U.S. NUCLEAR REGULATORY COMMISSION

DRAFT REGULATORY GUIDE DG-8057

Proposed Revision 1 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 release of patients who have been administered unsealed byproduct material or implants that contain radioactive material. The RG provides licensees with instructions for patients before and after they receive medical procedures involving the administration of radioactive material, as well as requirements for recordkeeping. The RG also lists dose rates that should be used by licensees for the release of patients in order to meet NRC and Agreement State regulatory requirements.

Applicability

This RG applies to all NRC and Agreement States medical licensees subject to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material," Section 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material" (Ref. 1).

Applicable Regulations

- 10 CFR Part 35 provides requirements and provisions for the radiation safety of workers, the general public, patients, and human research subjects.
    - 10 CFR 35.75 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 to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (mSv) (0.5 rem).[1]

[1] The 5 millisieverts (mSv) (0.5 rem) limit is a per treatment limit 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 is reasonably achievable (ALARA) if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breastfeeding infant or child could exceed 1 mSv (0.1 rem) if the patient does not interrupt breastfeeding, the instructions shall also include (1) guidance on the interruption or discontinuation of breastfeeding and (2) information on the consequences of failure to follow the guidance.

- 10 CFR 35.75(c) requires the licensee to maintain a record of the basis for authorizing the release of an individual for 3 years after the date of release.

- 10 CFR 35.75(d) requires the licensee to maintain a record of instructions provided to a breastfeeding female for 3 years after the date of release.

- 10 CFR 35.2040, "Records of written directives," provides a requirement for the length of time for keeping the written directives.

- 10 CFR 35.2063, "Records of dosages of unsealed byproduct material for medical use," provides a requirement of the length of time for keeping the records on administered prescribed dosages.[2]

- 10 CFR 35.2075, "Release of individuals containing unsealed byproduct material or implants containing byproduct material," provides a requirement for a licensee to retain a record of the basis for authorizing the release of an individual.

Related Guidance

- NUREG-1556, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses," Volume 9 (Ref. 2). NUREG-1556 Volume 9 references RG 8.39 for guidance on authorizing patient release.

- NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (Ref. 3). NUREG-1492 provides the regulatory basis for RG 8.39 and examines the costs and benefits.

Purpose of Regulatory Guides

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

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[2] Prescribed dosage(s), in accordance with 10 CFR 35.2, "Definitions," means: "The specified activity or range of activity of unsealed byproduct material as documented (1) in a written directive; or (2) in accordance with the directions of the authorized user for procedures performed pursuant to §§ 35.100 and 35.200." The term dosage(s) in this RG is used to mean the prescribed dosage and is specified in terms of activity.

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), approval number 3150-0010. Send comments regarding this information collection to the Information Services Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0010), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e-mail: oira_submission@omb.eop.gov.

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 the guide (Revision 1) provides licensees with more detailed instructions to patients before and after they have been administered radioactive material than was in Revision 0. In addition, the guide includes a new section on "Death of a Patient Following Radiopharmaceutical or Implants Administrations," as well as additional guidance on requirements for recordkeeping.

Also, Table 3, "Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child," has been revised to provide information for the recommended duration of interruption of breastfeeding to ensure that the dose to a nursing infant or child meets the NRC regulatory requirements.

The Commission directed the NRC staff in Staff Requirements Memorandum-COMAMM-14-0001/COMWDM-14-0001, "Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance," to "Revise Regulatory Guide 8.39, and subsequently NUREG-1556, Volume 9, to specify guidelines for patient information and instructional guidance."

Background

Title 10 of the *Code of Federal Regulations* (10 CFR) 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material," often referred to as the "Patient Release Rule," was promulgated in 1997. The NRC developed the subject regulation because the revision of 10 CFR Part 20 in 1991, which revised the dose limits for members of the general public in 10 CFR 20.1301, did not address exposure from the release of patients. The NRC determined that while doses should be maintained ALARA, a dose limit of 1 millisievert (mSv) (0.1 rem), or a dose limit of 5 mSv (0.5 rem) in certain circumstances, provides adequate protection. The Patient Release Rule allows a licensee to authorize the release of a patient from its control if the total effective dose equivalent (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 family or other caregivers, 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).

The activities at which patients could be released were calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," dated October 1, 1970 (Ref. 4). NCRP Report No. 37 uses the following equation to calculate the exposure until time 't' at a distance 'r' from the patient:

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

Where D(t) = Accumulated exposure at time t, in roentgens
34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44)
Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm
Q_0 = Initial activity of the point source in millicuries, at the time of the release
T_p = Physical half-life in days
r = Distance from the point source to the point of interest in centimeters
t = Exposure time in days

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

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

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

- Appendix A to this guide provides the exposure rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures.
- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.

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

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

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

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

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

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

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

Equations 2 and 3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent) relative to the external gamma-ray dose (see Appendix B, Section B-3). Further, the equations above do not apply to the dose to nursing infants or children who continue to nurse. Separate consideration must be given to patients who are breastfeeding an infant or child, as discussed in Section 2.2.1 in Section C of this guide.

