautions should be followed. Studies have shown the greatest exposure pathway risk to bystanders from the released patient is from external exposure (Ref. 5). However, bystander uptake has been identified when patients did not abstain from intimate contact and other physician instructions following treatment. Therefore, instructions to minimize contamination and potential for internal uptake should be included as appropriate. As a guideline, the licensee should consider using several (three to five) effective half-lives of the administered radionuclide to determine the duration for the instructions to be followed.

a. Minimize the amount of time spent in close proximity to other people, especially children and pregnant women (a general guideline is no closer than a meter (3.28 feet) for more than 1 hour per day). Try to maximize your distance from others as much as possible two meters (6.56 feet).

b. Sleep alone in a separate bedroom.

c. Abstain from kissing or any intimate contact with another person.

d. Use a dedicated sole-use bathroom, if possible. Males should sit to urinate to avoid splashing. Flush the toilet twice after each use.

e. Avoid direct contact or sharing of personal items that may result in the contamination of others with your body fluids (saliva, urine, sweat), especially pregnant women and young children.

f. Wash hands frequently and bathe daily. Use separate towels and washcloths.

g. Avoid handling or preparing food for others and avoid sharing food.

h. Use dedicated or disposable kitchen utensils, and do not share them with others.

i. Wash laundry, including linens, separately from others.

j. Use disposable gloves and wipes when cleaning.

k. Discard trash separately and hold it to allow for radioactive decay.

l. Avoid public facilities and the use of public transportation.

m. Maintain good hydration, as directed by a physician.

n. Inform medical personnel of these instructions when seeking any medical care.

o. Carry these instructions when traveling and provide them to law enforcement authorities if detained for triggering a radiation monitor. Radiation detection devices used at border crossings, airports, and federal facilities for homeland security purposes may be sensitive enough to detect the radioactivity levels in a patient's body for up to several weeks.

The licensee should instruct the patient on how to clean up an area contaminated with body fluids (e.g., urine, vomit) and how to dispose of the cleaning materials. The licensee should also instruct family members and caregivers to notify the treating medical facility of a medical emergency or if a patient dies. Section 4.3 includes further information on the death of a patient following radiopharmaceutical administration or implants.

4.2.4 Patient Acknowledgement of Instructions

The patient should acknowledge receipt of instructions before the patient is released, and the licensee should acknowledge that the patient received the instructions as communicated using a form signed by both parties. Through the form, the patient acknowledges the receipt of the following:

a. Patient has received a clear explanation of the treatment process before treatment.

b. Patient has been informed of the need to limit exposure to others, especially to young children and pregnant individuals, and has been informed on how long to exercise this special care.

c. Patient has discussed with the healthcare provider final plans for the following:

(1) transportation from the clinic to home or to the posttreatment destination,

(2) arrangements for protecting others once the patient has arrived at the posttreatment destination,

(3) minimization of the exposure of people both inside and outside the home,

(4) management of biological wastes and trash,

(5) emergency care, and

(6) contact information (i.e., the name and telephone number of a knowledgeable person) if questions arise about the radiation safety instructions during the recovery period.

4.3 Death of a Patient Following Radiopharmaceutical Administration or Implants

The licensee should instruct the patient's family to notify the treating authorized user and the radiation safety office (RSO) immediately if a patient has died after recent administration of a therapeutic quantity of radioactive material. If the death occurs in a hospital or medical facility licensed by the NRC or an Agreement State, the facility should have internal procedures to handle the death of a radioactive patient and instructions that can be provided to the family, including any cultural aspects. If the facility does not have a radioactive material license, the licensee that administered the radioactive material or a nearby licensee should provide radiation safety support information to the non-licensed medical facility to control access to the room occupied by the deceased.

For the vast majority of administered radiopharmaceuticals, activity levels in released patients will not result in radioactive cadaver exposure exceeding the dose limits of 10 CFR Part 20. However, the analysis of administration of I-131 (in five different pharmaceuticals), holmium-166, lutenium-177, and rhenium-188—using very conservative assumptions—indicates that dose rates exceeding 0.02 mSv/h (2 mrem/h) and potential total doses of more than 25 percent of the 1 mSv (0.1 rem) dose limit are possible if an unexpected death were to occur within hours of release and knowledge of the radioactive administration is not communicated (Ref. 12). Depending on the administered activity of a given pharmaceutical and the timing of the unexpected patient death, the potential exists for exceeding a regulatory limit for several identified procedures. Radionuclides with a hypothetical total dose to a bystander above 1 mSv (0.1 rem) exceeded the limit by no more than a factor of 2 with conservative exposure assumptions. Dose rates, however, are more restrictive because potential dose rates were found

to exceed 0.02 mSv/h (2 mrem/h) by more than an order of magnitude within a short time after patient release. For a deceased patient, limiting the dose rate to an acceptable level for all radionuclides will be protective in terms of total dose. No radioactive implant was identified as potentially important from the perspective of external exposure following patient death. For patient death outside the medical facility, there is a low likelihood that regulatory limits on external dose would be exceeded if the radioactive implant were to remain in place.

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 burial or cremation:

a. If the activity remaining in the body results in an external dose that is greater than the regulatory public dose limits of 10 CFR Part 20, the RSO should determine the radiation precautions that should be followed.

b. Precautions should be based on dose limits, a generic safety assessment of the need for monitoring personnel who carry out these procedures, the need for monitoring the premises, the need for minimizing external radiation exposure, and the potential for contamination (Ref. 6).

The administering licensee should provide precautions to the funeral director for family members and the public to follow during visitation before burial or internment. While the licensee has the responsibility to ensure regulations are followed, the licensee should consider engaging the NRC or the Agreement State regulatory authorities to determine how best to proceed.

5. Records

5.1 Records of Release

The NRC has no requirement for recordkeeping on the release of patients who were released in accordance with the information in column 1 of table 1. However, if the release of the patient is based on a dose calculation that considered retained activity, an occupancy factor of less than 0.25 at 1 m, the effective half-life, or shielding by tissue, 10 CFR 35.2075(a) requires the licensee to maintain a record of the basis for authorizing the patient's release. Therefore, calculating and releasing patients based on patient-specific thresholds will often require a record unless the occupancy factor is equal to or greater than 0.25 and geometry, biokinetic, and attenuation factors are equal to or greater than 1.

This record should include the patient's identifier in a way that ensures that confidential patient information is not traceable or attributable to a specific patient, the radioactive material administered, the administered dosage, and the date of the administration. In addition, depending on the basis for authorizing the release of patients, records should include the following information:

a. **For Immediate Release of a Patient Based on a Patient-Specific Calculation.** To provide an adequate basis for the patient's release, the record should include the equation used and bases for the patient-specific modifying factors (see appendix B to this guide). The record should also provide a general description of how patient-specific information was acquired. Examples of appropriate bases for occupancy factors include patient questionnaires or notes from discussions with patients to determine their intended behavior following treatment and to acknowledge that they can follow instructions as given. In some situations, a calculation may be case specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients, but a basis may be necessary to demonstrate how this patient meets the class of patients. Appendix C includes

additional examples of appropriate bases for other modifying factors. As exposure is highly dependent on patient-specific behavior following release, use of generic instructions without patient discussion and acknowledgement should not be used as a basis for patient-specific modifying factors.

b. **For Immediate Release of a Patient Based on a Measured Dose Rate.** The record should include the results of the measurement, the specific survey instrument used, and the name of the individual performing the survey. If release is based on dividing the measurement threshold by the occupancy factor, a general description should be included on the basis of the occupancy factor being appropriate for the patient.

c. **For Delayed Release of a Patient Based on a Radioactive Decay Calculation.** The record should include the time of the administration, the date and time of release, and the results of the decay calculation. If release is based on patient-specific calculations in addition to radioactive decay, the record should include items listed in item a.

d. **For Delayed Release of a Patient Based on a Measured Dose Rate.** The record should include the results of the survey meter measurement, the specific survey instrument used, and the name of the individual who performed the survey. If the release is based on patient-specific calculations in addition to the measured dose rate, then the record should include items listed in item a. If release is based on dividing the measurement threshold by the occupancy factor, a general description should be included on the basis of the occupancy factor being appropriate for the patient.

Records should be kept in a manner that ensures the patient's privacy and confidentiality (i.e., the records should not contain the patient's name but instead a patient identification number, date, and treatment type). These recordkeeping requirements may be used to verify that licensees have proper procedures in place for assessing bystander exposure associated with and arising from exposure to patients administered radioactive material.

5.2 Records of Instructions for Breastfeeding Patients

In accordance with 10 CFR 35.2075(b), the licensee must retain a record that the instructions required by 35.75(b) were provided to a breastfeeding patient if the 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). Table 3, column 1, lists the radiopharmaceuticals commonly used in medical diagnosis and treatment and 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 ensures the confidentiality of the information.

6. Sources Separated from the Patient

While public dose limits in 10 CFR Part 20 do not apply to exposure from individuals administered radioactive material and released under 10 CFR 35.75, dose limits in 10 CFR Part 20 do apply if a radioactive sealed source or seed, such as a temporary implant, becomes separated from the patient. Public dose limits in 10 CFR 20.1301, "Dose limits for individual members of the public" are 0.1 rem in a year and 0.002 mrem in any one hour. If a licensee discovers a member of the public exceeds the public dose limits in 10 CFR 20.1301 from a source no longer affixed to a released patient, licensees must report the event in accordance with 10 CFR 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits."

Licensees should ensure all temporary and permanent implants are affixed to the patient so that they are highly unlikely to become dislodged. Patients should not be released from the licensed facility if it appears that the source or sources are not affixed properly and could become dislodged. Additionally, licensees must have preventive measures in place to ensure public dose limits are not exceeded in the event the source becomes dislodged after the patient's release. Potentially preventive measures include labeling of the source and providing patients with instructions on how to handle, control, and return the source if it becomes dislodged. Instructions should also include how to report a lost source to the licensee. Licensees must report lost sources in accordance with 10 CFR 20.2201, "Reports of theft or loss of licensed material," if an implant becomes dislodged and is not recovered or if temporary implants issued to a patient are not returned to the licensee.

