Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Public Teleconference Meeting

June 10, 2019

Meeting Handout

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ACMUI
MONTH DAY, 2019

U.S. NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

BYLAWS

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PREAMBLE

These bylaws describe (1) the procedures to be used by the Advisory Committee on the Medical Uses of Isotopes (ACMUI), established pursuant to Section 161a of the Atomic Energy Act of 1954, as amended, in performing its duties, and (2) the responsibilities of the members. For parliamentary matters not explicitly addressed in the bylaws, Robert's Rules of Order will be followed. Certain issues that come before the ACMUI may involve legal issues and may require input from the U.S. Nuclear Regulatory Commission's (NRC's) Office of General Counsel for their ultimate resolution.

These bylaws have as their purpose fulfillment of the ACMUI's responsibility to provide objective and independent advice to the Commission through the NRC staff in the Division of Materials Safety, Security, State, and Tribal Programs (MSST), Office of Nuclear Material Safety and Safeguards (NMSS), with respect to the development of standards and criteria for regulating and licensing medical uses of byproduct material. The procedures are intended to ensure that such advice is fairly and adequately obtained and considered, that the ACMUI members and the affected parties have an adequate opportunity to express their opinions, and that the resulting reports represent, to the extent possible, the best of which the ACMUI is capable. Any ambiguities in the following should be resolved in such a way as to support those objectives.

BYLAWS-ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

1. Scheduling and Conduct of Meetings

The scheduling and conduct of ACMUI meetings shall be in accordance with the requirements of the Federal Advisory Committee Act (FACA), as amended, 10 CFR Part 7, and other implementing instructions and regulations as appropriate.

1.1 Scheduling of Meetings:

1.1.1 ACMUI meetings must be approved or called by the Designated Federal Officer (DFO). At least two regular meetings of the ACMUI will be scheduled each year, one in the spring and one in the fall. Additionally, the ACMUI will meet with the Commission annually, unless the Chair or designated Chair of the ACMUI declines or the Commission declines such a meeting.

1.1.2 ACMUI meetings will be open to the public, except for meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

1.1.3 All ACMUI meetings, open or closed, will be transcribed. During portions of the meeting that are open to the public, electronic recording of the proceedings by members of the public will be permitted. Television recording of the meeting will be permitted to the extent that it does not interfere with ACMUI business or with the rights of the attending public.

1.1.4 Portions of ACMUI meetings that are open to the public should be broadcast or otherwise electronically disseminated (e.g. webcast) whenever possible, with closed captioning in accordance with the Americans with Disabilities Act.

1.1.5 All available meeting handouts should be electronically transmitted to the ACMUI members no later than two weeks prior to the meeting.

1.1.6 All publicly available meeting handouts should be posted on the ACMUI public website no later than three business days prior to the meeting.

1.2 Meeting Agenda:

The agenda for regularly scheduled ACMUI meetings will be prepared by the Chair of the ACMUI (referred to below as "the Chair") in consultation with the NMSS staff. The DFO must approve the agenda. The Chair, with the NMSS staff's assistance, will query

ACMUI members for agenda items prior to agenda preparation. A draft agenda should be provided to ACMUI members no later than 30 days prior to a scheduled meeting. The final agenda should be provided to members no later than 7 days prior to a scheduled meeting.

Before the meeting, the Chair and the DFO will review the findings of the Office of the General Counsel regarding possible conflicts of interest of members in relation to agenda items. Members will be recused from discussion of those agenda items with respect to which they have a conflict.

1.3 Conduct of the Meeting:

1.3.1 All ACMUI meetings will be held in full compliance with the FACA. Questions concerning compliance will be directed to the NRC Office of the General Counsel.

1.3.2 The Chair will preside over the meeting. The Vice Chair will preside if the Chair is absent or if the Chair is recused from participating in the discussion. The DFO will preside when both the Chair and the Vice Chair are absent and/or recused from the discussion or when directed to do so by the Commission.

1.3.3 A majority of the current membership of the ACMUI will be required to constitute a quorum for the conduct of business at an ACMUI meeting.

1.3.4 The Chair has both the authority and the responsibility to maintain order and decorum and may, at his or her option, recess the meeting, if these are threatened. The DFO will adjourn a meeting when adjournment is in the public interest.

1.3.5 Decisions shall be made by a majority vote of the current ACMUI membership. Should one or more members be unavailable for compelling reasons (such as extended incapacity or recusal), the current membership shall be regarded as reduced accordingly.

1.3.6 The Chair may take part in the discussion of any subject before the ACMUI and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject. In matters where the ACMUI Chair's unique experience and knowledge would be especially informative, the Chair may serve on relevant subcommittees. The Chair will serve at the discretion of the subcommittee members. However, the ACMUI Chair will not chair the subcommittee.

1.3.7 When a consensus appears to have developed on a matter under consideration, the Chair will summarize the results for the record. Any members who disagree with the consensus shall be asked to state their dissenting views for the record. Any ACMUI member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No ACMUI position will be final until it has been formally adopted by consensus or formal vote and the transcript written and certified.

2. TRANSCRIPTS

2.1 Transcripts of each meeting will be prepared by the ACMUI Chair with assistance from the NMSS staff in accordance with the requirements in 10 CFR Part 7. The Commission staff will prepare transcripts of ACMUI meetings with the Commission.

2.2 In accordance with 10 CFR section 7.13(c), the ACMUI Chair, or other individual who presided over the meeting in place of the ACMUI Chair, will certify the transcripts.

2.3 Copies of the certified transcripts will be made available to the ACMUI members and to the public no later than 90 days after the meeting.

2.4 NMSS staff will prepare a meeting summary, which will be made available to ACMUI members and to the public no later than 30 business days after the meeting.

3. APPOINTMENT OF MEMBERS

3.1 ACMUI members are appointed by the Director, NMSS, after consultation with the Commission. The Commission determines the size of the ACMUI. The NRC will solicit nominations by notice in the *Federal Register* and by such other means, as are approved by the Commission. Evaluation of candidates shall be by such procedures as are approved by the Director, NMSS. The term of an appointment to the ACMUI is 4 years, and the Commission has determined that no member may serve more than two consecutive terms (8 consecutive years), unless directed otherwise by the Commission.

3.2 The Chair will be appointed by the Director, NMSS, from the membership of the ACMUI. The Chair will serve at the discretion of the Director, NMSS.

3.3 The Vice Chair will be appointed by the Director, NMSS, from the membership of the ACMUI. The Vice Chair will serve at the discretion of the Director, NMSS.