Harmonization with 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 standards for protecting people and the environment from harmful effects of ionizing radiation. These standards provide a system of safety fundamentals, safety requirements, and safety guides reflecting an international consensus on what constitutes a high level of safety. This system includes guidance to be considered for patient release.

IAEA, with contributions from the International Commission on Radiological Protection, has developed Safety Report Series No. 63 titled "Release of Patients After Radionuclide Therapy," published in 2009 (Ref. 5). This report provides some practical guidance to Member States and the medical professionals involved in release of patients after therapy with unsealed radionuclides. The report addresses general guidance provided to patients after the administration of unsealed radioactive material, information to pregnant and breastfeeding women, and maximum dosages for patient release. The report references several of the documents that are also referenced in this DG as well as RG 8.39, version dated 1997. The instructions to patients included in the IAEA Safety Report Series No. 63 are similar to the instructions listed in DG 8.39.

C. STAFF REGULATORY GUIDANCE

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

1. Release Criteria

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

1.1 Release of Patients Based on the Administered Activity

One means of complying with the dose limit in 10 CFR 35.75(a) is to release patients from licensee control if the dosage administered is no greater than the activity in Column 1 of Table 1. The activities in Table 1 are based on a total effective dose equivalent of 5 mSv (0.5 rem) to an individual using the following conservative assumptions:

a. administered activity;

b. physical half-life;

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

d. no shielding by tissue.

The total effective dose equivalent is approximately equal to external dose because the internal dose is a small fraction of the external dose (see Appendix B, Section B-3). In this case, no record of the release of the patient is required unless the patient is breastfeeding an infant or child, as discussed in Section 3.2 below. The licensee may demonstrate compliance by using the records of dosage described in 35.40, "Written directives," which references 10 CFR 35.2040, "Records of written directives," and 35.2063, "Records of dosages of unsealed byproduct material for medical use."

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

If the licensee administers a radionuclide that is not listed in Table 1, it can demonstrate compliance with the regulation in 10 CFR 35.2075, "Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material," by maintaining a record of the calculation (for NRC inspection) of the release dosage that corresponds to the dose limit of 5 mSv (0.5 rem). Additional guidance can be found in Section C.3 of this guide. Equation 2 or 3 (listed above) may be used, as appropriate, to calculate the activity, Q, corresponding to 5 mSv (0.5 rem).

The release activities in Column 1 of Table 1 do not consider the dose to a nursing infant or child from the ingestion of radiopharmaceuticals contained in a patient's breast milk. When the patient is breastfeeding an infant or child, the activities in Column 1 of Table 1 do not apply to the infant or

child. In this case, it may be necessary to give instructions to the patient, as described in Sections 2.2 and 2.3 below, as a condition for release. If failure to interrupt or discontinue breastfeeding could result in a dose to the nursing infant or child in excess of 5 mSv (0.5 rem), 10 CFR 35.2075(b) requires the licensee to maintain a record that the patient was given instructions.

1.2 Release of Patients Based on the Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table 1 as long as the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table 1 for that radionuclide.

Table 1. Activities and Dose Rates for Authorizing Patient Release[a]

	COLUMN 1 ACTIVITY AT OR BELOW WHICH PATIENTS MAY BE RELEASED		COLUMN 2 DOSE RATE AT 1 METER, AT OR BELOW WHICH PATIENTS MAY BE RELEASED[b]	
RADIONUCLIDE	**(GBq)**	**(mCi)**	**(mSv/h)**	**(mrem/h)**
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6.0	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	(c)	(c)	(c)	(c)
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.20	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89	(c)	(c)	(c)	(c)
Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19
Y-90	(c)	(c)	(c)	(c)
Yb-169	0.37	10	0.02	2

a. The activity values were computed based on a 5-mSv (0.5-rem) total effective dose equivalent.

b. If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by 10 CFR 35.75(c) because the measurement includes shielding by tissue. See Staff Regulatory Guidance 3.1, "Records of Release," for information on records.

c. Activity and dose rate limits do not apply in this case because of the minimal exposures to members of the public resulting from dosages normally administered for diagnostic or therapeutic purposes.

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

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

1.3 Release of Patients Based on Patient-Specific Dose Calculations

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

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

2. Instructions

2.1 Activities and Dose Rates That Require Instructions

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

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

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

Table 2. Activities and Dose Rates above Which Instructions Should Be Given When Authorizing Patient Release[a]