Additionally, in accordance with 10 CFR 35.41, "Procedures for administrations requiring a written directive," licensees must have written procedures to determine if a medical event has occurred. If a patient is released in accordance with 10 CFR 35.75 while treatment is ongoing, these procedures should include how a licensee will determine whether the source moved or became dislodged to determine whether a medical event occurred. Medical event is defined in 10 CFR 35.3045, "Report and notification of a medical event."

D. IMPLEMENTATION

The NRC staff may use this regulatory guide as a reference in its regulatory processes, such as licensing, inspection, or enforcement. Backfitting, forward fitting, and issue finality considerations do not apply to 10 CFR Part 35 licensees and applicants because 10 CFR Part 35 does not include backfitting or issue finality provisions, and the forward fitting policy in Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests" (Ref. 15), does not apply to these licensees.

REFERENCES[2]

1. *U.S. Code of Federal Regulations*, "Medical Use of Byproduct Material," Part 35, Chapter I, Title 10, "Energy."

2. U.S. Nuclear Regulatory Commission (NRC), NUREG-1556, "Consolidated Guidance About Materials Licenses," Volume 9, Revision 3, "Program-Specific Guidance About Medical Use Licenses," Washington, DC, September 2019. (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19256C219)

3. *U.S. Code of Federal Regulations* (CFR), "Standards for Protection against Radiation," Part 20, Chapter I, Title 10, "Energy."

4. NRC, Staff Requirements Memorandum (SRM)-COMAMM-14-0001/COMWDM-14-0001, "Staff Requirements—COMAMM-14-00001/COMWDM-14-0001—Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance," Washington, DC, April 28, 2014. (ML14118A387)

5. NRC, SECY-18-0015, "Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release after Radioisotope Therapy," Washington, DC, January 29, 2018. (ML17279B139 (package) and ML17279B140)

6. National Council on Radiation Protection and Measurements (NCRP) Report No. 155, "Management of Radionuclide Therapy Patients," Bethesda, Maryland, December 2006.[3]

7. NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," Bethesda, Maryland, October 1, 1970.

8. NRC, "Nuclear Regulatory Commission International Policy Statement," *Federal Register*, Vol. 79, No. 132, July 10, 2014, pp. 39415–39418.

9. NRC, Management Directive 6.6, "Regulatory Guides," Washington, DC, May 2, 2016. (ML18073A170)

10. International Atomic Energy Agency, Safety Reports Series No. 63, "Release of Patients after Radionuclide Therapy," Vienna, Austria, 2009.

11. NRC, Advisory Committee on Medical Uses of Isotopes, "Subcommittee Review and Comments on Draft Final Proposed Regulatory Guide 8.39, 'Release of Patients Administered Radioactive Materials,' Revision 1 (Phase 1)," Final Report, Washington, DC, March 25, 2020. (ML20085H267)

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2 Publicly available NRC published documents are available electronically through the NRC Library on the NRC's public website 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, Maryland. For problems with ADAMS, contact the PDR staff at (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; or email pdr.resource@nrc.gov.

3 Copies of reports from the National Council on Radiation Protection and Measurements (NCRP) may be obtained through its website: http://www.ncrponline.org/Publications/Publications.html or by writing to the NCRP at 7910 Woodmont Avenue, Suite 400, Bethesda, Maryland, 20814-3095, Phone: (301) 657-2652, fax: (301) 907-8768.

12. RCD Radiation Protection Associates, RCD-21-181-0, "Activity Thresholds, Patient-Specific Modifying Factors, Breastfeeding Interruption Times, and Other Supporting Data," Research Information Letter Report for Phase 2 Revisions to Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material," Corvallis, Oregon, June 30, 2021. (ML21348A111)

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14. Smith, D.S., and M.G. Stabin, "Exposure rate constants and lead shielding values for over 1,100 radionuclides," *Health Physics*, 102(3): 271–291, 2012.

15. NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection," Washington, DC.

APPENDIX A

RADIONUCLIDE DATA TABLES

Table A-1. Radiological Half-Lives and Dose Rate Constants for Radionuclides

RADIONUCLIDE[a]	RADIOLOGICAL[e] HALF-LIFE, T_r (days)	DOSE RATE CONSTANT[f] AT 1 METER, $\Delta_{pr}\left(\frac{\text{mSv}}{\text{GBq h}}\right)$	MAXIMUM[g] ATTENUATION FACTOR, F_A
Ag-111	7.45	0.00442	1.00
At-211	0.3006	0.0288	1.00
Au-198	2.696	0.0615	1.00
Bi-213	0.0317	0.0218	N/A
C-11	0.0142	0.154	N/A
C-14[b,c]	2,080,000	0.00000502	1.00
Cr-51	27.703	0.00465	1.08
Cs-131	9.689	0.0144	1.10
Cs-131 implant[d]	9.689	0.0130	1.10
Cu-64	0.5292	0.0277	1.00
Cu-67	2.576	0.0150	1.41
Dy-165	0.09725	0.00464	1.11
Er-169[b]	9.4	0.000121	1.00
F-18	0.0762	0.148	1.00
Ga-67	3.261	0.0207	1.34
Ga-68	0.04702	0.143	1.00
Ho-166[b]	1.117	0.00507	1.10
I-123	0.553	0.0390	1.04
I-124	4.176	0.167	1.00
I-125	59.4	0.0332	1.04
I-125 implant[d]	59.4	0.0291	1.03
I-131	8.0207	0.0576	1.03
In-111	2.8047	0.0798	1.00
Ir-192	73.827	0.125	1.01
Ir-192 implant[d]	73.827	0.121	1.04
Kr-81m	0.000152	0.0385	N/A
Lu-177	6.647	0.00527	1.25
N-13	0.00692	0.154	N/A
O-15	0.00141	0.154	N/A
P-32[b]	14.263	0.00105	1.00
P-33[b]	25.4	0.0000887	1.00
Pd-103	16.991	0.0306	1.00
Pd-103 implant[d]	16.991	0.0220	1.00
Ra-223	11.43	0.0475	1.00
Rb-82	0.000884	0.172	N/A
Re-186	3.7183	0.00631	1.00

RADIONUCLIDE[a]	RADIOLOGICAL[e] HALF-LIFE, T_r (days)	DOSE RATE CONSTANT[f] AT 1 METER, $\Delta_{pr}\left(\frac{\text{mSv}}{\text{GBq h}}\right)$	MAXIMUM[g] ATTENUATION FACTOR, F_A
Re-188[b]	0.7085	0.0127	1.00
Ru-106[b]	373.59	0.00000212	1.00
Ru-106[b] implant[d]	373.59	0.00000188	1.00
Sc-47	3.3492	0.0140	1.43
Se-75	119.78	0.153	1.00
Sm-153	1.938	0.0115	1.51
Sn-117m	13.76	0.0364	1.00
Sr-89[b]	50.53	0.000875	1.00
Sr-90[b, c]	10,508	0.000255	1.00
Tc-99m	0.2506	0.0194	1.26
Tl-201	3.038	0.0405	1.00
Xe-127	36.41	0.0535	1.04
Xe-133	5.243	0.0128	1.18
Y-90[b]	2.67	0.00157	1.00
Yb-169	32.026	0.0477	1.54
Zr-89	3.267	0.207	1.00

a. This table does not include alpha-emitting radionuclides such as actinium-225, thorium-227, lead-212, and radium-224 because activity and dose rate thresholds are not applicable to these radionuclides due to minimal external exposures to members of the public resulting from the microcurie dosages normally administered for therapeutic purposes.

b. More than 5 percent of Δ_{pr} due to bremsstrahlung production.

c. The basic methodology presented in this guide is not acceptable for radionuclides with half-lives greater than 10 years. Dosages normally administered for current diagnostic purposes using these radionuclides are unlikely to lead to significant bystander exposure.

d. Implants and eye plaques are assumed to be encapsulated in 50 micrometers of titanium.

e. Nuclear decay data are based on International Commission on Radiological Protection Publication 107, "Nuclear Decay Data for Dosimetric Calculations," issued 2008 (Ref. A-1).

f. External dose equivalent rate to tissue from photon and electron emissions with bremsstrahlung for a point source surrounded by an infinitely thin sphere of tissue (Ref. A-2).

g. N/A appears in the maximum attenuation factor column for radionuclides with half-lives less than 1 hour, which are unlikely to lead to significant bystander exposures for dosages normally administered for diagnostic purposes.

REFERENCES FOR APPENDIX A

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A-2. RCD Radiation Protection Associates, RCD-21-181-0, "Activity Thresholds, Patient-Specific Modifying Factors, Breastfeeding Interruption Times, and Other Supporting Data," Research Information Letter Report for Phase 2 Revisions to Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material," Corvallis, Oregon, June 30, 2021. (Agencywide Documents Access and Management System Accession No. ML21348A111)

1 Publicly available NRC published documents are available electronically through the NRC Library on the NRC's public website 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, Maryland. For problems with ADAMS, contact the PDR staff at (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; or email pdr.resource@nrc.gov.