4. CONDUCT OF MEMBERS

4.1 All members of the ACMUI are subject to federal ethics laws and regulations and receive annual training on these requirements. If a member believes that he or she may have a conflict of interest, as that term is broadly used within 5 C.F.R. Part 2635, with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the DFO as soon as possible and before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from participating in any agenda item in which they may have a conflict of interest, unless they receive a waiver or prior authorization from the appropriate NRC official.

4.2 ACMUI members should submit their hours of work, as they relate to official ACMUI business, on the Thursday prior to the close of the pay period, unless noted otherwise. The hours shall be transmitted via the appropriate reporting method established by the DFO.

4.3 For meetings requiring travel, ACMUI members should submit travel authorizations by the travel reporting procedure as directed by NMSS staff. ACMUI members should submit vouchers for reimbursement by the travel procedure as directed by NMSS staff no later than 5 business days after the meeting.

4.4 Upon completing their tenure on the ACMUI, members will return any privileged documents and accountable equipment (as so designated by the NRC) provided for their use in connection with ACMUI activities, unless directed to dispose of these documents or equipment.

4.5. ACMUI members should to conform to all applicable NRC rules and regulations and are expected to attend meetings regularly and perform all assigned duties.

5. ADOPTION AND AMENDMENTS

5.1 Adoption or approval of an amendment of these bylaws shall require an affirmative vote of two-thirds of the current ACMUI membership and the concurrence of the Director, NMSS.

5.2 Any member of the ACMUI or NMSS staff may propose an amendment to these bylaws. The proposed amendment will be distributed to the members and scheduled for discussion at the next regular ACMUI meeting.

5.3 The proposed amendment(s) may be voted on as early as the next ACMUI meeting after distribution to the members.

5.4 The ACMUI shall consult with the Office of the General Counsel regarding conflicts that arise from the interpretation of the bylaws. After consultation, the ACMUI shall resolve interpretation issues by a majority vote of the current membership of the ACMUI.

U.S. Nuclear Regulatory Commission (NRC)
Advisory Committee on the Medical Use of Isotopes (ACMUI)

Subcommittee Review and Comments on

Draft Proposed Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," Revision 1 (Phase 1)

Draft Report
Submitted: May 23, 2019

Subcommittee Members:

Dr. Vasken Dilsizian
Ms. Melissa Martin
Dr. A. Robert Schleipman
Mr. Michael Sheetz (Chair)
Ms. Megan Shober
Ms. Laura Weil

NRC Staff Resource: Dr. Said Daibes-Figueroa

Charge

During the September 20-21, 2018 ACMUI Meeting, ACMUI Chairman, Dr. Christopher Palestro, established a subcommittee to review the NRC staff's draft proposed revision to Regulatory Guide (RG) 8.39, "Release of Patients Administered Radioactive Materials."

Background

The NRC's current RG 8.39, Revision 0, was issued in April 1997, following the rule change in 10 CFR 35.75 to allow the release of patients administered radioactive material on a solely dose-based basis. Since that time, there have been several challenges to the appropriateness of the release criteria and the associated precautions that are required to be provided to minimize radiation exposure to other individuals from the released patient. The NRC requested public comments on the Patient Release Program in 2017 (Docket ID NRC–2017–0094). The NRC also created a webpage to provide potential patients with information on radioactive iodide (RAI) treatment procedures so that the patients will understand the reason for the procedures, the process, and how to reduce radiation exposure to others (https://www.nrc.gov/materials/miau/patient-release.html).

NOTE: RG 8.39 is being revised in two phases. This Phase 1 revision of RG 8.39, updates the patient release guidance, including information for patient instructions and updates to Table 3, "Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients who are Breast-Feeding an Infant or Child." In Phase 2, the dosimetric equations, methodologies, and tables used to calculate dose to members of the public from released patients will be updated. The following Subcommittee comments and recommendations only pertain to the Phase 1 revision.

Changes and Recommendations to Regulatory Guidance Considered by the Subcommittee

General Comment:

The Subcommittee supports the addition of a Table of Contents to the RG and expanding the section on "Content of Instructions" to include subsections on "Pretreatment Discussions", "Patient Precautions", "Patient Instructions", and "Patient Acknowledgement of Instructions".

Specific Comments:

Pg 1, Under Introduction: Change the heading "Applicable Regulations" to "Regulations".

Pg 2, Under "Purpose of Regulatory Guide", 1st sentence: Replace the words "and to provide guidance to applicants" with "and to provide guidance to licensees".

Pg 4, Under "Reason for Revision": Change 2nd sentence "By updating the NRC guidance with this information, the patient will be better informed and can make better choices when following the instructions" to read "By updating the NRC guidance with this information, the licensee will be better informed on what instructions and options should be provided to the patient."

Pg 5, Under "Background", last sentence: Delete reference to Staff Regulatory Guidance Position 2.3, as it does not pertain to breastfeeding infants or children.

Pg 6, Section 1.1 Release of Patients Based on the Administered Activity, last paragraph: Delete reference to Staff Regulatory Guidance Position 1.1, as it does not pertain to breastfeeding infants or children.

Pg 7, Table 1. Activities and Dose Rates for Authorizing Patient Release: This table should be updated to include the new and potential radionuclides used in medicine.

Pg 9, Table 2. Activities and Dose Rates above Which Instructions Should be Given When Authorizing Patient Release: This table should be updated to include the new and potential radionuclides used in medicine.

Pg 9, Table 2. Activities and Dose Rates above Which Instructions Should be Given When Authorizing Patient Release, Notes: Delete the sentences "Although the NRC does not regulate nonbyproduct material, this RG includes information on nonbyproduct material for the licensee's convenience. Agreement State regulations may vary."

Pg 10, Section 2.2 Additional Instructions for Release of Patients Who Could be Breastfeeding after Their Release, 2nd paragraph: Change the sentence "The patient should also be informed if breastfeeding would have no consequences on the infant or child." to read "The patient should also be informed if breastfeeding would not likely result in consequences to the infant or child."

Pg 11, Table 3. Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child: This table should be

updated to include the radionuclides, activities, and recommended duration of interruption of breastfeeding as contained in the ACMUI Subcommittee report on "Nursing Mother Guidelines for the Medical Administration of Radioactive Materials, Final Report, January 31, 2019."

Pg 11, Table 3. Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child, Notes: Delete the sentences "Although the NRC does not regulate nonbyproduct material, this RG includes information on nonbyproduct material for the licensee's convenience. Agreement State regulations may vary."

Pg 12, Section 2.3 Content of Instructions, 2nd paragraph: Add "currently" after "I-131 is". Add "iodine" before "(I)-125". Delete the sentence "None of these radioisotopes have the high-energy gamma emission and volatility of I-131; therefore they present a lower external radiation hazard than I-131 does." Add "the treating" before "physician". Change the last sentence "The instructions should include the name of a knowledgeable person and his or her telephone number, to contact if the patient has any questions" to read "The instructions should include a telephone number, to contact if the patient has any questions".