	COLUMN 1 ACTIVITYABOVE WHICH INSTRUCTIONS ARE REQUIRED		COLUMN 2 DOSE RATE AT 1 METER ABOVE WHICH INSTRUCTIONS ARE REQUIRED	
RADIONUCLIDE	**(GBq)**	**(mCi)**	**(mSv/h)**	**(mrem/h)**
Ag-111	3.8	100	0.02	2
Au-198	0.69	19	0.04	4
Cr-51	0.96	26	0.004	0.4
Cu-64	1.7	45	0.05	5
Cu-67	2.9	77	0.04	4
Ga-67	1.7	47	0.04	4
I-123	1.2	33	0.05	5
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2
I-131	0.24	7	0.02	2
In-111	0.47	13	0.04	4
Ir-192 implant	0.011	0.3	0.002	0.2
P-32	(b)	(b)	(b)	(b)
Pd-103 implant	0.3	8	0.007	0.7
Re-186	5.7	150	0.03	3
Re-188	5.8	160	0.04	4
Sc-47	2.3	62	0.03	3
Se-75	0.018	0.5	0.001	0.1
Sm-153	5.2	140	0.06	6
Sn-117m	0.21	6	0.009	0.9
Sr-89	(b)	(b)	(b)	(b)
Tc-99m	5.6	150	0.12	12
Tl-201	3.1	85	0.04	4
Y-90	(b)	(b)	(b)	(b)
Yb-169	0.073	2	0.004	0.4

a. The activity values were computed based on a 1-mSv (0.1-rem) total effective dose equivalent.

b. Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from dosages normally administered for diagnostic or therapeutic purposes.

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

2.2 Additional Instructions for Release of Patients Who Could Be Breastfeeding after Their Release

The requirement in 10 CFR 35.75(b) that a licensee must give the patient instructions presumes that the licensee will ask the patient, as appropriate, about her breastfeeding status. The purpose of the instructions, including guidance on interruption or discontinuation of breastfeeding, is to permit licensees to release a patient who could be breastfeeding an infant or child when the dose to the infant or child could exceed 1 mSv (0.1 rem) if the patient does not interrupt breastfeeding.

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

If the licensee administers a radiopharmaceutical that is not listed in Table 3 to a patient who could be breastfeeding, it should evaluate whether instructions or records (or both) are required. The licensee can calculate the dose to the infant or child by using the dose conversion factors given for a newborn infant by M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine" (Ref. 6) and maintain a record of the calculation as required by 10 CFR Part 35.2075(b).

If additional instructions are required because the patient is breastfeeding, the instructions should include appropriate recommendations on whether to interrupt breastfeeding; the length of time to interrupt breastfeeding; or, if necessary, the discontinuation of breastfeeding according to the Advisory Committee on the Medical Uses of Isotopes (ACMUI), "Nursing Mother Guidelines for the Medical Administration of Radioactive Materials" (Ref. 7). The instructions should inform the patient of the consequences of failure to follow the recommendation to interrupt or discontinue breastfeeding. The licensee should explain the consequences in a manner that will help the patient understand that, in some cases, breastfeeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving iodine (I)-131 is that continued breastfeeding could harm the infant's or child's thyroid.

Table 3. Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child

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

RADIOPHARMACEUTICAL	COLUMN 1 ACTIVITY ABOVE WHICH INSTRUCTIONS ARE REQUIRED (MBq)	(mCi)	COLUMN 2 ACTIVITY ABOVE WHICH A RECORD IS REQUIRED (MBq)	(mCi)	COLUMN 3 EXAMPLES OF RECOMMENDED DURATION OF INTERRUPTION OF BREASTFEEDING[a]
Tc-99m MDP	1,000	30	6,000	150	24 hours[b]
Tc-99m PYP	900	25	4,000	120	24 hours[b]
Tc-99m Red Blood Cell In Vivo Labeling	400	10	2,000	50	24 hours[b]
Tc-99m Red Blood Cell In Vitro Labeling	1,000	30	6,000	150	24 hours[b]
Tc-99m Sulphur Colloid	300	7	1,000	30	24 hours[b]
Tc-99m DTPA	1,000	30	6,000	150	24 hours[b]
Tc-99m DTPA Aerosol	1,000	30	6,000	150	24 hours[b]
Tc-99m MAG3	1,000	30	6,000	150	24 hours[b]
Tc-99m White Blood Cells	100	3	600	15	24 hours[b]
Ga-67	1	0.04	7	0.2	28 days[b]
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells	10	0.2	40	1	6 days[b]
Tl-201 Chloride	40	1	200	5	4 days[b]
C-11, N-13, O-15, Rb-82	The activity to the infant or child can be calculated by using the dose conversion factors given by M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine" (Ref. 6).				No interruption[b]
F-18 FDG					4 hours[b]
Lu-177 Octreotate , diagnostic or therapeutic					Complete cessation (for this infant or child) [b]
Ra-223 and all alpha emitters					Complete cessation (for this infant or child) [b]
Zr-89					28 days[b]
Ga-68 Octreotate					4 hours[b]
In-111 Octreotate					6 days[b]
I-124 NaI					Complete cessation (for this infant or child)[b]

a. The duration of interruption of breastfeeding is selected to reduce the maximum dose to a newborn infant to less than 1 mSv (0.1 rem), although the regulatory limit is 5 mSv (0.5 rem). The actual doses that most infants would receive would be far below 1 mSv (0.1 rem). The physician may use discretion to recommend increasing or decreasing the duration of interruption as long as his or her instructions would ensure that the dose to the child is less than the regulatory limit of 5 mSv (0.5 rem).

b. These recommendations on the interruption or discontinuation of breastfeeding are from the ACMUI Subcommittee on "Nursing Mother Guidelines for the Medical Administration of Radioactive Materials." If there is no recommendation in Column 3 of this Table, the maximum activity normally administered is below the activities that require instructions on interruption or discontinuation of breast-feeding. (For Tc-99m labeled radiopharmaceuticals, rather than a radiopharmaceutical-specific interruption period, a single 24-hour interruption period is recommended. Although this time interval may be longer than necessary for some Tc-99m labeled radiopharmaceuticals, it is compliant with the 0.1-rad dose limit and simplifies the guidance, thereby avoiding confusion and reducing the likelihood of error.)