APPENDIX B

PATIENT-SPECIFIC MODIFYING FACTORS AND METHODS

Licensees may authorize the release of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (mSv) (0.5 rem) in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 35.75(a). Basic activity thresholds in table 1 of the first-tier approach in the regulatory guide were calculated using such highly conservative assumptions that can be used without patient-specific information (see section C.1 of the regulatory guide). However, with the second-tier approach, licensees may use patient-specific information to make modifications to the conservative assumptions to demonstrate compliance to release a patient above the basic thresholds. The type and amount of patient-specific information necessary for release is dependent on the risk that a bystander would be likely to exceed 5 mSv (0.5 rem) from exposure to the released individual, in accordance with 10 CFR 35.75(a).

$$D = 1.44 \cdot T_r \cdot \Delta_{pr} \cdot A_0 \cdot F_B \cdot F_O \cdot F_G \cdot F_A \qquad \text{(equation B-1)}$$

where

D	=	external dose equivalent, mSv
1.44	=	constant for reciprocal of the natural logarithm of 2
T_r	=	radiological (physical) half-life, hours (h)
Δ_{pr}	=	dose rate constant for a point source at 1 m, $\frac{\text{mSv}}{\text{GBq h}}$
A_0	=	activity of the radionuclide administered to the patient, gigabecquerels (GBq)
F_B	=	biokinetic modifying factor, unitless
F_O	=	occupancy modifying factor, unitless
F_G	=	geometry modifying factor, unitless
F_A	=	attenuation modifying factor, unitless

This appendix presents several acceptable approaches for determining the modifying factors. To use the second-tier approach, the licensee must determine the likely dose to the maximally exposed bystander (i.e., person for whom the product of modifying factors is greatest) to demonstrate compliance with 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material." To demonstrate that the TEDE is below 5 mSv (0.5 rem), modifying factors for biokinetics, occupancy, geometry, and attenuation are incorporated into a patient-specific activity threshold as follows:

$$Q' = \frac{Q}{F_B \cdot F_O \cdot F_G \cdot F_A} \qquad \text{(equation B-2)}$$

where

Q	=	basic activity threshold, GBq
Q'	=	patient-specific activity release threshold at administration, GBq

Patient-specific activity thresholds should be calculated before administration. This assures the licensee, and the patient are prepared in case the patient needs to be held following treatment. In addition, this allows the licensee to determine appropriate and realistic modifying factor values specific to each patient. Before administration, licensees should confirm that any instructions needed to ensure dose limits

are ones that the patient or caregivers can and are willing to follow; if not, a patient might not be able to be released in accordance with 10 CFR 35.75.

Modifying factors for geometry and attenuation can take values greater than 1 as described below. The assumption of unity for all four modifying factors, including occupancy and biokinetics, provides significant conservatism to account for this. However, if a licensee chooses to use realistic patient-specific information to modify occupancy or biokinetic factors, assuming 1 for geometry and attenuation without patient-specific information could result in underestimation of TEDE to the maximally exposed bystander. Therefore, if a licensee chooses realistic patient-specific information to modify occupancy or biokinetic factors, licensees should verify unity is conservative for geometry and attenuation factors before using it or the licensee should modify these factors. If a licensee chooses to use realistic patient-specific information to modify occupancy or biokinetic factors such that a record is required in accordance with 10 CFR 35.2075, "Records of the release of individuals containing unsealed byproduct material or implants containing unsealed byproduct material," a basis for geometry and attenuation factors should also be provided, as their values could realistically be greater than 1.

A patient questionnaire, such as that shown in figure B-1, is one acceptable method to gather patient-specific information. This questionnaire can be used to support selection of modifying factors for occupancy and geometry. Licensee information on the patient pertaining to biokinetic and attenuation modifying factors is assumed to be maintained separately. Modification of the survey is encouraged for the types of procedures performed at the medical facility. Licensees may need additional discussions based on the patient's responses to the questions to determine patient-specific modifying factors.

Patient Questionnaire to Determine Patient-Specific Occupancy and Geometry Modifying Factors to Ensure Compliance with 10 CFR 35.75 Release Criteria

Patient Name: **Referring Physician:**

Patient Identification Number: _____ **Age:**_____

Prescribed Dose:_____**Radiopharmaceutical:** _____

1. For female patients between 12-55 years old:
   - Confirmation that the patient is not pregnant
     - Date of negative pregnancy test: _____ (Should be within 24 hours of dosing)
     - Other (Tubal Ligation, Hysterectomy, etc.): _____
   - Is the patient breastfeeding? Yes _____ No _____ NA _____
2. What will be the mode of transportation for the patient to travel to place of residence (e.g., car, train, bus), how long will it take to travel, and who will be traveling with the patient?
   _____
3. List individuals who will have significant contact with the patient after administration. For each individual, list the type(s) of close contact to determine distance and geometry and length of time they expect to have contact with the patient? Consider all places where patient will spend significant time such as work and residence (Additional fields maybe necessary if the patient has significant contact with more individuals).

   The following questions should be used to support filling out the table.
   - Who will the patient reside with after administration?
   - Will the patient share a bed with anyone after administration?
   - Will the patient care for any young children or individuals requiring assistance?
   - Will the patient require living or medical assistance?
   - Will the patient have close contact at their occupation or other places outside their residence?

Person	Type of Close Contact	Length of Time (hrs/day)

4. Is the patient scheduled for travel, vacation, or medical procedure for 2 weeks after administration? Yes _____ No _____
5. Is the patient incontinent or have any urinary bladder control problems? Yes ____ No____
6. Is the patient able and willing to follow any necessary discharge instructions, including behavior restrictions, based on discussions before administration? Yes _____ No _____
7. Are there any other issues that would prevent the patient from being able to comply with radiation safety instructions? Yes _____ No _____
   Explain: _____

Individual completing questionnaire: _____ Date: _____

Individual who verified questionnaire answers and patient understanding of instructions (as necessary) on date of administration: _____ Date:_____

Figure B-1. Example patient questionnaire for determining patient-specific modifying factors

B.1 Modifying Factor for Occupancy, F_O

The basic dose assessment provided in the first-tier approach described in section C.1 assumes 100 percent occupancy of a bystander at 1 meter (m) from a patient for the entire decay of the administered activity without biological removal. These highly conservative assumptions serve as a basis for releasing patients without knowledge of patient-specific information. In the second-tier approach, licensees may modify this with patient-specific information using a modifying factor for occupancy, F_O. This factor represents the fraction of exposure the bystander receives compared to the total radiation released from the patient. To modify this factor, licensees need to understand when a bystander will be near the patient and for what length of time.

Licensees are permitted to release a patient if the exposure to any other individual is unlikely to exceed 5 mSv (0.5 rem). Therefore, if licensees chose to use the second-tier approach, licensees must determine the likely dose to the maximally exposed bystander to ensure compliance. All exposure scenarios expected for the patient should be evaluated to determine the maximally exposed bystander and use the occupancy factor for that individual as a basis for release. Licensees should note that the maximally exposed bystander is not always the bystander with the highest occupancy but is likely the bystander who has the highest product of both the geometry and occupancy factors.

While the maximally exposed bystander in most cases is an individual who lives with the patient, licensees should access other potential exposure scenarios, such as travel and work situations. The lower the proposed occupancy factor, the greater the justification for concluding that other exposure situations do not apply to the patient. To ensure bystander exposure is unlikely to exceed limits in 10 CFR 35.75, patient instructions should tell patients to limit contact with bystanders to less time than that used to determine the occupancy factor. When the licensee instructs a patient to follow specific behavior restrictions, the occupancy factor can be based on anticipated bystander exposure based on these instructions when appropriate and the patient states they are able and willing to follow the instructions.

When speaking to the patient, a licensee should determine the full set of scenarios for bystander exposure to the patient. This should include, but is not limited to, interactions expected during employment, travel especially using public transportation, hotel lodging, and time spent at home.

If a patient's contact with bystanders is expected to be relatively uniform throughout the entire period of biological removal and radioactive decay, licensees may set F_O to the fraction of time in a day that a bystander is expected to be exposed to the patient. In addition, the licensee may conservatively choose to set F_O to the maximum fraction of time in a day that a bystander is exposed to the patient without considering delay in exposure. This is demonstrated in appendix C.

However, for many scenarios, the fraction of time a bystander is exposed to a patient is expected to change throughout the period of biological removal and radioactive decay, which could impact bystander dose, such as when exposure occurs during long travel times. In these cases, licensees should either use the most conservative fraction or calculate separate components of the total occupancy factor for the different time periods, such as periods during and after travel. If the same bystander is exposed during multiple periods, the total modifying factor for occupancy is the sum of the occupancy factor for each period. Appendix C demonstrates this.

Occupancy during the initial period of time immediately following release, normally the travel period, is calculated as:

$$F_1 = s_1\left[e^{-0.693(n_0)} - e^{-0.693(n_0+n_1)}\right] \qquad \text{(equation B-3)}$$

where

F_1 = occupancy factor for the maximally exposed bystander during initial period, unitless
s_1 = fraction of time bystander spends in close contact with the patient during initial period, unitless
n_0 = number of effective half-lives between medical administration and patient release, unitless
n_1 = number of effective half-lives for the initial period following patient release, unitless

such that

$$n_0 = \frac{t_0}{T_e} \quad \text{(equation B-4)}$$

and

$$n_1 = \frac{t_1}{T_e} \quad \text{(equation B-5)}$$

where

t_0 = time between medical administration and patient release, h
t_1 = initial time period following patient release, h
T_e = effective half-life of the radionuclide in the patient, h

Note, if biological removal for the patient is not known, the radiological (physical) half-life can be conservatively used to replace the effective half-life. Licensees exercising this option for occupancy will automatically assign $F_B = 1$ and can skip section B.3.

In many travel situations (e.g., airplane, bus, car) when the patient travels with a companion, the bystander exposure fraction for close contact with the patient can be conservatively assumed to be 100 percent ($s_1 \approx 1$). Also, when time between medical administration and patient release is short relative to the effective half-live, t_0 can be conservatively assumed to be 0. Equation B-3 can also accommodate single exposure events for which the start and end times may be different from travel when necessary.