Pg 13, Section 2.3.1 Pretreatment Discussions on the Administration of Radiopharmaceuticals: Change the 1st paragraph to read "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, 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 allows the licensee to determine whether the patient will be able to follow the release instructions."

Pg 13, Section 2.3.1, i: Add "hotel" to the list of examples of post treatment lodging the patient may use.

Pg 13, Section 2.3.1, ii: Delete "2. If the patient is driving, will he or she be too impaired to drive?"

Pg 13, Section 2.3.1, ii: Delete "3. If the patient is driving, will he or she be driving alone (preferred)?"

Pg 13, Section 2.3.1, ii: 4: Add the sentence "Emphasis should be made to minimize the number of traveling companions."

Pg 13, Section 2.3.1, iv: Delete "i. Are there any concerns about breastfeeding or pregnancy?"

Pg 13, Section 2.3.1: Add the pretreatment discussion topic "Potential restrictions on burial or cremation should the patient passes away within a certain period of time following treatment."

Pg 14, Section 2.3.1, last paragraph: Add the sentence "It will also allow the licensee to assess the patient's capacity to understand the procedure and precautions."

Pg 14, Section 2.3.2 Patient Precautions, a: Add the precaution "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."

Pg 14, Section 2.3.2, a. (7): Separate the patient precaution "Emphasize abstention from all forms of intimate contact. 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." into two different instructions.

Pg 14, Section 2.3.2, a. (8): Replace the word "breast milk" with "urine".

Pg 14, Section 2.3.2, a. (9): Replace the word "Emphasize" with "Evaluate".

Pg 14, Section 2.3.2, a. (9): Change the last sentence "Holding trash to allow for radioactive decay is important because the landfill may detect the radiation and send the trash back to the patient." To read "Holding trash to allow for radioactive decay may be important if the landfill will detect the radiation and send the trash back to the patient."

Pg 15, Section 2.3.2, b.: Add the sentence "Provide information to a family member or caregiver to contact the treating medical facility if the patient has a medical emergency or passes away."

Pg 15, Section 2.3.2, 1st paragraph, last sentence: Add the word "likely" before "exceed 5 mSv (0.5 rem)."

Pg 15, Section 2.3.2, 2nd paragraph, last sentence: Change the word "key" to "important".

Pg 15, Section 2.3.2, 4th paragraph, first sentence: Change the words "3 months or more" to "several weeks or months".

Pg 15, Section 2.3.3 Patient Instruction, 1st paragraph, Change the last two sentences to read "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."

Pg 16, Section 2.3.3: Add "Minimize the amount of time spent near other people, especially children and pregnant women" to the list of instructions.

Pg 16, Section 2.3.4 Patient Acknowledgement of Instructions, c. (4): Delete "in accordance with NRC, State, and local requirements".

Pg 16, Section 2.3.4, c. (6): Change the sentence "contact information (i.e., the name and telephone number of a knowledgeable person) in the event that questions arise during the recovery

period" to "contact information in the event that questions arise about the radiation safety instruction".

Pg 17, Section 2.4 Death of a Patient Following Radiopharmaceutical Administration or Implants, 1st paragraph: Add the word "therapeutic" before "quantity of radioactive material". Add a second sentence to read "The RSO should perform an assessment of the type and amount of retained activity, based on the patient records."

Pg 17, Section 2.4, 1st paragraph: Begin a new paragraph with "If the death occurs in a hospital…" to read "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."

Pg 17, Section 2.4, 3rd paragraph: Begin a new paragraph after the sentence "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." to read "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."

Pg 17, Section 2.4: Begin a new paragraph after the one above to read "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."

Pg 17, Section 2.4, 4th paragraph: Delete the sentences "Bodies that contain gamma-emitting radionuclides will result in some external exposure to crematorium employees." and "Each crematorium should maintain records of the type and activity in bodies cremated, when known (Ref. 9)."

Pg 17, Section 2.4, last paragraph: Change the last paragraph to read "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."

Pg 18, Section 2.5 Precautions for Long-Lived Contaminants in Radiopharmaceutical Therapy, 1st sentence: Change the words "radioactive decay" to "their method of production".

Other Recommendations

1. In the Patient Precautions and Instructions Sections, it should be emphasized that the major source of radiation dose to other individuals will be from external exposure from the patient (Ref 1). After completion of the Phase II revisions, these sections should also include the recommended time period for following the precautions.
2. While there is adequate guidance on the precautions to take to minimize radiation exposure for post mortem activities of a patient who has died after being administered a therapeutic quantity of radioactive material (Ref 2, 3), there is little or no consistent guidance on what retained activity or time period when the precautions should be followed. The Subcommittee recommends that a dose based model be developed to provide guidance on when precautions or restrictions would be appropriate following the death of a patient administered a therapeutic quantity of radioactive material.

References

1. ICRP Publication 94, Release of Patients After Therapy with Unsealed Radionuclides, 2004
2. NCRP Report No. 155, Management of Radionuclide Therapy Patients, 2006
3. Canadian Nuclear Safety Commission, Radiation Protection Guidelines for Safe Handling of Decedents, Regulatory document REGDOC-2.7.3, 2018

Respectfully submitted, May 23, 2019,
Subcommittee on Regulatory Guide 8.39 Release of Patients Administered Radioactive Materials,
Advisory Committee on the Medical Use of Isotopes (ACMUI),
U.S. Nuclear Regulatory Commission (NRC)

RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS

A. INTRODUCTION

Purpose

This regulatory guide (RG) provides guidance to the licensee on determining (1) when the licensee may authorize the release of a patient who has been administered radiopharmaceuticals or implants containing radioactive material, (2) when instructions to the patient are required, and (3) when records are required to be generated and maintained. The RG lists activities for commonly used radionuclides and their corresponding dose rates with which a patient may be released in compliance with the applicable dose limits.

Applicability

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

Applicable Regulations

- 10 CFR 35.75 permits licensees to authorize the release from its control of any individual who has been administered radiopharmaceuticals or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem). In this guide, the individual to whom the radioactive material has been administered is called the "patient."

- 10 CFR 35.75(b) requires that the licensee provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is

likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include (1) guidance on the interruption or discontinuation of breast-feeding and (2) information on the consequences of failure to follow the guidance.

- 10 CFR 35.75(c) requires that the licensee maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by (1) using the retained activity rather than the activity administered, (2) using an occupancy factor less than 0.25 at 1 meter, (3) using the biological or effective half-life, or (4) considering the shielding by tissue.