NOTES: Activities are rounded to one significant figure, except when the use of two significant figures was considered

appropriate. NUREG-1492 describes the calculations in detail Agreement State licensees should check with their State regulations before using the values on the Table.

2.3 Content of Instructions

This section describes different aspects that the licensee should consider before and after a patient's treatment when it is developing patient release instructions. 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 consider the patient's destination upon his or her release and the ability of the patient or caregiver to understand and follow the release instructions. The licensee should thoroughly ascertain the patient's posttreatment destination and the method by which he or she plans to travel to that destination to best estimate the likely cumulative radiation exposures to other members of the public (e.g., family and other caregivers) and, therefore, to direct appropriate protective measures to keep doses ALARA and ensure that the dose limit will likely be met.

I-131 is currently the medical radioisotope of highest concern, as it is the most commonly used radionuclide in radiopharmaceutical therapy and has the potential for a higher external exposure to members of the public because of its high-energy gamma emission and volatility as documented in SECY-18-0015, "Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release after Radioisotope Therapy" (Ref. 8). However, the regulations in 10 CFR 35.75 apply to other medical radioisotope therapies such as phosphorus (P)-32, strontium (Sr)-89, yttrium (Y)-90, iodine (I)-125, lutetium (Lu)-177, and radium (Ra)-223. Instructions should be specific to the type of treatment given and should include additional information for individual situations. Note that instructions should not interfere with or contradict the best medical judgment of the treating physician. The instructions should include a telephone number, to contact if the patient has any questions.

2.3.1 Pretreatment Discussions on the Administration of Radiopharmaceuticals

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

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

a. What type of posttreatment lodging (e.g., group home, apartment, townhome, detached single family home) will the patient use?

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

    (1) Will the patient use a private vehicle, taxi service, or public transportation (i.e., bus,

train, hotel, or airplane)? The use of public transportation should be discouraged, if possible.

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

c. Which household members, if any (e.g., gender, age, nursing infant, pregnant woman), will be present at the patient's posttreatment recovery location?

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

(1) Can the patient take care of himself or herself, is he or she capable of complying with the release instructions, and does he or she sleep alone?

(2) Is the patient incontinent?

(3) Are there any necessary household or dietary changes (e.g., preexisting medical conditions)?

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

(5) What consequences would occur if the patient did not follow the release instructions?

(6) Can the patient delay returning to work?

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

By gathering this information before the treatment (i.e., during the treatment planning stage), the licensee can modify assumptions used in its release calculations, as necessary, to (1) provide a patient-specific estimate of the likely cumulative dose to other members of the public, (2) direct appropriate protective measures, and (3) allow the patient time to plan for his or her potential isolation after release. It will also allow the licensee to assess the patient's capacity to understand the procedure and precautions.

2.3.2 Patient Precautions

The licensee should consider following precautions/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:

a. The licensee should discuss the following precautions and measures with the patient as appropriate. Note that this list is not inclusive and should be modified for each treatment or radioactive material administered. If the patient is traveling with other individuals to the post treatment lodging location, emphasis should be made to minimize the number of traveling companions and to maximize the distance from the patient.

(1) Emphasize the importance of keeping an adequate distance from others, especially

children and pregnant women. Can arrangements be made for family members (including children and any pregnant household members) to lodge elsewhere temporarily?

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

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

(4) 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.

(5) Encourage the use of disposable gloves, flushable wipes, and frequent hand washing.

(6) Encourage the laundering of a patient's clothing separately from other household members' clothing.

(7) Emphasize abstention from all forms of intimate contact.

(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 to clean up an area contaminated with body fluids (e.g., urine, vomit).

(10) Evaluate the need to dispose of patient-related trash in a separate 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 may be important if the landfill may detect the radiation and send the trash back to the patient.

b. 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 passes away.

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

If the patient or caregiver is mentally or physically unable to comply with the release instructions, the licensee may have to consider holding the patient as an inpatient following treatment until the patient can be released without having to follow any specific instructions. Similarly, if the licensee determines that the patient's posttreatment plans, including any instructions that it believes the patient cannot follow, planned mode of transportation, and posttreatment destination, are likely to cause a dose to other individuals that will exceed 5 mSv (0.5 rem), the licensee may not release the patient until the dose to other individuals is not likely to exceed 5 mSv (0.5 rem).