If occupancy is uniform after the initial period, the second occupancy factor can be calculated as:

$$F_2 = s_3\left[e^{-0.693(n_0+n_1)}\right] \quad \text{(equation B-6)}$$

where

F_2 = occupancy factor for the maximally exposed bystander after the initial period, unitless
s_3 = fraction of time bystander spends in close contact after the instruction period, unitless

In equation B-6, the fraction of time the bystander spends in close contact with the patient is expected to be constant after t_1. This fraction of time should be based on the typical patient and bystander relationship without instructions as determined by the licensee through patient-specific discussions.

If a licensee needs to include more realism as a basis to demonstrate compliance with 10 CFR 35.75, licensees should include occupancy considerations during an additional period of time. For example, a licensee may decide to include the effect of instructions on the occupancy factor. Note, licensees should only include the effect of instructions on the occupancy factor if the licensee has determined that a patient is willing and able to follow instructions to minimize bystander exposure. Occupancy for exposure after travel that includes behavior modifications during the instructional period can be calculated as:

$$F_2 = s_2\left[e^{-0.693(n_0+n_1)} - e^{-0.693(n_0+n_1+n_2)}\right] + s_3\left[e^{-0.693(n_0+n_1+n_2)}\right] \quad \text{(equation B-7)}$$

where

F_2 = occupancy factor for the maximally exposed bystander after travel, unitless
s_2 = fraction of time bystander spends in close contact during the instruction period, unitless
s_3 = fraction of time bystander spends in close contact after the instruction period, unitless
n_2 = number of effective half-lives for the instruction period, unitless

such that

$$n_2 = \frac{t_2}{T_e} \quad \text{(equation B-8)}$$

where

t_2 = instruction period duration, h
T_e = effective half-life of the radionuclide in the patient, h

It is inappropriate and unrealistic to assume a patient will isolate or physically separate from bystanders if the patient has difficulty understanding or following dose-minimizing instructions, such as someone needing assistance to perform daily tasks. In addition to direct discussions with the patient, questionnaire responses can be useful to determine whether a patient can follow instructions and be anticipated to reduce contact with bystanders. If the licensee does not have confidence the patient is willing and able to adjust behavior during the instructional period, it should not adjust the occupancy factor based on instructions and should use equation B-6. If the licensee determines that a patient is willing and able to follow instructions to minimize bystander exposure, then it can modify s_2 based on the instruction and use equation B-7 instead.

In accordance with 10 CFR 35.2075(a)(2), a record of the basis for authorizing release is required when an occupancy factor less than 0.25 at 1 m is used. A patient questionnaire, similar in format to figure B-1, and its conclusions may be used as a basis for patient-specific information. Licensees should exercise caution when determining low occupancy factors. If the occupancy factor for demonstrating compliance is determined to be less than 0.1 due to minimal close contact with bystanders on a typical basis, licensees should obtain detailed knowledge of the patient's specific plans following treatment, including planned residence and travel, to ensure the instructions match this expected behavior and justify the maximum bystander exposure is not likely to exceed 5 mSv (0.5 rem).

B.2 Modifying Factor for Geometry, F_G

For the basic dose assessment described in section 1, the geometry between a patient and the bystander was conservatively assumed to be a point source to a single exposure point on the bystander. A distance of 1 m was also assumed as a conservative estimator for typical close contact over time.

Licensees may modify the geometry to provide realism using the geometry modifying factor. The geometry modifying factor, F_G, is a unitless factor to represent the dose rate ration for a source-bystander geometry at a distance, r, compared to the dose rate using the basic conservative point-to-point geometry. As shown in table B-1, this factor is highly dependent on the patient-to-bystander separation distance (Ref. B-1). F_G is set to unity (1) in the basic assessment. When performing patient-specific calculations that remove conservatism from other factors, licensees should verify patients are not expected to have significant close contact at distances less than 1 m before selecting 1 for F_G. In addition, the geometry factor can be modified to remove conservatism from an assumption that both the source and bystander are points (Ref. B-1).

Table B-1 provides F_G for a variety of distances and geometries. These values are similar to, but more conservative than, those described in Report No. 155 by the National Council on Radiation Protection and Measurements (NCRP) Report No. 155, "Management of Radionuclide Therapy Patients," issued December 2006 (Ref. B-2, section A.1.3). For simplicity, licensees may conservatively choose to use unity (1) for the modifying factor in patient-specific calculations when the patient is not expected to spend a significant amount of time closer than 1 m to a bystander. For many patients, licensees may have confidence this condition will be met through discussions and instructions. However, licensees may need to modify F_G to be greater than 1 for situations where a patient is expected to spend significant time at distances of less than 1 m to a bystander. This is especially important to prevent underestimations of exposure when contact is within two effective half-lives following administration and a licensee uses a realistic and less conservative occupancy factor. Example situations of contact closer than 1 m include patients who need mobility assistance or other significant close-contact care, will spend time holding another person such as a child, will be traveling immediately after release, or intend to sleep in the same bed with another person following treatment. Patient instructions must match or recommend a farther distance than used to determine F_G to demonstrate compliance with 10 CFR 35.75.

Licensees may conservatively use the point-point geometry for all scenarios. However, the point-point assumption greatly overestimates doses at very close distances. If more realism is needed as a basis for release, licensees should select a different geometry for the bystander based on distribution of the radioisotope in the patient and the size of the bystander. Point-line refers to a point-like source inside a patient at a distance from the end of a 0.7 m line representing sensitive organs in a typical adult bystander. Point-line geometry is recommended for calculating adult bystander exposure to point-like sources such as implants or radionuclides concentrating in a particular organ (e.g., hyperthyroid retention of radioiodine in the thyroid or prostate implants). Line-line refers to a broad 1.7 m source length inside a patient with a 0.7 m line for the bystander. Line-line geometry is recommended for calculating adult bystander exposure in cases of more widely distributed radionuclides within the patient's body (e.g., radioiodine treatment for thyroid cancer). Because the receptor line is modeled for a typically sized adult, licensees should not use line-line geometry to calculate external exposure of a child but can use a point source across from the end of a line as described in supporting documentation (Ref. B-1) or assume the conservative point-point geometry for small children. Alternatively, licensees may make patient-specific geometric adjustments or perform more detailed three-dimensional modeling to calculate F_G (Ref. B-1). Appendix C demonstrates a selection of geometry factors. As shown in table B-1, added realism for irradiation geometry is more meaningful for separating distances of less than 2 m.

Table B-1. Geometric Modifying Factors, F_G, at Various Bystander Separation Distances, r (m)

Patient-to-Bystander Separation Distance, r (m)	Point-Line[a] F_G (unitless)	Line-Line F_G (unitless)	Point-Point F_G (unitless)
0.3 (typical for mobility assistance, holding child[b], holding while co-sleeping[b])	5.6	4.6	11
0.5	2.7	2.3	4.0
0.7 (typical for travel seating)	1.6	1.4	2.0
1.0 (typical for close contact[b] activities)	0.87	0.79	1
1.5	0.42	0.39	0.44
2.0	0.25	0.25	0.25
Distances greater than 2 m	$\frac{1}{r^2}$	$\frac{1}{r^2}$	$\frac{1}{r^2}$

a. Point-line geometry models point-like concentration of radionuclide activity in the patient across from one end of the line representing sensitive organs in the bystander (Ref. B-1). These geometries would be typical for radionuclide concentrations in the thyroid or prostate.

b. Distances provided in NCRP Report No. 155. Licensees are permitted to use distances from 0.3 m to 1.0 m for co-sleeping when conditions for the specific patient justify use of those distances.

Licensees cannot authorize release in accordance with 10 CFR 35.75 without considering dose to a travel partner or other bystanders if it is possible that dose limits could be exceeded. This includes public transportation and ride sharing. Travel includes the return trip home (or to work) and would include time spent in lodging during the trip. When the patient travels alone using private transportation, exposure to members of the public during travel would be small and can be neglected when the maximally exposed bystander is associated with exposure after travel. Judgment should be applied on when and to whom external doses are expected to be the largest. For the combination of very short-lived radionuclides with patient travel times that represent several half-lives, retained activity in the patient after travel can be a small fraction of that at the beginning of travel. In this situation, the travel period would be important to consider. Include both occupancy (time spent) and geometry (separation distance) in exposure considerations when exposure is expected to be significant at distances closer than 1 m. For patients who require mobility assistance or aid, another person can be assumed to hold that person for 2 h per day unless patient-specific details indicate differently. Although exposures to bystanders more than 3 m away and not within the direct line of sight of the patient are seldom limiting, patients who live alone in an apartment or other facility with nearby occupants may expose those bystanders for prolonged periods of time.

B.3 Modifying Factor for Time-Integrated Biokinetics, F_B

The biokinetics factor, F_B, is the fraction for the total disintegrations occurring in the patient relative to the total disintegrations of the administered activity. Licensees may use retention data from a single point in time to determine a conservative estimation of the biokinetic modifying factor as shown:

$$F_{\mathrm{B}} = \frac{T_e}{T_r} = -\frac{0.693\ t_n}{T_r \cdot \ln(R_n)} \qquad \text{(equation B-10)}$$

where

T_e = effective half-life of the radionuclide in the patient, h
T_r = radiological (physical) half-life for the radionuclide, h
t_n = time after administration when latest retention fraction is determined, h
R_n = retention fraction in the patient at time t_n after administration, unitless

Values for t_n and R_n represent a data point in the patient's retention curve. Note that $t_n > 48$ h is recommended for radionuclides with $T_r > 24$ h. For example, given a patient who exhibits a 19 percent retention, or R_n, 96 h after administration of a radionuclide with a radiological half-life of 160 h, equation B-5 yields:

$$F_{\mathrm{B}} = -\frac{0.693 \cdot 96\ h}{160\ h \cdot \ln(0.19)} = 0.24. \qquad \text{(equation B-11)}$$

As an alternative to equation B-11, licensees with patient retention data for the radiopharmaceutical can use the generalized template shown in figure B-2. After plotting patient retention data on the template, the retention curve can be drawn from the initial point at 100 percent through each data point. The value of F_B equals the smallest template value intercepted by the data. To accommodate all radionuclides, time after administration was converted into the number of radiological half-lives. For the same example above with a radiological half-life of 160 h, 96 h represents 0.6 radiological half-lives. Plotting 19 percent at 0.6 radiological half-lives generates a data point below the dashed line for 0.3. Thus, $F_B = 0.3$ from the template in figure B-2, which is slightly more conservative than equation B-7. Radionuclide retention can also be inferred from several dose rate measurements at the same distance

from the patient. For therapeutic procedures with a pretreatment planning administration, the patient's pretreatment may be able to estimate retention for the therapeutic dosage of the radiopharmaceutical.