- 10 CFR 35.75(d), the licensee is required to maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 milliSieverts (0.5 rem).

Related Guidance

- NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses", (Ref. 2)

- NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," (Ref 3)

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 applicants. RGs are not substitutes for regulations and compliance with RGs 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.

Paperwork Reduction Act

This RG provides guidance for implementing the information collections in 10 CFR Parts 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 numbers 3150-0011 and 3150-0151. Send comments regarding this information collection to the Information Services Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0011, 3150-0151), 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 provides updated NRC patient release guidance that includes information for patient instructions and updates to Table 3 (Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients who are Breast-Feeding an Infant or Child). By updating the NRC guidance with this information, the patient will be better informed and can make better choices in following the instructions. This revision does not update the technical information, i.e., equations, methods, and tables, contained herein.

Background

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", (Ref 4).

NCRP Report No. 37 uses the following equation to calculate the exposure until time t at a distance r from the patient:

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

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 millisieverts (1 rem).
- The exposure rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Appendix A to this guide.
- 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 release is based on biological elimination (i.e., the effective half-life) rather than just 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 no consideration of biological elimination, it is assumed that the individual 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. Selection of 25 percent of the dose to total decay at 1 meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis (Ref. 3) that indicate 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 less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25 because 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 greater than 1 day:

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

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 dose (see Section B.3, "Internal Dose," of Appendix B). Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child must be considered separately, as discussed in Staff Regulatory Guidance 1.1, "Release of Patients Based on Administered Activity."

Documents Discussed in Staff Regulatory Guidance

This RG endorses the use of one or more codes or standards developed by external organizations, and other third party guidance documents. These codes, standards and third party guidance documents may contain references to other codes, standards or third party guidance documents ("secondary references"). If a secondary reference has itself been incorporated by reference into NRC regulations as a requirement, then licensees and applicants must comply with that standard as set forth in the regulation. If the secondary reference has been endorsed in a RG as an acceptable approach for meeting an NRC requirement, then the standard constitutes a method acceptable to the NRC staff for meeting that regulatory requirement as described in the specific RG. If the secondary reference has neither been incorporated by reference into NRC regulations nor endorsed in a RG, then the secondary reference is

neither a legally-binding requirement nor a "generic" NRC approved acceptable approach for meeting an NRC requirement. However, licensees and applicants may consider and use the information in the secondary reference, if appropriately justified, consistent with current regulatory practice, and consistent with applicable NRC requirements.

C. STAFF REGULATORY GUIDANCE

This section provides detailed descriptions of 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 containing radioactive material in accordance with regulatory requirements.

1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in 10 CFR 35.75(a), licensees may release patients from licensee control if the activity 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 millisieverts (0.5 rem) to an individual using conservative assumptions of (1) administered activity, (2) physical half-life, (3) occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day, and, for conservatism, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day, and (4) 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 Section B.3, "Internal Dose," of Appendix B). In this case, no record of the release of the patient is required unless the patient is breast-feeding an infant or child as discussed in Regulatory Position 3.2, "Records of Instructions for Breast-Feeding Patients." The licensee may demonstrate compliance by using the records of activity that are already required by 10 CFR 35.32 and 35.53.

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, a record is required by 10 CFR 35.75(c) because the patient's release is based on the retained activity rather than the administered activity. The activities in Column 1 of Table 1 were calculated using either Equation 2 or 3, depending on the physical half-life of the radionuclide.

If a radionuclide not listed in Table 1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for NRC inspection, a calculation of the release activity that corresponds to the dose limit of 5 millisieverts (0.5 rem). Equation 2 or 3 may be used, as appropriate, to calculate the activity Q corresponding to 5 millisieverts (0.5 rem).

The release activities in Column 1 of Table 1 do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in a patient's breast milk. When the patient is breast-feeding an infant or child, the activities in Column 1 of Table 1 are not applicable to the infant or child. In this case, it may be necessary to give instructions as described in Staff Regulatory Guidance 2.2 and 2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d).

1.2 Release of Patients Based on 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 provided 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. In this case,

however, 10 CFR 35.75(c) requires a record because the release is based on considering shielding by tissue.

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/hr)**	**(mrem/hr)**
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 5 millisieverts (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 are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

NOTES: The millicurie values were calculated using Equations 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 are calculated based on the millicurie values and the exposure rate constants. In general, the values are rounded to two significant figures. However, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (Ref. 3). Agreement State regulations may vary. Agreement State licensees should check with their State regulations prior to using these values.

If a radionuclide not listed in Table 1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5 millisievert (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. A record of the release is required by 10 CFR 35.75(c). 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 $\Gamma Q/10{,}000$ cm^2.

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, based on 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 millisieverts (0.5 rem), the patient may be released. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table 1 by taking into account 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, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c).

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

2. Instructions

2.1 Activities and Dose Rates Requiring Instructions

Based on 10 CFR 35.75(b), for some administrations the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable (ALARA) after the patients are released. Licensees may use Column 1 of Table 2 to determine the activity 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 breast-feeding an infant or child, additional instructions may be necessary (see Staff Regulatory Guidance 2.2, "Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release").

The activities or dose rates in Table 2 may be used for determining when instructions must be given. When patient-specific calculations (as described in Appendix B) are used, instructions must be provided if the calculation indicates a dose that is greater than 1 millisievert (0.1 rem).

If a radionuclide not listed in Table 2 is administered, the licensee may calculate the activity or dose rate that corresponds to 1 millisievert (0.1 rem). Equation 2 or 3, as appropriate, may be used.

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

	COLUMN 1 ACTIVITY ABOVE WHICH INSTRUCTIONS ARE REQUIRED		COLUMN 2 DOSE RATE AT 1 METER ABOVE WHICH INSTRUCTIONS ARE REQUIRED	
RADIONUCLIDE	**(GBq)**	**(mCi)**	**(mSv/hr)**	**(mrem/hr)**
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 1 millisievert (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 activities normally administered for diagnostic or therapeutic purposes.

NOTES: The millicurie values were calculated using Equations 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 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (Ref. 2).

Although non-byproduct materials are not regulated by the NRC, information on non-byproduct material is included in this regulatory guide for the convenience of the licensee. Agreement State regulations may vary. Agreement State licensees should check with their State regulations prior to using these values.

2.2 Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release

The requirement in 10 CFR 35.75(b) that a licensee provide instructions including guidance on the discontinuation or the interruption period of breast-feeding, and the potential consequences of failing to follow the recommendation, presumes that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient. The purpose of the instructions including guidance (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breast-feeding an infant or child when the dose to the infant or child could exceed 1 millisievert (0.1 rem) if there is no interruption of breast-feeding.