The release instructions may include measures that are necessary to limit the transfer of radioactive contamination to others. The licensee may encourage patients to have available plastic bags, disposable gloves, and flushable 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, surfaces, and the spread of radioactive contamination. Patient education and

awareness of how to minimize, isolate, and clean radioactive contamination is important in minimizing exposure to others.

With regard to female patients of child-bearing age, the NRC recognizes that pregnancy tests have limited ability to detect early pregnancies. The NRC encourages licensees to advise their patients to contact the licensee immediately if a female patient discovers that she was pregnant at the time the medical treatment was administered. Licensees must report any dose to an embryo/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/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, 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.

2.3.3 Patient Instructions

The licensee must comply with 10 CFR 35.75 by ensuring that the radiation dose to other individuals is not likely to exceed 5 mSv (0.5 rem) from a released patient who has been administered radiopharmaceuticals or permanent implants that contain radioactive material. However, once a patient is released, the licensee has no control of the patient. At that point, the patient or caregiver assumes responsibility for managing radiation exposure to other individuals based on the release instructions provided by the licensee. The instructions should be easy to follow to enable the patient to understand how to minimize radiation exposure to other individuals (ACMUI, "Patient Release Report," 2010) (Ref. 9). 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. The list below provides some basic posttreatment instructions that the patient may need to follow for managing radiation exposure to other individuals. The instructions should always be tailored to the specific patient situation and type and amount of radioactive material administered or implanted.

a. Wash his or her hands frequently.

b. Wash his or her laundry separately from other people's laundry.

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

d. Use a bathroom reserved exclusively for him or her, if possible.

e. Use disposable gloves and flushable wipes when cleaning.

f. Discard his or her trash separately and hold it to allow for radioactive decay.

g. Sleep alone.

h. Abstain from all forms of intimate contact.

i. Avoid preparing or sharing food with others.

j. Avoid using public transportation, if possible.

k. Minimize the amount of time spent near other people, especially children and pregnant women.

The licensee should instruct family members and caregivers to notify the treating medical facility of a medical emergency or if a patient passes away. The licensee should again tell the patient how to clean up an area contaminated with body fluids (e.g., urine, vomit).

2.3.4 Patient Acknowledgement of Instructions

The patient should acknowledge receipt of instructions before he or she is released, and the licensee may 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. He or she has received a clear explanation of the treatment process.

b. He or she has been informed of the need to limit exposure to others, especially to young children and pregnant women, and has been informed on how long he or she must exercise special care.

c. He or she has discussed with the healthcare provider plans for the following:

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

(2) arrangements for protecting others once he or she 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 in the event that questions arise about the radiation safety instruction.

2.4 Death of a Patient Following Radiopharmaceutical Administration or Implants

If the licensee learns that a patient has died shortly after a therapeutic quantity of administration of radioactive material, the treating medical practitioner and the radiation safety office (RSO) should be notified immediately. The RSO should perform an assessment of the type and amount of retained activity, based on the patient records.

If the death occurs in a hospital, access to the room occupied by the deceased should be controlled until the room has been surveyed, and decontaminated if necessary. A specified form of identifier (e.g., bracelet, badge) should be used to identify the radioactive body. A body bag may need to be used to contain the leakage of radioactive material. To minimize external radiation, the body may need to be retained in a secured area. Radiation safety procedures to be applied in practice for handling the body should be determined in close consultation with the RSO at the facility where the therapy was administered.

Unsealed radioactive material may be present in a particular body cavity or organ, or it may have concentrated after systemic administration (e.g., I-131 in the thyroid gland). Drainage of the cavity or excision of the organ will reduce exposure if undertaken at the start of the autopsy. In addition, care should be given with respect to organs with significant activity. If the patient received a dose of

beta-emitting colloid or spheres (e.g., P-32 chromic phosphate into a body cavity, Y-90 microspheres into the liver), significant activity may be present in the cavity fluid or in the organ. Beta radiation sources may provide significant dose to the hands because they will be in close contact with body tissues and fluids (NCRP Report No. 155, "Management of Radionuclide Therapy Patients,") (Ref. 10).

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

The RSO should notify the morgue or funeral home that the body contains therapeutic quantities of radioactive material and provide precautions to minimize radiation exposures and radioactive contamination for embalming and burial. These include the use of gloves and protective clothing and proper cleaning of equipment.

If the body is to be cremated, the RSO should provide precautions on handling the body to crematorium employees who may receive external exposure from the radioactive body or from contamination of the crematorium or internal exposure from inhalation of radioactive particles while handling the ashes. A proportion of the activity retained will appear in cremated remains and may be a concern, particularly in the case of long-lived radionuclides, that will require specified controls. The main concern is in regard to the scattering of ashes, although contact dose rates with the container may have to be considered if cremation takes place shortly after administration of the treatment.

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

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

a. If the activity remaining in the body is greater than regulatory limits or if regulatory limits have not been established, 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 NCRP Report No. 155, "Management of Radionuclide Therapy Patients."