When retention data are unknown, F_B can be conservatively be set to unity (1). Licensees may also assume the patient exhibits slow biological clearance according to the manufacturer or peer reviewed scientific journal article excretion information unless the patient's medical condition or voiding habits affect biological clearance and excretion rates. Medical conditions such as reduced kidney or liver function may affect clearance rates. For permanent encapsulated implants or seeds, or when biological clearance rates are unknown, licensees should use $F_B = 1$.

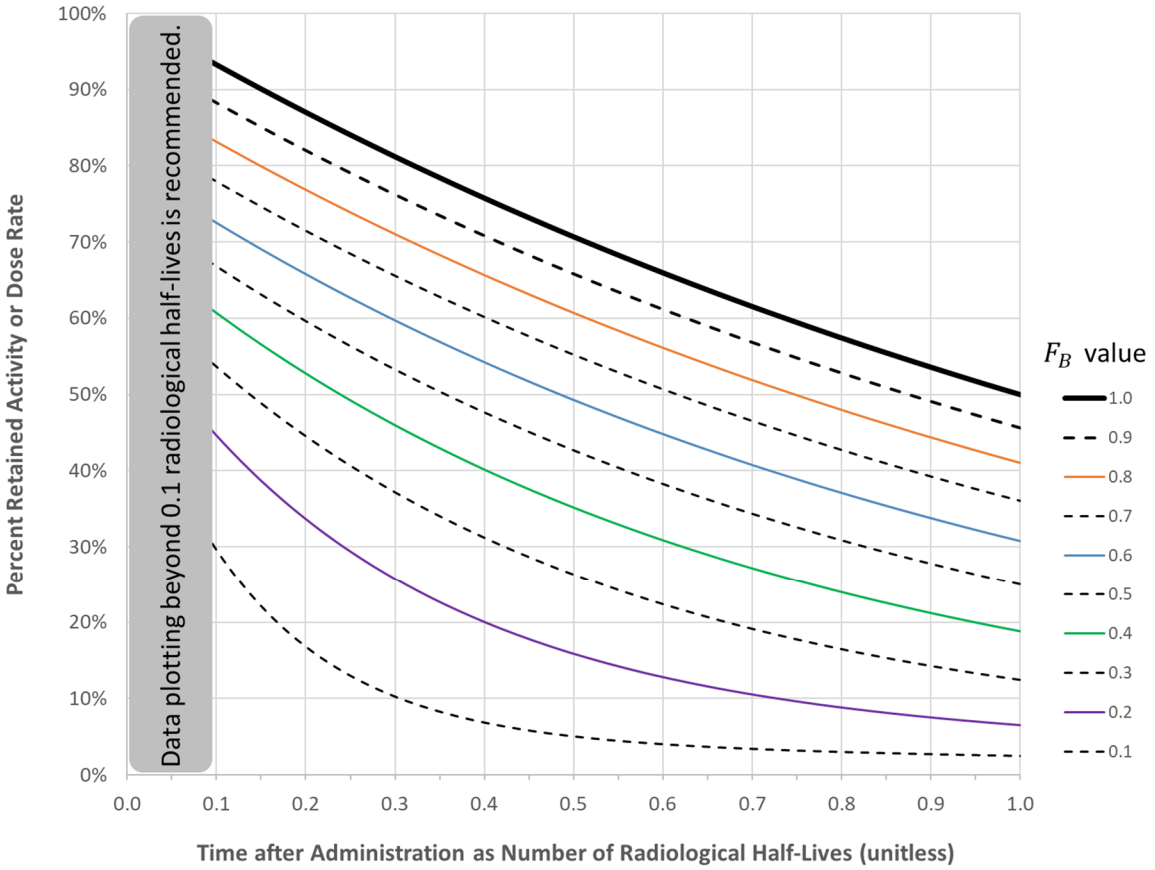

Figure B-2. Generalized graphical template to determine F_B from patient retention data

Mathematical integration of more detailed retention functions (e.g., double exponential relationships for fast and slow clearance) provides the greatest flexibility when specific exposure times are either known or approximated from patient-specific data. Equations in this subsection were derived from mathematical integration with radiopharmaceutical retention modeled by a single exponential. Modifications for double exponential retention can be pursued on a case-by-case basis. This is demonstrated in example D in appendix C. Supporting details are available (Ref. B-1).

B.4 Modifying Factor for Attenuation, F_A

The modifying factor for attenuation, F_A, accounts for photon scatter, buildup, and absorption at patient tissue thicknesses different than standard zero thickness of tissue. F_A is unitless. Provided in appendix A, dose rate constants from a point source at 1 m assume no shielding from tissue and were used

in calculating the activity and measurement thresholds in tables 1 and 2. These thresholds can be modified using F_A to account for photon scatter, buildup, and absorption in tissue. As an example, figure B-3 provides the influence of tissue thickness on the standard dose rate constant for technetium-99m. As shown, values of F_A can exceed unity (1) when photons only travel through a short distance of tissue before leaving the body. Patient attenuation and buildup can be significant; F_A should be justified in the calculation of patient-specific thresholds when other patient-specific modifying factors are used to remove conservatism. For simplicity, licensees should choose the most conservative value provided in table A-1 when tissue thickness is unknown. However, when licensees wish to include more patient-specific realism, they should select the tissue thickness appropriate for the patient by estimating torso radius for widely distributed radionuclides or the thickness of tissue overlying the thyroid for radioiodine treatments. Attenuation factors have been precalculated for 40 radionuclides and are provided in plots (Ref. B-1).

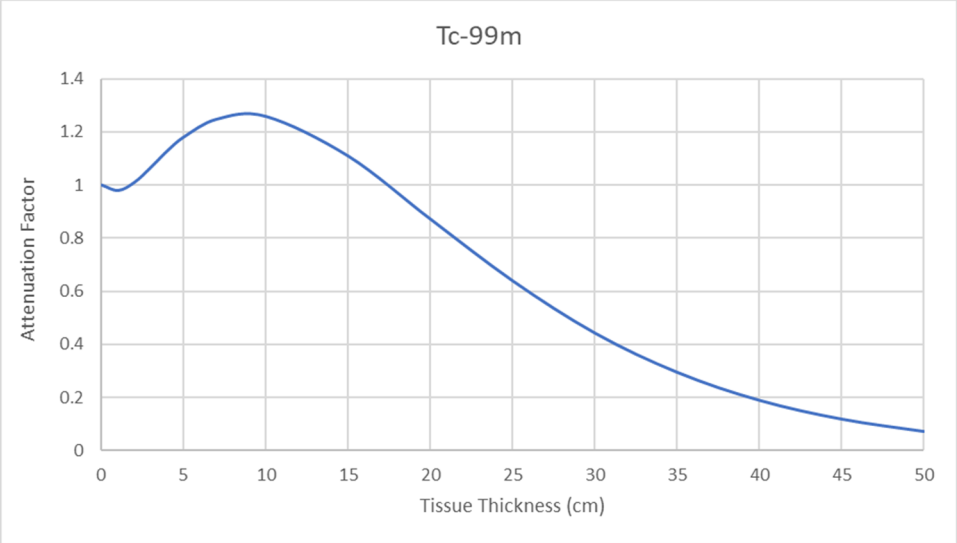

Figure B-3. Attenuation modifying factor for Tc-99m as a function of attenuating tissue thickness

REFERENCE FOR APPENDIX B

B-1. RCD Radiation Protection Associates. RCD-21-181-0, "Activity Thresholds, Patient-Specific Modifying Factors, Breastfeeding Interruption Times, and Other Supporting Data," Research Information Letter Report for Phase 2 Revisions to Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material," Corvallis, Oregon, June 30, 2021. (Agencywide Documents Access and Management System Accession No. ML21348A111)

B-2. National Council on Radiation Protection and Measurements (NCRP) Report No. 155, "Management of Radionuclide Therapy Patients," Bethesda, Maryland, December 2006.[2]

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1 Publicly available NRC published documents are available electronically through the NRC Library on the NRC's public website 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, Maryland. For problems with ADAMS, contact the PDR staff at (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; or email pdr.resource@nrc.gov.

2 Copies of reports from the National Council on Radiation Protection and Measurements (NCRP) may be obtained through its website: http://www.ncrponline.org/Publications/Publications.html or by writing to the NCRP at 7910 Woodmont Avenue, Suite 400, Bethesda, Maryland 20814-3095, Phone: (301) 657-2652, fax: (301) 907-8768.

APPENDIX C

EXAMPLE CALCULATIONS

Several examples illustrate the methodologies discussed in this guide.

EXAMPLE A—RELEASE OF PATIENT BASED ON ADMINISTERED ACTIVITY

A 56-year-old male receives an administration of 1.29 gigabecquerels (GBq) of yttrium (Y)-90 microspheres for the treatment of hepatocellular carcinoma. As shown in columns 1 and 2 of table 1 in this regulatory guide, the basic activity thresholds are 34 GBq for authorizing patient release and 6.8 GBq for requiring dose-minimizing instructions. Because the administered activity of 1.29 GBq is below these basic thresholds, the licensee is authorized to release the patient without dose-minimizing instructions. Although some licensees may independently decide to issue dose-minimizing instructions to the patient, there is no regulatory requirement to do so. In this case, a patient-specific determination of modifying factors for biokinetics, occupancy, geometry, and attenuation is unnecessary. A record of instructions provided to the patient is not required.