If the patient could be breast-feeding 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, instructions on discontinuation or on the interruption period for breast-feeding and the potential consequences of failing to follow the recommendation must be provided. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. Table 3 also provides recommended duration (column 3) of interrupting or discontinuing breastfeeding to minimize the dose to below 1 millisievert (0.1 rem) if the patient has received certain radiopharmaceutical doses (column 1). The radiopharmaceuticals listed in Table 3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table 3 is administered to a patient who could be breast-feeding, the licensee should evaluate whether instructions or records (or both) are required. The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant by Stabin (Ref. 5).

If additional instructions are required because the patient is breast-feeding, the instructions should include appropriate recommendations on whether to interrupt breast-feeding, the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding (Ref.6). The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breastfeeding. The consequences should be explained so that the patient will understand that, in some cases, breastfeeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving 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 Breast-Feeding 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 BREAST-FEEDING[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	7 days
I-123 OIH	100	4	700	20	No interruption
I-123 mIBG	70	2	400	10	24 hr for 370 MBq (10 mCi)
I-125 OIH	3	0.08	15	0.4	No Interruption
I-131 OIH	10	0.30	60	1.5	Complete cessation (for this infant or child)
Tc-99m DTPA	1,000	30	6,000	150	24 hr
Tc-99m MAA	50	1.3	200	6	24 hr
Tc-99m Pertechnetate	100	3	600	15	24 hr
Tc-99m DISIDA	1,000	30	6,000	150	24 hr
Tc-99m Glucoheptonate	1,000	30	6,000	150	24 hr
Tc-99m HAM	400	10	2,000	50	24 hr
Tc-99m MIBI	1,000	30	6,000	150	24 hr
Tc-99m MDP	1,000	30	6,000	150	24 hr
Tc-99m PYP	900	25	4,000	120	24 hr
Tc-99m Red Blood Cell In Vivo Labeling	400	10	2,000	50	24 hr
Tc-99m Red Blood Cell In Vitro Labeling	1,000	30	6,000	150	24 hr
Tc-99m Sulphur Colloid	300	7	1,000	30	24 hr
Tc-99m DTPA Aerosol	1,000	30	6,000	150	24 hr
Tc-99m MAG3	1,000	30	6,000	150	24 hr
Tc-99m White Blood Cells	100	3	600	15	24 hr
Tc-99m Tetrofosmin					24 hr
Ga-67 and Zr-80-labeled	1	0.04	7	0.2	28 days
Cr-51 EDTA	60	1.6	300	8	No interruption
In-111 White Blood Cells	10	0.2	40	1	7 days

Tl-201 Chloride	40	1	200	5	14 days
C-11, N-13, O-15, Rb-82 labeled					None
F-18 labeled					12 hr
Lu-177, diagnostic					28 – 35 days
Ra-223 and all alpha emitters					Complete cessation (for this infant or child)
Ga-55 labeled					12 hr
Kr-81m, Xe-133 Gas					No interruption
Rb-82 Chloride					No interruption
Zr-89 Antibodies					21 days

a. The duration of interruption of breast-feeding is selected to reduce the maximum dose to a newborn infant to less than 1 millisievert (0.1 rem), although the regulatory limit is 5 millisieverts (0.5 rem). The actual doses that would be received by most infants would be far below 1 millisievert (0.1 rem). The physician may use discretion, recommending increasing or decreasing the duration of interruption, as long as their instructions would result in the dose to the child less than the regulatory limit is 5 millisieverts (0.5 rem).

NOTES: Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (Ref. 2). The recommendations in Column 3 of this table are in the Advisory Committee on the Medical Use of Isotopes' (ACMUI) Nursing Mother Guidelines for the Medical Administration of Radioactive Materials (Ref. 6) on the interruption or discontinuation of breast-feeding. Although non-byproduct materials are not regulated by the NRC, information on non-byproduct material is included in this regulatory guide for the convenience of the licensee. Agreement State regulations may vary. Agreement State licensees should check with their State regulations prior to using these values.

2.3 Content of Instructions

This section provides licensees with different aspects to consider before and after treatment when developing patient release instructions. Generally, when licensees release patients, it is to the patients' home where family or other caregivers may be present. To provide adequate release instructions under 10 CFR 35.75(b), licensees need to consider patient destination upon their release, and the ability of the patient and/or caregiver to understand and follow the release instructions. The licensee should thoroughly ascertain the patient post-treatment destination, and the method they plan to travel there, in order to best estimate the likely cumulative radiation exposures to other members of the public (e.g., family and other caregivers), and thus, direct appropriate protective measures to keep doses ALARA and ensure the dose limit will likely be met.

Iodine-131 (I-131) is the medical radioisotope of highest concern as it is the most commonly used radionuclide in radiopharmaceutical therapy and given its potential for a higher external exposure to members of the public due to its high energy gamma emission and volatility (Ref. 7). However, the regulations in 10 CFR 35.75 apply to other medical radioisotope therapies such as Phosphorus-32 (P-32), Strontium-89 (Sr-89), Yttrium-90 (Y-90), Iodine-125 (I-125), Lutetium-177 (Lu-177), and Radium-223 (Ra-223). None of these radioisotopes have the high energy gamma emission and volatility of I-131, and thus, they present a lower external radiation hazard than I-131. 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 physicians. The instructions should include the name of a knowledgeable person to contact and that person's telephone number in case the patient has any questions.

2.3.1 Pre-Treatment Discussions Regarding Radiopharmaceutical Administrations

Engaging the patient early in the treatment process (i.e., during treatment planning) may help licensees better familiarize the patient and caregivers with post treatment radiation safety precautions and protective measures, as well as the treatment procedure, potential complications, side effects, dietary and medication changes, pre- and post-treatment expectations.

Additionally, early engagement with the patient affords the patient with the opportunity to ask questions of the licensee that will help the patient be more compliant with the release instructions. It also provides the licensee with the opportunity to determine if the patient will be able to follow the release instructions.