2.5 Precautions for Long-Lived Contaminants in Radiopharmaceutical Therapy

With certain radionuclides used in radiopharmaceutical therapy, long-lived contaminants could be present from their method of production. As advances in radiopharmaceutical therapy result in the use of new radionuclides, licensees need to consider the radioactive emissions from the contaminants that may be present, and their half-lives, when preparing release instructions for patients. Additional information is provided in the NRC memorandum, "Licensing of Lutetium-177" (Ref. 11).

3. Records

3.1 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 meter, 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. This record should include the patient's identifier, 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**. The record should include the equation used, including the patient-specific factors and the bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Appendix B to this guide) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The record should include the basis for the selection of each of these values.

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.

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.

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.

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.

Records should be kept in a manner that ensures the patient's confidentiality (i.e., the records should not contain the patient's name or any other information that could identify the patient). These recordkeeping requirements may also be used to verify that licensees have proper procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients administered radioactive material.

3.2 Records of Instructions for Breastfeeding Patients

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

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

4. Summary Table

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

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

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

D. IMPLEMENTATION

The purpose of this section is to provide information on how licensees may use this guide and information regarding the NRC's plans for using this RG.

Use by Licensees

Licensees may voluntarily use the guidance in this document to demonstrate compliance with the NRC regulations. Methods or solutions that differ from those described or referenced in this RG may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations.

Licensees may use the information in this RG for actions that do not require NRC review and approval. Licensees may use the information in this RG or applicable parts to resolve regulatory or inspection issues.

Use by NRC Staff

The NRC staff does not intend or approve any imposition of the guidance in this RG. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this RG, unless the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this RG to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action which would require the use of this RG. Examples of such unplanned NRC regulatory actions include issuance of an order, issuance of a generic communication, or promulgation of a rule requiring the use of this RG.

The staff may discuss with licensees various actions consistent with staff positions in this RG, as one acceptable means of meeting the NRC regulatory requirement. However, unless this RG is part of the license for a facility, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this RG constitutes a violation.

REFERENCES[3]

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

2. U.S. Nuclear Regulatory Commission (NRC), NUREG-1556, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses," Volume 9, Washington, DC.

3. NRC, NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," Washington, DC, February 1997.

4. National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," Bethesda, MD, October 1, 1970.[4]

5. International Atomic Energy Agency, "Release of Patients after Radionuclide Therapy," Safety Reports Series No. 63, Vienna, Austria, 2009.[5]

6. Stabin, M., "Internal Dosimetry in Pediatric Nuclear Medicine," Pediatric Nuclear Medicine, S. Treves (Editor), Springer Verlag, New York, NY, pp. 556–581, 1995.

7. NRC, Advisory Committee on the Medical Uses of Isotopes (ACMUI), "Nursing Mother Guidelines for the Medical Administration of Radioactive Materials," Washington, DC, January 31, 2019. (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19038A498).

8. NRC, SECY-18-0015, "Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release after Radioisotope Therapy," Washington, DC, 2018. (ADAMS Accession No. ML17279B139 (package)).

9. NRC, ACMUI, "Patient Release Report," Washington, DC, December 13, 2010 (ADAMS Accession No. ML103481099).

10. NCRP Report No. 155, "Management of Radionuclide Therapy Patients," Bethesda, MD, December 11, 2006.

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

[4] Copies of reports from The National Council on Radiation Protection and Measurements (NCRP) may be obtained through its Web site: 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.

[5] Copies of International Atomic Energy Agency (IAEA) documents may be obtained through its Web site at WWW.IAEA.Org/ or by writing the International Atomic Energy Agency, P.O. Box 100 Wagramer Strasse 5, A 1400 Vienna, Austria; telephone (+431) 2600-0; fax (+431) 2600-7; or e mail Official.Mail@IAEA.Org.

11. NRC, “Licensing of Lutetium-177,” Memorandum to the NRC regions, Washington, DC, June 1, 2018. (ADAMS Accession No. ML18136A824).

APPENDIX A

TABLE A-1. HALF-LIVES AND EXPOSURE RATE CONSTANTS OF RADIONUCLIDES USED IN MEDICINE

RADIONUCLIDE	HALF-LIFE (days)[a]	EXPOSURE RATE CONSTANT[b] (R/mCi-h at 1 cm)	RADIONUCLIDE	HALF-LIFE (days)[a]	EXPOSURE RATE CONSTANT[b] (R/mCi-h at 1 cm)
Ag-111	7.45	0.150	Pd-103 implant	16.96	0.86[d]
Au-198	2.696	2.3	Re-186	3.777	0.2
Cr-51	27.704	0.16	Re-188	0.708	0.26
Cu-64	0.529	1.2	Sc-47	3.351	0.56
Cu-67	2.578	0.58	Se-75	119.8	2.0
Ga-67	3.261	0.753	Sm-153	1.946	0.425
I-123	0.55	1.61	Sn-117m	13.61	1.48
I-125	60.14	1.42	Sr-89	50.5	NA[e]
I-125 implant	60.14	1.11[c]	Tc-99m	0.251	0.756
I-131	8.04	2.2	TI-201	3.044	0.447
In-111	2.83	3.21	Y-90	2.67	NA[e]
Ir-192 implant[c]	74.02	4.594	Yb-169	32.01	1.83
P-32	14.29	NA[e]			

a. See K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11: Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, issued September 1988 (Ref. A-1).