EXAMPLE B—RELEASE OF PATIENT WHO IS BREASTFEEDING

A 35-year-old female, who is breastfeeding a child, receives 0.74 GBq of fluorine (F)-18 fluorodeoxyglucose for positron emission tomographic imaging. From columns 1 and 2 of table 1, the basic activity release threshold for F-18 is 13 GBq, and the threshold for instruction is 2.5 GBq. The assessment progresses through multiple stages as numerated in figures C-1 and C-2 and described below.

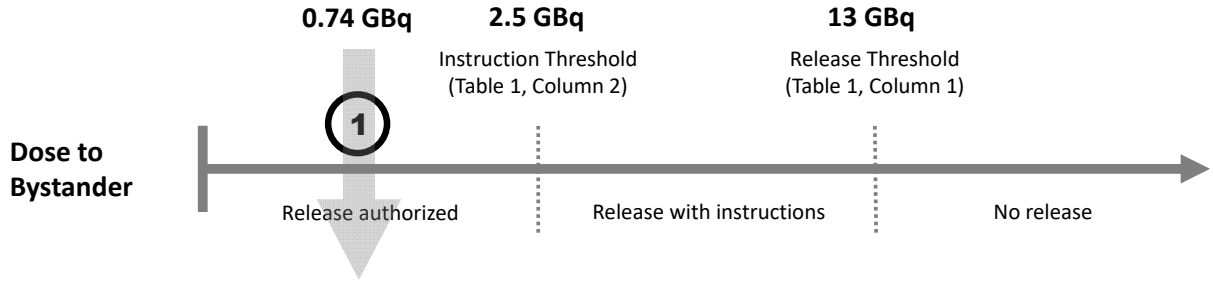

Figure C-1. Administered activity comparison to instruction and patient release thresholds

The administered activity is less than both basic thresholds (release and instruction). Dose-minimizing instructions are not required to satisfy regulatory requirements for Title 10 of the *Code of Federal Regulations* (10 CFR) 35.75(a). Although some licensees may independently decide to issue dose-minimizing instructions in the patient's discharge instructions, there is no regulatory requirement to issue instructions. In this case, a patient-specific determination of modifying factors for biokinetics, occupancy, geometry, and attenuation is unnecessary.

Because the patient is breastfeeding, dose to the child from nursing is initially assessed assuming no breastfeeding interruption. From column 2 of table 3 in the regulatory guide, the administered activity of 0.74 GBq is shown to exceed the 1 millisievert (mSv) (0.1 rem) activity threshold $Q_{B|ins}$ of 0.20 GBq. Therefore, the licensee must provide guidance on the interruption or discontinuation of breastfeeding and information on the potential consequences, if any, of failure to follow such guidance.

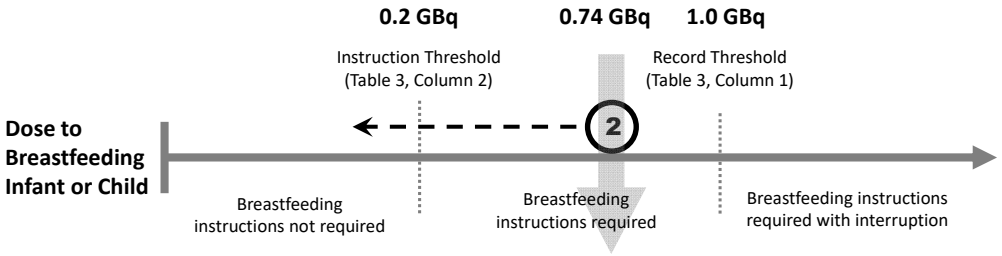

Figure C-2. Administered activity comparison to breastfeeding thresholds

The licensee provides guidance to the patient with a breastfeeding interruption time corresponding to a child dose of less than 1 mSv (0.1 rem). From column 2 of table 3, the retained activity in the patient of 0.20 GBq for $Q_{B|ins}$ equates to a child dose of 1 mSv (0.1 rem) for breastfeeding. For F-18 ($T_r = 1.83$ h) fluorodeoxyglucose, the licensee estimates the biological half-life specific to this patient as $T_b = 100$ h. The effective half-life is calculated as 1.80 h from equation 5 in the main body of this guide. According to equation 6 for a retained activity equaling the tabulated $Q_{B|ins}$ value of 0.20 GBq, the breastfeeding interruption time is calculated to be 3.4 hour (h) from $1.44 \cdot 1.80 \cdot \ln\left(\frac{0.74}{0.20}\right)$. This interruption time is consistent with the recommendation in table 4 in this regulatory guide.

Because the administered activity exceeds $Q_{B|ins}$, the licensee is required to issue breastfeeding instructions if the patient could be breastfeeding after release. The patient can be released with instructions to interrupt breastfeeding and discard breastmilk for the specified time. As an alternative to discarding pumped breastmilk, breastmilk storage for radioactive decay can be permitted under direction by the licensee if desired. Because the administered activity did not exceed the record threshold $Q_{B|rec}$ of 1 GBq shown in column 1 of table 3, a record of instructions provided to the patient is not required.

EXAMPLE C—USE OF QUESTIONNAIRE TO DETERMINE MODIFYING FACTORS

Information collected by the questionnaire can support modifying factor selection. Two examples of completed questionnaires for different patients emphasize the occupancy factor. The geometric modifying factor is also discussed in the context of determining the maximally exposed bystander. Other examples in this appendix address determinations for the remaining modifying factors.

Example 1: A patient rides 1 h home in a private automobile driven by their spouse after a medical administration of a radiopharmaceutical with an effective half-life of 30 h. The patient agrees to ride in the back of the car as far as possible away from their spouse during the drive. The patient lives only with their spouse and agrees to sleep alone and isolate for the first day but needs mobility assistance for about 2 h a day from then on. The patient is retired and agrees to minimize exposures to others.

In this example, the maximally exposed bystander is the spouse. For simplicity, this licensee chooses to conservatively set the occupancy factor based on the time that the patient needs mobility assistance, ignoring the first day with less exposure. Therefore, F_O is set to $\frac{2}{24}$ or approximately 0.08, and the licensee assigns F_G to 5.6 for mobility assistance, assuming a point-line geometry from table B-1, which is more conservative than the line-line geometry for a radionuclide distributed in the patient. While this will overestimate exposure, the licensee chooses to not do further calculations, as they are unnecessary in this example to justify release. During the day of administration, the patient indicates that sometimes she receives her grandson after daycare when a family member attends an infrequent afternoon appointment. This rarely happens and is estimated to occur about once a month. When this does occur, the patient explains that she spends about 90 minutes of close contact with the child, who is 2 years old.

To evaluate the potential for exposure to a child, the licensee approximates the child's length to be 0.7 m. This length equals the bystander length used in table B-1 for the point-line irradiation geometry. Therefore, the licensee assigns F_G to 5.6. In other words, the geometric modifying factor for exposure of the child equals the conservative geometric modifying factor of 5.6 selected by the licensee for the bystander who provides mobility assistance to the patient. Because the occupancy factor for close contact with a child for 90 minutes will be less than that for the bystander who provides 2 h of mobility assistance per day, the child will not be the maximally exposed bystander even if close contact with the child were to occur following patient release. The licensee updates the release documentation with this additional information and releases the patient.

Example 2: On Friday afternoon, a patient travels home by private automobile without a companion after a medical administration of a radiopharmaceutical with an effective half-life of 60 h. The patient lives alone and returns to work on Monday morning. Figure C-3 shows a completed questionnaire.

The maximally exposed bystanders will likely be coworkers, as this patient lives and travels home alone in a private vehicle. Because the patient does not expect to return to work until Monday morning, the total time elapsed between administration and the start of coworkers' prolonged exposure is about 66 h or $\frac{66}{60} = 1.1$ effective half-lives. Through discussion with the patient, the licensee understands the patient's typical workday is 8 h. For an 8-h workday, the fraction of time for bystander close contact, s_3, is $\frac{8}{24}$ or approximately 0.33. As this is the only expected significant occupancy, licensees could choose to conservatively use 0.33 for F_O for simplicity.

If more realism is desired, licensees could perform further calculations to account for decay before the first exposure. For this patient, equation B-3 is not necessary for calculating the occupancy factor because there is no bystander exposure during travel. Additionally, there is no close bystander contact during the instruction period while the patient is home alone before returning to work. For these conditions, equation B-6 simplifies as follows:

$$F_2 = s_3\left[e^{-0.693(n_0+n_1+n_2)}\right] \qquad \text{(equation C-2)}$$

where

F_2	=	occupancy factor for the maximally exposed bystander after travel, unitless
s_3	=	fraction of time for bystander close contact after the instruction period, unitless
$n_0 + n_1 + n_2$	=	total effective half-lives elapsed between medical administration and bystander exposure, unitless

For the parameter values described above, the following calculation is performed

$$F_2 = 0.33\left[e^{-0.693(1.1)}\right] = 0.15 \qquad \text{(equation C-3)}$$

The occupancy factor, F_O, is 0.15 for this patient. In this example, the licensee uses table B-1 to determine the geometry factor for a patient-to-bystander separation distance of 2.7 m (9 ft) for the closest bystander at work. Although the administration is expected to spread throughout the patient's body, table B-1 indicates that the geometry factor can be reasonably approximated by $\frac{1}{r^2}$ for separation distances greater than 2 m. Therefore, the more realistic geometry factor is $F_G = \frac{1}{2.7^2} = 0.14$ for the coworker as the maximally exposed bystander.