As soon as radiopharmaceutical or implant therapy is considered as a treatment option, the licensee should conduct an interview with the patient and/or caregiver to fully assess the patient's specific circumstances. Topics to discuss and consider during the pre-treatment discussion should include:

- Type of post-treatment lodging (e.g., group home, apartment, townhome, detached single family home)
- Patient travel plans to their post-treatment recovery location:
    - Will the patient use a private vehicle, taxi service, or public transportation (i.e., bus, train, or airplane)? The use of public transportation should be discouraged, if possible.
    - If driving, will the patient be too impaired to drive?
    - If driving, will the patient be driving alone (preferred)?
    - If the patient is traveling with other individuals, what is the duration of the trip and based on the duration of the trip, can the patient keep an adequate distance from others?
- Household members, if any (gender, age, nursing infant, pregnant woman)
- Can the patient be appropriately isolated from others in the household post-treatment?
- Is the patient capable of self-care, compliance with release instructions, and sleeping alone?
- Is the patient incontinent?
- Are there necessary household or dietary changes (e.g., preexisting medical conditions)?
- Any factors that might be the basis for withholding treatment (e.g., breastfeeding, pregnancy)
- Concerns regarding breastfeeding or pregnancy?
- What consequences would occur if release instructions are not followed?
- Can the patient delay returning to work?

By gathering this information prior to the treatment (i.e., during treatment planning), the licensee can modify assumptions used in their release calculations, as necessary, to provide a patient-specific estimate of the likely cumulative dose to other members of the public; direct appropriate protective measures; and allow the patient time to plan for his/her potential isolation after release.

2.3.2 Patient Precautions

The following precautions/measures should be considered for most patients to minimize exposures to others and keep radiation exposures to others at or below the 5 millisieverts (0.5 rem) limit:

- The licensee should discuss the following precautions and measures with the patient as appropriate. Note: This list is not inclusive and should be modified for each treatment or radioactive material administered.
    - 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?
    - Encourage the patient not to prepare or share food with others.
    - Encourage the use of a bathroom reserved exclusively for the patient, if possible.
    - Encourage the use of kitchen utensils dedicated to the patient, not shared with other household members and washed separately from other dishes. Alternately, encourage patients to use disposable eating utensils.
    - Encourage the use of disposable gloves, flushable wipes, and frequent hand washing.
    - Encourage the laundering of a patient's clothing separately from other household members' clothing.
    - Emphasize abstention from all forms of intimate contact. Advise the patient on the recommended length of time the patient should wait before becoming pregnant to minimize radiation exposures to a developing fetus.
    - Discuss how to clean up an area contaminated with body fluids (e.g., breast milk, vomit).
    - Emphasize disposing of patient-related trash in a separate plastic bag that is not mixed with other household members' trash, withholding the patient-related trash to allow for radioactive decay, and ways to reduce radiation exposure from this trash. Holding trash for decay is important because the landfill may detect the radiation and send the trash back to the patient.
- Discuss how the patient may contact the licensee if needed.
- Provide post-treatment release instructions to the patient verbally and in writing, including how long the release instructions should be followed.

If the patient, or caregiver, is mentally and/or physically unable to comply with the release instructions provided, licensees 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 patients post treatment plans, including any instructions that are believed cannot be followed, planned mode of transportation, and post treatment destination, are likely to cause a dose to another individual that will exceed 5 millisieverts (0.5 rem), the licensee must hold the patient until the dose to other individuals will not exceed 5 millisieverts (0.5 rem).

Information provided in the release instructions may include measures to limit the transfer of radioactive contamination to others. The licensee may encourage patients to have available plastic bags, disposable gloves, and flushable wipes prior to treatment. Specific information on how to limit direct contact with others and measures to limit the contamination of objects, surfaces, and the spread

of radioactive contamination, should be provided. Patient education and awareness of how to minimize, isolate, and clean radioactive contamination is key 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 in instances where a female patient discovers she was pregnant at the time the medical treatment was administered. Licensees must report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of the treatment to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user in accordance with 10 CFR 35.3047.

Patients receiving radiopharmaceutical treatment need to be aware that they might trigger the alarms of radiation detectors at national borders, airports, within cities, or at their place of employment for 3 months or more following treatment. Consequently, the licensee may consider issuing the patient a letter or card containing appropriate information about the treatment in case law enforcement agents need to verify that information.

2.3.3 Patient Instructions

Licensees 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 patients who have been administered radiopharmaceuticals or permanent implants containing 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 so that the patient will understand how to minimize radiation exposure to other individuals (Ref. 8). For most therapies, experience shows that radiation exposure from patients can be safely controlled through appropriate instructions, specific for the treatment, provided by licensees and followed by patients. Below are some instructions that licensee's may provide patients post-treatment.

- Wash hands frequently
- Launder clothing separately from others'
- Use dedicated or disposable kitchen utensils, and don't share them with others
- Use of a bathroom reserved exclusively for patient, if possible
- Use of disposable gloves and flushable wipes when cleaning
- Disposal of patients trash separately, and hold it to allow for radioactive decay
- Sleep alone
- Abstain from all forms of intimate contact
- Do not prepare or share food with others
- Do not use public transportation, if possible

Instructions should be provided to family members and caregivers to notify the treating medical facility of medical emergency or if a patient passes away. Licensee should also inform the patient how to clean up an area contaminated with body fluids (e.g., urine, vomit). Travel arrangements and recovery location should be discussed in detail prior to treatment.

2.3.4 Patient Acknowledgement of Instructions

Prior to release of the patient, the patient should acknowledge receipt of instructions and the licensee should acknowledge the patient understands the instructions as communicated. These acknowledgements could be obtained by using a form signed by both parties. Through the form, the patient acknowledges that he or she:

- Has received a clear explanation of the treatment process.
- Understands the need to limit the exposure to others, especially to young children and pregnant women, and has been informed on how long special care must be exercised.
- Has worked with the healthcare provider to develop plans for:
    a) Transportation from the clinic to home or post-treatment destination
    b) Arrangements for protecting others once arriving at the post-treatment destination
    c) Minimizing the exposure of people both inside and outside the home
    d) Managing biological wastes and trash in accordance with NRC, state, and local requirements
    e) Emergency care
    f) Whom to contact in the event that questions arise during the recovery period.

2.4 Death of a Patient Following Radiopharmaceutical Administration or Implants

In the event that the licensee learns of a patient death while still containing a quantity of radioactive material, the treating medical practitioner and the RSO shall be notified immediately. In cases where the death occurs in a hospital, access to the room occupied by the deceased should be controlled until the room has been decontaminated and surveyed. Radioactive bodies should be identified by a specified form of identifier (e.g., bracelet, badge). Identification of the possibility that a body may contain radioactive material relies on information provided in the patient records, the information card, or information gleaned from relatives or others. 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. The dose constraints for the pathology staff responsible for the conduct of autopsy examinations will be either those for the general public or those for radiation workers, depending on the training and classification of the staff concerned. These constraints and the radiation safety procedures to be applied in practice should be determined in close consultation with the RSO in which the therapy was administered.

Unsealed radioactive material may be present in a particular body cavity or organ, or they 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. In cases where the patient had received a dose of beta-emitting colloid or spheres (e.g., P-32 chromic phosphate into a body cavity, Y-90 microspheres into the liver), significant activity may be present in the cavity fluid or in the organ. Beta radiation sources may provide significant dose to the hands because they will be in close contact with body tissues and fluids (Ref. 9).