b. Values for the exposure rate constant for gold (Au)-198, chromium (Cr)-51, copper (Cu)-64, iodine (I)-131, scandium (Sc)-47, and selenium (Se)-75 are from page 135 of the Radiological Health Handbook issued by the U.S. Department of Health, Education, and Welfare in 1970 (Ref. A-2). For Cu- 67, I-123, indium (In)-111, rhenium (Re)-186, and Re-188, the values for the exposure rate constant are from NUREG/CR-4444, "Radiation Safety Issues Related to Radiolabeled Antibodies," issued 1991 (Ref. A-3). For silver (Ag)-111, gallium (Ga)-67, I-125, samarium (Sm)-153, tin (Sn)-117m, technetium (Tc)-99m, thallium (T1)-201, and ytterbium (Yb)-169, the exposure rate constants were calculated because the published values for these radionuclides were either an approximation, presented as a range, or varied from one reference to another. Table A.2 of Appendix A to NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," issued February 1997, shows the calculation of the exposure rate in detail (Ref. A-4).

c. See R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of ^{125}I and ^{192}Ir Interstitial Brachytherapy Sources," *Medical Physics*, 17(6):1032–1040, issued November 1990. The exposure rate constant given is a measured value averaged for several source models and accounts for the attenuation of gamma rays within the implant capsule (Ref. A-5).

d. See A.S. Meigooni S. Sabnis, and R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, issued April 1990. The exposure rate constant given is an "apparent" value (i.e., with respect to an apparent source activity) and accounts for the attenuation of gamma rays within the implant capsule (Ref. A-6).

e. This exposure rate constant is not applicable (NA) because the release activity is not based on beta emissions.

REFERENCES FOR APPENDIX A[6]

A-1. K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11: Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, issued in September 1988.

A-2. Radiological Health Handbook, U.S. Department of Health, Education, and Welfare, 1970.

A-3. NUREG/CR-4444, "Radiation Safety Issues Related to Radiolabeled Antibodies," issued in 1991.

A-4. NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," issued in February 1997.

A-5. R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of ^{125}I and ^{192}Ir Interstitial Brachytherapy Sources," *Medical Physics*, 17(6):1032–1040, issued in November 1990.

A-6. A.S. Meigooni S. Sabnis, and R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, issued in April 1990.

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

APPENDIX B

PROCEDURES FOR CALCULATING DOSES BASED ON PATIENT-SPECIFIC FACTORS

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

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

The following equation can be used to calculate doses:

$$D(t) = \frac{34.6\ \Gamma\ Q_0\ \ T_P\ E\ (1 - e^{-0.693t / T_p}}{r^2}), \qquad \text{(Equation B-1)}$$

where $D(t)$ = accumulated dose to time t in rem

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

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

Q_0 = initial activity at the start of the time interval

T_p = physical half-life in days

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

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

t = exposure time in days

B-1. Occupancy Factor

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

In Table 1 of this regulatory guide, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members and considerations of normal human behavior (as discussed in the supporting regulatory analysis discussed in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (Ref. B-1)) suggest that an occupancy factor of 0.25 at

1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

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

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

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

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

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

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

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

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

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

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

Solution: Use Equation B-1 to calculate the dose to total decay (t = ∞) based on the physical half-life. (This calculation illustrates the use of physical half-life. To account for biological elimination, use the calculations described in the next section.)

$$D(\infty) = \frac{34.6\ \Gamma\ Q_o T_p E}{\mathrm{r}^2}$$

Because the patient was given instructions on how to reduce exposure, as recommended for an occupancy factor of E = 0.125, the occupancy factor of 0.125 at 1 meter may be used.

$$D(\infty) = \frac{34.6\ \left(2.2\ \frac{R \cdot cm^2}{mCi\ \cdot\ hr}\right)(8.04d)(0.125)}{(100\ \mathrm{cm})^2}$$

$$D(\infty) = 4.59\ millisieverts\ (0.459\ rem)$$

Because the dose is less than 5 mSv (0.5 rem), the patient may be released; however, 10 CFR 35.75(b) requires that the licensee instruct the patient on how to maintain doses to others as low as is reasonably achievable. The license must maintain a record of the calculation in accordance with 10 CFR 35.2075(a) because it used an occupancy factor less than 0.25 at 1 meter.