EXAMPLE FOR ILLUSTRATION

Patient Questionnaire to Determine Patient-Specific Occupancy and Geometry Modifying Factors to Ensure Compliance with 10 CFR 35.75 Release Criteria

Patient Name: Jane Doe **Referring Physician:** Elizabeth Majors MD

Patient Identification Number: JD063864229 **Age:** 63

Radiopharmaceutical: Lu-177 dotatate (LUTATHERA) **Prescribed Dose:** 7.4 GBq

1. For female patients between 12-55 years old:
   - Confirm patient is not pregnant. Is the patient pregnant? Yes ___ No ___ Unknown ___ NA ✓
     - Date of negative pregnancy test: n/a, age > 55 (Should be within 24 hours of dosing)
     - Other (Tubal Ligation, Hysterectomy, etc.): _____
   - Is the patient breastfeeding? Yes ___ No ✓ NA ___
2. Patient travel
   - Mode of transportation to patient's place of residence (e.g., car, train, bus, etc.)? own car
   - How long will it take to travel, and who will be traveling with the patient? _____
     10 minutes. No travel companion. Patient plans to drive herself home.
3. List individuals who will have significant contact with the patient after administration. For each individual, list the type(s) of close contact to determine distance and geometry and expected length of time they expect to have contact with the patient. Consider all places where patient will spend significant time such as work and residence. Additional entries may be necessary if the patient has significant contact with more individuals.
   The following questions should be used to support filling out the table.
   - Who will the patient reside with after administration?
   - Will the patient share a bed with anyone after administration?
   - Will the patient care of any young children or individuals requiring assistance?
   - Will the patient require living or medical assistance?
   - Will the patient have close contact at their occupation or other places outside their residence?

Person	Type of Close Contact with Patient	Length of Time (hours per day)
Coworker	Work stations are separated by 9 feet	8 hours per workday

4. Is the patient scheduled for travel, vacation, or medical procedure for 2 weeks after administration? Yes _____ No ✓
5. Is the patient incontinent or have any urinary bladder control problems? Yes _____ No ✓
6. Is the patient able and willing to follow any necessary discharge instructions, including behavior restrictions, based on discussions before administration? Yes ✓ No _____
7. Are there issues preventing the patient from being able to comply with radiation safety instructions? Yes _____ No ✓
   Explain: _____

Individual completing questionnaire: (signature to be completed) Date: (date)

Individual who verified questionnaire answers and patient understanding of instructions (as necessary) on date of administration: (signature to be completed) Date: (date)

Figure C-3. Completed questionnaire for example patient who lives and travels home alone

Example 3: A different patient travels a long distance with a companion to arrive at the medical facility for the same radiopharmaceutical administration and effective half-life of 60 h. The companion is the patient's spouse, and they share a bed. The patient is released 6 h after the administration. This delay time equates to $\frac{6}{60} = 0.1$ effective half-lives. The spouse and patient travel together on Friday and during the weekend and return home on Sunday. The full duration of travel is estimated to be 42 h after release or $\frac{42}{60} = 0.7$ effective half-lives. Through a discussion with the licensee, the patient indicated that during the day at home, close contact with the spouse is not expected. At night, however, the patient will typically spend 8 h (equal to 0.33 fraction of a day) in the same bed, and the patient is unable to change this pattern. Based on discussions with the patient, the licensee determines that the maximally exposed bystander is the patient's spouse. Figure C-4 shows a completed patient questionnaire.

Exposure to the patient's spouse should be considered during travel and at home after travel. The licensee conservatively assumes the patient is in close contact with the spouse during the entire trip. The occupancy factor is calculated from equations B-3 and B-6. Occupancy during travel is calculated as:

$$F_1 = s_1\left[e^{-0.693(n_0)} - e^{-0.693(n_0+n_1)}\right] \quad \text{(equation C-4)}$$

where

F_1 = occupancy factor for the maximally exposed bystander during travel, unitless
s_1 = fraction of time bystander spends in close contact with the patient during travel, unitless
n_0 = number of effective half-lives between medical administration and patient release, unitless
n_1 = number of effective half-lives for the initial period following patient release, unitless

For the parameter values described above, the following occupancy calculation is performed during travel:

$$F_1 = 1\left[e^{-0.693(0.1)} - e^{-0.693(0.1+0.7)}\right] = 0.36 \quad \text{(equation C-5)}$$

After travel, no difference in behavior is expected for this patient. As shown in figure C-4, the patient is not willing to follow behavior changes in posttreatment instructions to minimize exposure to bystanders. For this reason, an instruction period, during which restrictions would be followed, is unnecessary for determining bystander occupancy after travel. Therefore, the licensee uses equation B-6

$$F_2 = s_3\left[e^{-0.693(n_0+n_1)}\right] \quad \text{(equation C-6)}$$

For the parameter values described above, bystander occupancy during the potential second exposure after travel is calculated as

$$F_2 = 0.33\left[e^{-0.693(0.1+0.7)}\right] = 0.19 \quad \text{(equation C-7)}$$

Because bystander occupancy during and after travel relate to the same person (patient's spouse), these results are summed to yield an occupancy factor of 0.55 for the maximally exposed bystander.

As the patient co-sleeps with their spouse, the licensee selects the most conservative patient-to-bystander separation distance of 0.3 m. Because the radionuclide does not remain in a single location of the patient's body, the licensee selects the line-to-line exposure geometry, which results in a geometry factor F_G of 4.6.

Figure C-4 also shows that the licensee elected to not estimate overlying tissue thickness when acquiring patient-specific information to reduce conservatism and modify thresholds. Use a conservative

value when patient-specific modification is pursued, and no information is available to justify a modifying factor. In this case, the largest value of 1.25 is selected for the attenuation factor, as found in table A-1 for the administered radionuclide.

EXAMPLE FOR ILLUSTRATION

Patient Questionnaire to Determine Patient-Specific Occupancy and Geometry Modifying Factors to Ensure Compliance with 10 CFR 35.75 Release Criteria

Patient Name: Samantha Jacobs **Referring Physician:** Gerard Polk MD

Patient Identification Number: SJ71148065 **Age:** 72

Radiopharmaceutical: Lu-177 dotatate (LUTATHERA) **Prescribed Dose:** 7.4 GBq

1. **For female patients between 12-55 years old:**
   - **Confirm patient is not pregnant. Is the patient pregnant? Yes ___ No ___ Unknown ___ NA ✓**
     - **Date of negative pregnancy test:** n/a, age > 55 **(Should be within 24 hours of dosing)**
     - **Other (Tubal Ligation, Hysterectomy, etc.):** _____
   - **Is the patient breastfeeding? Yes ___ No ✓ NA ___**
2. **Patient travel**
   - **Mode of transportation to patient's place of residence (e.g., car, train, bus, etc.)?** personal car
   - **How long will it take to travel, and who will be traveling with the patient?** A 3-day trip is planned after release with two overnight stays in a hotel. Travel companion is the patient's spouse.
3. **List individuals who will have significant contact with the patient after administration. For each individual, list the type(s) of close contact to determine distance and geometry and expected length of time they expect to have contact with the patient. Consider all places where patient will spend significant time such as work and residence. Additional entries may be necessary if the patient has significant contact with more individuals.**
   The following questions should be used to support filling out the table.
   - **Who will the patient reside with after administration?**
   - **Will the patient share a bed with anyone after administration?**
   - **Will the patient care of any young children or individuals requiring assistance?**
   - **Will the patient require living or medical assistance?**
   - **Will the patient have close contact at their occupation or other places outside their residence?**

Person	Type of Close Contact with Patient	Length of Time (hours per day)
Spouse	Spouse and patient share a bed	8 hours per day

4. **Is the patient scheduled for travel, vacation, or medical procedure for 2 weeks after administration? Yes ✓ No _____**
5. **Is the patient incontinent or have any urinary bladder control problems? Yes _____ No ✓**
6. **Is the patient able and willing to follow any necessary discharge instructions, including behavior restrictions, based on discussions before administration? Yes ✓ No _____**
7. **Are there issues preventing the patient from being able to comply with radiation safety instructions? Yes ✓ No _____**
   Explain: Patient shares a bed with spouse and is unwilling to change this routine.

Individual completing questionnaire: (signature to be completed) **Date:** (date)

Individual who verified questionnaire answers and patient understanding of instructions (as necessary) on date of administration: (signature to be completed) **Date:** (date)

Figure C-4. Completed questionnaire for example patient with a travel and living companion

EXAMPLE D—RELEASE OF PATIENT BASED ON PATIENT-SPECIFIC INFORMATION

A 46-year-old female receives 2.0 GBq of iodine (I)-131 as sodium iodide for hyperthyroidism (i.e., thyroid ablation). From columns 1 and 2 of table 1, the basic activity threshold of I-131 for patient release is 0.32 GBq and the threshold over which instructions are needed to be provided is 0.063 GBq. The administered activity is greater than both basic thresholds. The licensee proceeds to the second tier approach and calculates patient-specific thresholds to determine whether immediate release is allowable.

Applying a double exponential model for I-131 retention, the licensee determines uptake fractions of 0.2 and 0.8 are appropriate for the extrathyroidal and thyroid components for this specific patient with respective effective half-lives of 7.7 h and 125 h. The biokinetic modifying factor for double exponential retention is calculated as a weighted sum of effective half-lives relative to the radiological half-life (Ref. C-2):

$$F_B = \frac{(0.20)(7.7\text{ h}) + (0.80)(125\text{ h})}{192\text{ h}} = 0.53. \qquad \text{(equation C-8)}$$

During initial treatment plan discussions, the patient stated that she will be sleeping with her spouse 8 h a day at home but can have minimal contact the rest of the day. The licensee determined that the spouse was the maximally exposed individual and the patient-specific occupancy factor was estimated to be 0.33. Because the patient's sleeping accommodations at home are spacious and holding while sleeping is not typical for this couple, the licensee estimates the geometry factor to be 0.87 from table B-1 for a separation distance of 1 m for close contact with a point-like source for I-131 concentrated in the thyroid. To account for attenuation and buildup for this patient, the licensee assigns 2 centimeters (cm) as the tissue thickness overlying the thyroid and obtains F_A = 1.0 from figure C-5, as reproduced from precalculated plots (Ref. C-2).