Autopsy and pathology staff should wear standard protective clothing (i.e., gloves, lab coats, eye protection) and personnel monitoring should be considered. For beta emitters, double surgical gloves may be helpful in reducing skin exposures. An intake of airborne material inadvertently released during cutting or movement of radioactive tissue or organs can be prevented by wearing a face shield, or eye protection and a face mask. A proportion of the activity retained will appear in cremated remains and may be a concern, particularly in the case of long lived radionuclides, to require controls to be specified. The main

concern is in respect to the scattering of ashes, although contact dose rates with the container may have to be considered if cremation takes place shortly after administration.

Crematorium employees 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. Bodies that contain gamma emitting radionuclides will result in some external exposure to crematorium employees. Cremation of non-volatile radionuclides might result in contamination of the furnace. As there is a potential for inhalation of contaminated ash particles during cleaning of the furnace, it is appropriate for workers who clean the furnace to wear dust masks and protective garments. The most likely hazard to the general population in the vicinity of the crematorium is the inhalation of radioactive material emitted with the stack gases. Each crematorium should maintain records of the type and activity in bodies cremated, when known (Ref. 9).

The RSO should be consulted to determine the amount of activity remaining in the deceased patient. No special precautions are required, provided that the activity remaining in the corpse is not in excess of the applicable regulatory limits.

- 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 to be followed.

- 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. 9).

2.5 Precautions for Long-lived Contaminants in Radiopharmaceutical Therapy

With certain radionuclides used in radiopharmaceutical therapy, there is the potential for long-lived contaminants to be present from radioactive decay. 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-life when release instructions are prepared for patients (Ref. 10).

3. Records

3.1 Records of Release

There is no requirement for recordkeeping on the release of patients who were released in accordance with 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 less than 0.25 at 1 meter, effective half- life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c). This record should include the patient 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 activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information.

1. **For Immediate Release of a Patient Based on a Patient-Specific Calculation:** The equation used, including the patient-specific factors and their 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 of this guide) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical hal-life was

assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.

2. **For Immediate Release of a Patient Based on Measured Dose Rate:** The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.

3. **For Delayed Release of a Patient Based on Radioactive Decay Calculation:** The time of the administration, date and time of release, and the results of the decay calculation.

4. **For Delayed Release of a Patient Based on Measured Dose Rate:** The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing 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, as required by 10 CFR 35.75(c), should be kept in a manner that ensures the patient's confidentiality, that is, the records should not contain the patient's name or any other information that could lead to identification of 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 Breast-Feeding Patients

If failure to interrupt or discontinue breast-feeding could result in a dose to the infant or child in excess of 5 millisievert (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d). Column 2 of Table 3 states, for the radiopharmaceuticals commonly used in medical diagnosis and treatment, the activities that would require such records when administered to patients who are breast-feeding.

The 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 radiopharmaceutical administered, the administered activity, the date of the administration, and whether instructions were provided to the patient who could be breast-feeding an infant or child.

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		Additional instructions required if: Administered activity > Column 1 of Table 3 or Licensee calculated dose from breast-feeding > 1 mSv (0.1 rem) to the infant or child	Records that instructions were provided if: Administered activity > Column 2 of Table 3 or Licensee calculated dose from continued breast-feeding > 5 mSv (0.5 rem) to the infant or child

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC's plans for using this regulatory guide.

Use by Applicants and Licensees

Applicants and 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 regulatory guide 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 regulatory guide for actions that do not require NRC review and approval. Licensees may use the information in this regulatory guide 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 regulatory guide. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this regulatory guide, 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 regulatory guide to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action that would require the use of this regulatory guide. Examples of such unplanned NRC regulatory actions include issuance of an order, generic communication, or rule requiring the use of this regulatory guide.

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

If an existing licensee voluntarily seeks a license amendment or change and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this regulatory guide, and (2) the specific subject matter of this regulatory guide is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this regulatory guide or provide an equivalent alternative process that demonstrates compliance with the NRC regulatory requirements.

REFERENCES

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

2. U.S. Nuclear Regulatory Commission, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses", NUREG-1556, Volume 9, Washington, DC 20555, 2008.

3. U.S. Nuclear Regulatory Commission, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492, Washington, DC 20555, 1997.

4. National Council on Radiation Protection and Measurements (NCRP), NCRP Report 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides", Bethesda, MD 1970.

5. Stabin, M., "Internal Dosimetry in Pediatric Nuclear Medicine," *Pediatric Nuclear Medicine,* Edited by S. Treves, Springer Verlag, New York, p. 556 – 581, 1995.

6. Advisory Committee on the Medical Uses of Isotopes (ACMUI), "Nursing Mother Guidelines for the Medical Administration of Radioactive Materials," 2018, Agencywide Documents Access and Management System (ADAMS) Accession No. ML18177A451.

7. U.S. Nuclear Regulatory Commission, "Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release After Radioisotope Therapy," SECY-18-0015, Washington, DC 20555, 2018, Agencywide Documents Access and Management System (ADAMS) Accession No. ML17279B139.

8. Advisory Committee on the Medical Uses of Isotopes (ACMUI), "Patient Release Report," 2010, Agencywide Documents Access and Management System (ADAMS) Accession No. ML103481099.

9. National Council on Radiation Protection and Measurements (NCRP), NCRP Report 155, "Management of Radionuclide Therapy Patients," Bethesda, MD 2006.

10. U.S. Nuclear Regulatory Commission, "Licensing of Lutetium-177," Memorandum to the NRC Regions, June, 2018, Agencywide Documents Access and Management System (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	74.02	4.594	Yb-169	32.01	1.83
P-32	14.29	NA[e]			

a. 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, 1988.

b. Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the Radiological Health Handbook, U.S. Department of Health, Education, and Welfare, pg. 135, 1970. For Cu- 67,1-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D. E. Barber, J. W. Baum, and C. B. Meinhold, "Radiation Safety Issues Related to Radiolabeled Antibodies," NUREG/CR-4444, U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc- 99m, T1-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," U.S. NRC, February 1997.

c. R. Nath, A. S. Meigooni, and J. A. Meli, "Dosimetry on Transverse Axes of 125I and 192Ir Interstitial Brachytherapy Sources," Medical Physics, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.

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

e. Not applicable (NA) because the release activity is not based on beta emissions.

APPENDIX B

PROCEDURES FOR CALCULATING DOSES BASED ON
PATIENT-SPECIFIC FACTORS

A licensee may release a patient who has been administered an activity 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 potential total effective dose equivalent to any individual would be no greater than 5 millisieverts (0.5 rem).