B-2. Effective Half-Life

A licensee may account for the effective half-life of the radioactive material to demonstrate compliance with the dose limits for individuals exposed to the patient that are stated in 10 CFR 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material." The effective half-life is defined as follows:

$$T_{eff} = \frac{T_b\ x\ T_p}{T_b + T_p}\ , \qquad \text{(Equation B-2)}$$

where T_b = biological half-life of the radionuclide
T_p = physical half-life of the radionuclide

The behavior of I-131 can be modeled using two components: (1) extrathyroidal iodide (i.e., existing outside of the thyroid) and (2) thyroidal iodide following uptake by the thyroid. The effective half-lives for the extrathyroidal and thyroidal fractions (F1 and F2, respectively) can be calculated with the following equations:

$$T_{1eff} = \frac{T_{b1}\ x\ T_p}{T_{b1} + T_p} \qquad \text{(Equation B-3)}$$

$$T_{2eff} = \frac{T_{b2}\ x\ T_p}{T_{b2} + T_p} \qquad \text{(Equation B-4)}$$

where T_{b1} = biological half-life for extrathyroidal iodide
T_{b2} = biological half-life of iodide following uptake by the thyroid T_p = physical half-life of I-131

However, simple exponential excretion models do not account for (1) the time for the I-131 to be absorbed from the stomach to the blood and (2) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this guide makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80 percent of the I-131 administered is removed from the body at a rate determined only by the physical half-life of I-131.

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

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

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

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

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

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

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

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

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

a. See M.G. Stabin, C.S. Marcus, E.E. Watson, and R.D. Salk, "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine,* 32(5):808–813, issued June 1991. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this cited document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight line fit that accounts for about 75 percent of the data points shown in Figure 1 of this cited document (Ref. B-7).

b. See International Commission on Radiological Protection (ICRP) No. 53, "Radiation Dose to Patients from Radiopharmaceuticals," issued March 1987. The data in this ICRP document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. If other data are lacking, apply this value to hyperthyroid and thyroid cancer patients. For thyroid cancer, ICPR No. 53 suggests that the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid) (Ref. B-8).

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

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

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

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

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

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

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

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

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

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

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

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

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

B-3. Internal Dose

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

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

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

Q = activity administered to the patient in millicuries

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

DCF = dose conversion factor used to convert an intake in millicuries to an internal committed effective dose equivalent (tabulated in the Eckerman, K.F., A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11: Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion" (Ref. B-2))

Equation B-6 uses a value of $1x10^{-5}$ as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb was developed in Brodsky, A., "Resuspension Factors and Probabilities of Intake of Material in Process (or "Is 10^{-6} a Magic Number in Health Physics?"

(Ref. B-3)) for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility; however, it does not specifically apply to cases of intake by an individual exposed to a patient. However, two studies in Buchanan, R.C.T., and J.M. Brindle, "Radioiodine Therapy to Out-patients—The Contamination Hazard" (Ref. B-4), and Jacobson, A.P., P.A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131" (Ref. B-5), of the intakes of individuals exposed to patients administered I-131 indicated that intakes were generally of the order of 1 millionth of the dosage administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of $1x10^{-5}$ has been assumed.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient who has been administered 1,110 MBq (33 mCi) of I-131. The ingestion pathway was selected because most of the intake would likely be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

Solution: Use Equation B-6 for the solution to this example. The DCF for the ingestion pathway is 53 rem/mCi from Table 2.2 of Reference B-2.

Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is as follows:

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi}) \quad D_i = 0.17 \text{ mSv } (0.017 \text{ rem})$$

In this case, the external dose to the other person would be no greater than 5 mSv (0.5 rem), whereas the internal dose would be about 0.17 mSv (0.017 rem). Thus, the internal dose is about 3 percent of the external gamma dose. Internal doses may be ignored in the calculations if they are likely to be less than 10 percent of the external dose because the internal dose would be significantly less than the uncertainty in the external dose.

The National Council on Radiation Protection and Measurements (NCRP) also concluded that internal contamination is relatively unimportant in the case of patient release. NCRP addressed the risk of intake of radionuclides from a patient's secretions and excreta in NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," dated February 28, 1995 (Ref. B-6). NCRP concluded that "a contamination incident that could lead to a significant intake of radioactive material is very unlikely." NUREG-1492 further discusses the subject.

REFERENCES FOR APPENDIX B[7]

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

B-2. Eckerman, K.F., A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11: Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," U.S. Environmental Protection Agency, Washington, DC, September 1988.

B-3. Brodsky, A., "Resuspension Factors and Probabilities of Intake of Material in Process (or "Is 10^{-6} a Magic Number in Health Physics?")," *Health Physics,* 39(6):992–1000, January 1981.

B-4. Buchanan, R.C.T., and J.M. Brindle, "Radioiodine Therapy to Out-patients—The Contamination Hazard," *British Journal of Radiology,* 44(523):557, August 1971. [8]

B-5. Jacobson, A.P., P.A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," *American Journal of Public Health,* 68(3):225–230, March 1978.

B-6. National Council on Radiation Protection and Measurements Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," Bethesda, MD, February 28, 1995.

B-7. M.G. Stabin, C.S. Marcus, E.E. Watson, and R.D. Salk, "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine,* 32(5):808–813, issued June 1991.

B-8. International Commission on Radiological Protection (ICRP) No. 53, "Radiation Dose to Patients from Radiopharmaceuticals," issued March 1987.

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

8 This reference can be found at: https://www.birpublications.org/.