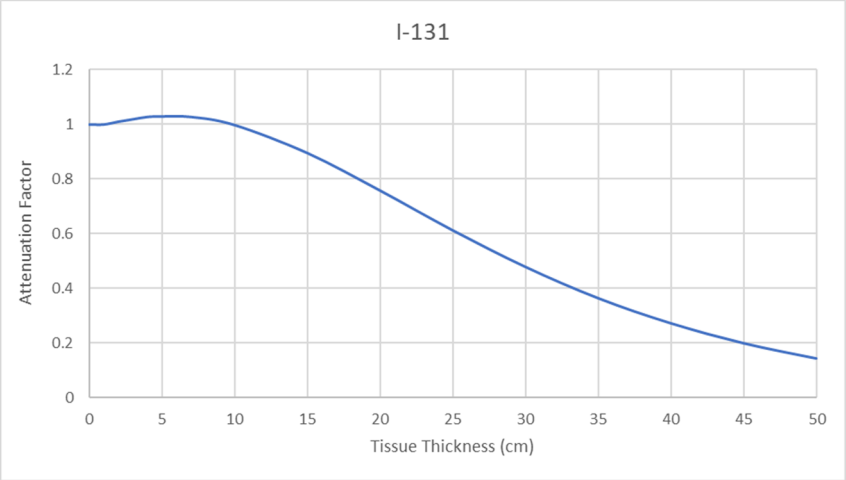

Figure C-5. Attenuation modifying factor for I-131 as a function of attenuating tissue thickness

Using this initial information and equation 8 (of section 2 in the main body), the licensee calculates the following patient-specific thresholds for release and instruction:

$$Q'_{rel} = \frac{0.32\ GBq}{0.53 \cdot 0.33 \cdot 0.87 \cdot 1.0} = 2.1\ GBq \qquad \text{(equation C-9)}$$

and

$$Q'_{ins} = \frac{0.063\ GBq}{0.53 \cdot 0.33 \cdot 0.87 \cdot 1.0} = 0.41\ GBq \qquad \text{(equation C-10)}$$

The patient is authorized for release with dose-minimizing instructions following the 2.0 GBq administration, and 10 CFR 35.2075, "Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material," requires a record of the basis for release.

EXAMPLE E—RELEASE OF PATIENT AFTER A HOLD TIME

A 63-year-old male receives the first administration of 18.5 GBq of I-131 iobenguane (AZEDRA) for cancer treatment. From columns 1 and 2 of table 1, the basic activity threshold of I-131 for patient release is 0.32 GBq, and the threshold over which instructions are needed to be provided is 0.063 GBq. The administered activity is greater than both basic thresholds. The licensee decides to calculate patient-specific thresholds to determine whether immediate release is allowable and whether instructions are required. An evaluation of patient release initially considers release at 56 h after administration and the patient's spouse accompanying the patient on the 1 h trip home by private automobile. In accordance with the licensee's direction and instruction, the patient agrees to sleep in a separate bed and minimize close contact with others for 7 days after returning home but requires physical assistance while at home. Dose-minimizing instructions are prepared consistent with these restrictions, and the daily close contact for physical assistance is assumed to be 2.4 h (10 percent) during the instruction period. After the instruction period of 7 days, the licensee anticipates that the patient and spouse will resume sharing a bed during the night and increases the fraction of daily close contact to 12 h (50 percent) after the instruction period.

The licensee obtains biokinetic information from pretreatment dosimetric data and finds the patient retained 38 percent of radioactivity at 96 h after administration. Therefore, according to equation B-10,

$$F_B = -\frac{0.693\ t_n}{T_r \cdot \ln(R_n)} = -\frac{(0.693)\ (96\ \text{h})}{(192\ \text{h}) \cdot \ln(0.38)} = 0.36 \qquad \text{(equation C-11)}$$

and the effective half-life can be approximated as:

$$T_e = F_B \times T_r\ = 0.36\ \times 192\ \text{h}\ = 69\ \text{h} \qquad \text{(equation C-12)}$$

For the delay, travel, and instruction times, equations B-4, B-5, and B-8 become:

$$n_0 = \frac{56\ \text{h}}{69\ \text{h}} = 0.812;\ \ n_1 = \frac{1\ \text{h}}{69\ \text{h}} = 0.014;\ \text{and}\ \ n_2 = \frac{168\ \text{h}}{69\ \text{h}} = 2.43 \qquad \text{(equation C-13)}$$

Exposure to the patient's spouse is considered during travel and at home after travel. The licensee assumes the patient is in close contact with the spouse during the 1 h trip home. The occupancy factor is calculated from equations B-3 and B-6.

For the parameter values described above, occupancy during travel is calculated from equation B-3 as:

$$F_1 = 1\left[e^{-0.693(0.812)} - e^{-0.693(0.826)}\right] = 0.006 \qquad \text{(equation C-14)}$$

For this patient, the bystander occupancy during travel is small because the 1 h trip is a small fraction of the 69-h effective half-life, and the trip begins after a delay time of nearly one effective half-life.

According to equation B-7, occupancy after travel includes exposure during and after the instruction period as follows:

$$F_2 = 0.1\left[e^{-0.693(0.826)} - e^{-0.693(3.256)}\right] + 0.5\left[e^{-0.693(3.256)}\right] = 0.098 \quad \text{(equation C-15)}$$

Because bystander occupancy during and after travel relates to the same person (patient's spouse), these results are summed to yield an occupancy factor of 0.104 for the maximally exposed bystander. A record of the basis for authorizing patient release is required when the licensee uses an occupancy factor less than 0.25.

For the geometry factor, line-line geometry is assumed as iobenguane can be distributed throughout the body. While typical mobility assistance in table B-1 recommends a separation distance of 0.3, this licensee determined this patient's physical assistance normally occurs at a distance of 0.7 m. Therefore, a separation distance of 0.7 m can be assumed for this patient. According to table B-1, a geometry factor of 1.4 is selected.

To account for attenuation and buildup in the patient, the licensee obtains a girth measurement to estimate the torso radius (a measure of average tissue thickness) of 14 cm for this patient. From figure C-6, as reproduced from supporting documentation (Ref. C-1), the licensee determines that $F_A = 0.92$.

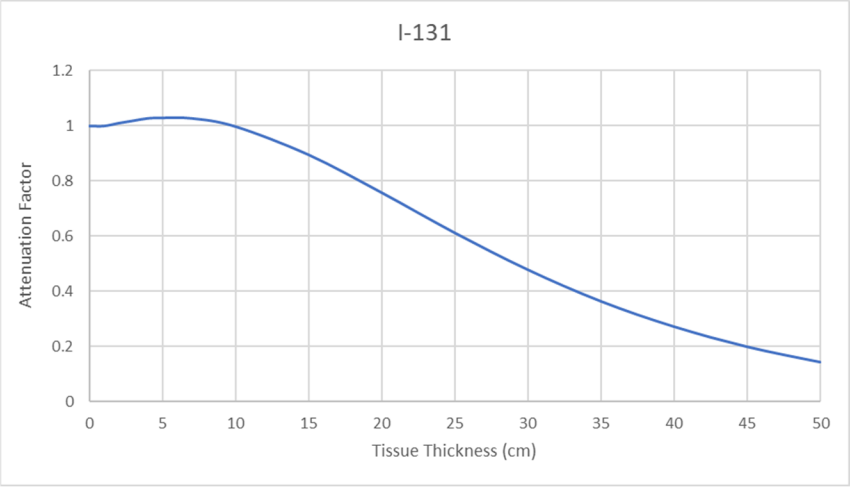

Figure C-6. Attenuation modifying factor for I-131 as a function of attenuating tissue thickness

From equation 8 (of section 2 of the main guide), patient-specific thresholds for release and instruction become:

$$Q'_{rel} = \frac{0.32\ GBq}{0.36 \cdot 0.104 \cdot 1.4 \cdot 0.92} = 6.6\ GBq \quad \text{(equation C-16)}$$

and

$$Q'_{ins} = \frac{0.063\ GBq}{0.36 \cdot 0.104 \cdot 1.4 \cdot 0.92} = 1.3\ GBq \quad \text{(equation C-17)}$$

The administered activity of 18.5 GBq is greater than both patient-specific thresholds, so a hold time is calculated according to equation 11 (of section 2.3) as:

$$t_{hold} = \frac{96\ \text{h}}{\ln(0.38)} \ln\left(\frac{6.6}{18.5}\right) = 102\ \text{h} \quad \text{(equation C-18)}$$

Due to the high administered activity and patient-specific conditions, this patient will need to be held in the medical facility with radiation controls for a total of 102 h after administration before being

released to ensure the 5 mSv (0.5 rem) dose limit will not likely be exceeded. After this hold time, the patient's retained activity is calculated to be less than the patient-specific release threshold (Q'_{rel}) but greater than the patient-specific instruction threshold (Q'_{ins}). A record of the basis for release is required by 10 CFR 35.2075.

REFERENCE FOR APPENDIX C

C-1. RCD Radiation Protection Associates, RCD-21-181-0, "Activity Thresholds, Patient-Specific Modifying Factors, Breastfeeding Interruption Times, and Other Supporting Data," Research Information Letter Report for Phase 2 Revisions to Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material," Corvallis, Oregon, June 30, 2021. (Agencywide Documents Access and Management System Accession No. ML21348A111)

1 Publicly available NRC published documents are available electronically through the NRC Library on the NRC's public website 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, Maryland. For problems with ADAMS, contact the PDR staff at (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; or email pdr.resource@nrc.gov.