If the release of a patient is based on a patient-specific calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis of the release is required by 10 CFR 35.75(c).

The following equation can be used to calculate doses:

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

Where D(t) = Accumulated dose to time t, in rems

34.6 = Conversion factor of 24 hrs/day times total integration of decay (1.44)

F = Exposure rate constant for a point source, R/mCi × hr at 1 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 around 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

In Table 1 in 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 as well as considerations of normal human behavior (as discussed in the supporting regulatory analysis (Ref. B-1)) suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

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 hence, the dose is delivered over a short time. Specifically, the assumptions regarding 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 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. Thus, 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 I 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 provided to the patient before release. The following occupancy factors, E, at 1 meter, may be used for patient-specific calculations.

- 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.
- E = 0.25 when an effective half-life is greater than 1 day if the patient has been given instructions, such as,
  - Maintain a prudent distance from others for at least the first 2 days,
  - Sleep alone in a room for at least the first night,
  - Do not travel by airplane or mass transportation for at least the first day,
  - Do not travel on a prolonged automobile trip with others for at least the first 2 days,
  - Have sole use of a bathroom for at least the first 2 days, and
  - Drink plenty of fluids for at least the first 2 days.
- E = 0.125 when an effective half-life is greater than 1 day if the patient has been given instructions, such as,
  - Follow the instructions for E = 0.25 above,
  - Live alone for at least the first 2 days, and
  - Have few visits by family or friends for at least the first 2 days.
- In a two-component model (e.g., uptake of I-131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to one day but is greater than one 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 (60 millicuries) of I-131. The patient has been provided with 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: The dose to total decay (t = ∞) is calculated based on the physical half-life using Equation B-1. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

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

Since the patient has been provided with instructions for reducing exposure as recommended for an occupancy factor of E = 0.125, the occupancy factor of 0.125 at 1 meter may be used.

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

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

Since the dose is less than 5 millisieverts (0.5 rem), the patient may be released, but 10 CFR 35.75(b) requires that instructions be given to the patient on maintaining doses to others ALARA. A record of the calculation must be maintained pursuant to 10 CFR 35.75(c) because an occupancy factor less than 0.25 at 1 meter was used.

B-2. Effective Half-Life

A licensee may take into account 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. The effective half-life is defined as:

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

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: extrathyroidal iodide (i.e., existing outside of the thyroid) and 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:

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

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

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 (a) the time for the I-131 to be absorbed from the stomach to the blood and (b) 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. The full equation is shown as Equation B-5.

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

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.

All the other parameters are as defined in Equations B-1, B-3, and B-4. Acceptable values for F_1, T_{1eff}, F_2, and T_{2eff} are shown in Table B-1 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.

The record of the patient's release required by 10 CFR 35.75(c) is described in Regulatory Position 3.1 of this guide.

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

Solution: In this example, we will calculate the dose by 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 provided to the patient to justify the occupancy factor (see Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations," of this appendix).

Table B-1. Uptake Fractions and Effective Half-Lives for Iodine-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. M. G. Stabin et al., "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine,* Volume 32, Number 5, May 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 referenced 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 *Journal of Nuclear Medicine* document.

b. International Commission on Radiological Protection (ICRP), "Radiation Dose to Patients from Radiopharmaceuticals," ICRP Publication No. 53, March 1987. (Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.) The data in this ICRP document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid and thyroid cancer patients. For thyroid cancer, the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid) as suggested in this ICRP document.

c. The thyroidal uptake fraction of 0.05 was recommended by Dr. M. Pollycove, M.D., NRC medical visiting fellow, as an upper limit postthyroidectomy for thyroid cancer.

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

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

$D(\infty)$ = 4.53 millisieverts (0.453 rem)

Therefore, thyroid cancer patients administered 7,400 megabecquerels (200 millicuries) 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 is not greater than 5 millisieverts (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 megabecquerels (55 millicuries) of I-131 for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, we will again 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. An occupancy factor, E, of 0.25 at 1 meter will be used 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, "Occupancy Factors To Consider for Patient-Specific Calculations").

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

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

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

Therefore, hyperthyroid patients administered 2,035 megabecquerels (55 millicuries) of I-131 would not have to remain under licensee control 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, there may be concerns that the internal dose of an individual from exposure to a released patient could be significant. A rough estimate of the maximum likely committed effective dose equivalent from internal exposure can be calculated from Equation B-6.

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

Where D_i = Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rems

Q = Activity administered to the patient in millicuries

10^{-5} = Assumed fractional intake

DCF = Dose conversion factor to convert an intake in millicuries to an internal committed effective dose equivalent (such as tabulated in Reference B-2).

Equation B-6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb was developed in Reference B-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, but it does not specifically apply for cases of intake by an individual exposed to a patient. However, two studies (Refs. B-4 and B-5) regarding the intakes of individuals exposed to patients administered I-131 indicated that intakes were generally of the order of 1 millionth of the activity 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 10^{-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 megabecquerels (33 millicuries) of I-131. The ingestion pathway was selected since it is likely that most of the intake would be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

Solution: This is an example of the use of Equation B-6. The dose conversion factor DCF for the ingestion pathway is 53 rems/millicurie from Table 2.2 of Reference B-2.

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

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

$$D_i = 0.17 \text{ mSv } (0.017 \text{ rem})$$

In this case, the external dose to the other person would be no greater than 5 millisieverts (0.5 rem), while the internal dose would be about 0.17 millisievert (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 since the internal dose would be significantly less than the uncertainty in the external dose.

The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP. The NCRP addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients" (Ref. B-6). The NCRP concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely." For additional discussion on the subject, see Reference B-1.

REFERENCES FOR APPENDIX B

B-1. U.S. Nuclear Regulatory Commission, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492, Washington, DC 20555, 1997.[1]

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

B-3. A. Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10^{-6} a Magic Number in Health Physics?')," *Health Physics,* Volume 39, Number 6, 1980.

B-4. R. C. T. Buchanan and J. M. Brindle, "Radioiodine Therapy to Out-patients–The Contamination Hazard," *British Journal of Radiology,* Volume 43, 1970.

B-5. A. P. Jacobson, P. A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," *American Journal of Public Health,* Volume 68, Number 3, 1978.

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

[1] Copies may be purchased at current rates from the U.S. Government Printing Office, P. 0. Box 37082, Washington, DC 20402-9328 (telephone (202) 512-2249; or from the National Technical Information service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161. Copies of drafts are also available for inspection and copying for a fee from the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. The PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202) 634-3273; fax (202) 634- 3343.