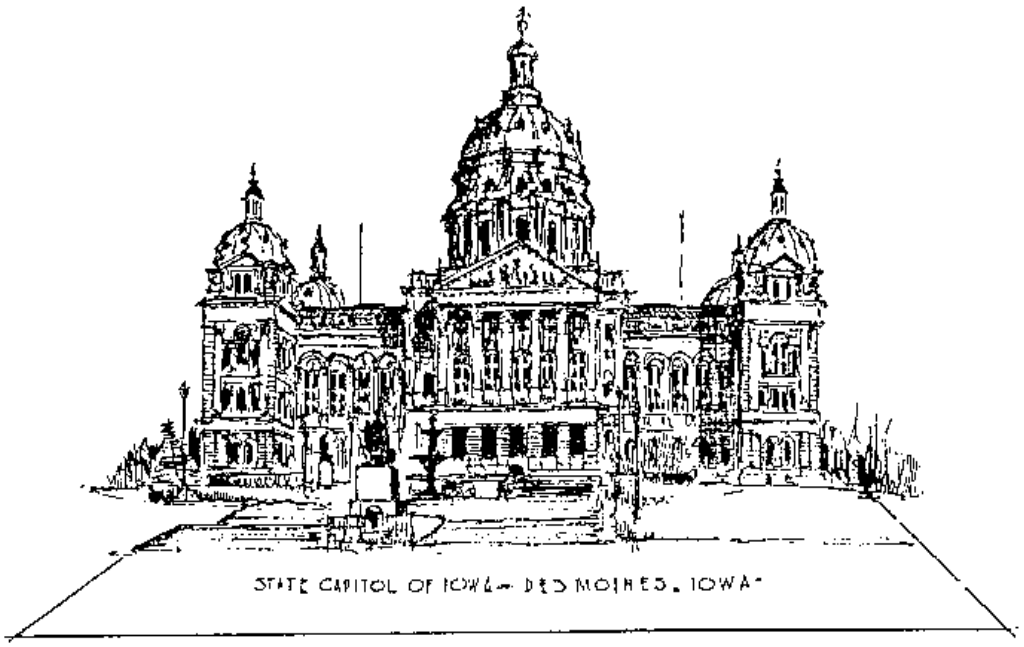
IOWA DEPARTMENT OF PUBLIC HEALTH

REGULATORY GUIDE FOR THE RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS



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REGULATORY GUIDE
FOR RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS

A. INTRODUCTION

Iowa Radiation Machines and Radioactive Materials Rules 641-41.2(27), "Release of Individuals Containing Radiopharmaceuticals or Permanent Implants," permits a licensee to release any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent (TEDE) to any other person coming into contact with the released in individual is not likely to exceed 0.5 rem (5 millisieverts).

Further, 641-41.2(39) 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 0.1 rem (1 millisievert). If the dose to a breast-feeding child could exceed 0.1 rem (1 millisievert) 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.

The licensee should maintain a record of the basis for authorizing the release of an individual, for three 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.

The licensee should maintain a record that instructions were provided to a breast-feeding woman if the radiation dose to the child from continued breast-feeding could result in a total effective dose equivalent exceeding 0.5 rem (5 millisieverts). The record should be retained for three years after the date of release.

In this guide, the individual administered the radioactive material is called the "patient."

This document provides guidance to the licensee on determining:

(1) When the licensee may authorize the release of a patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material;
(2) When instructions to the patient are required; and
(3) When records are generated and maintained.

The guide lists the activities of commonly used radionuclides and their corresponding dose rates that a patient may contain and be released in compliance with the dose limits in 641-41.2(27).

B. DISCUSSION

The activities at which patients could be released are calculated by using 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. 1).

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

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

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_o = 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, $(1 - e^{-0.693t/Tp})$ 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 up-take 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. 2). The analysis indicates 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:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_p\ (0.25)}{100\ cm^2} \qquad \text{(Equation 2)}$$

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

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_p\ (1)}{100\ cm^2} \qquad \text{(Equation 3)}$$

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 must be considered separately.

C. REGULATORY POSITION

1. RELEASE CRITERIA

Licensees should use one of the following options to release a patient who has been administered radiopharmaceuticals or permanent 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 41.2(27), 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 0.5 rem (5 millisieverts) 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. The licensee may demonstrate compliance by using the records of activity that are already required by 41.2(14)"f"(1) and 41.2(19).

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 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 IDPH inspection, a calculation of the release activity that corresponds to the dose limit of 0.5 rem (5 millisieverts). Equation 2 or 3 may be used, as appropriate, to calculate the activity Q corresponding 0.5 rem (5 millisieverts).

The release activities in Column 1 of Table 1 do not include consideration of the dose to a breast-feeding child from ingestion of radiopharmaceuticals contained in a patient's breast milk. When the patient is breast-feeding, the activities in Column 1 of Table 1 are not applicable to the child. In this case, it may be necessary to give specific instructions as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding child more than 0.5 rem (5 millisieverts), a record that instructions were provided is required.

1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients who are administered radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table 1 provided that 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, a record is required because the release considers shielding by tissue.

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 0.5 rem (5 millisieverts) 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. 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 Γ 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, 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 0.5 rem (5 millisieverts), 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.

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

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 after the patients are released.[1] 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, additional instructions may be necessary.

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 0.1 rem (1 millisievert).

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

2.2 Additional Instructions for Release of Patients who could be Breast-Feeding After Release

Licensees must provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation. This presumes that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient.[1] The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breast-feeding when the dose to the child could exceed 0.5 rem (5 millisieverts) if there is no interruption of breast-feeding.

Instructions on discontinuation or on the interruption period for breast-feeding and the consequences of

[1] IDPH does not intend to enforce patient compliance with instructions nor is it the licensee's responsibility to do so.

failing to follow the recommendation must be provided if the patient could be breast-feeding a child after release. Instructions must also be provided if the patient was administered a radiopharmaceutical with an activity above the value stated in Column 1 of Table 3. The patient should also be informed if there would be no consequences to breast-feeding. Table 3 also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 0.1 rem (1 millisievert) if the patient has received certain radiopharmaceutical doses. 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, records, (or both) are required. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50 percent of the administered activity is excreted in the breast milk (Ref. 2). The dose to the child can be calculated by using the dose conversion factors given for a newborn infant by Stabin (Ref. 3).

2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations. However, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable person to contact and that person's telephone number in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided.

Table 1. Activities and Dose Rates for Authorizing Patient Released				
Radionuclide	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	
	(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	0.074	2	0.008	0.8
P-32	**	**	**	**
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	**	**	**	**
Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

* If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record because the measurement includes shielding by tissue.

** Activity and dose rate limits are not applicable in this case because of the minimal exposure 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, less than 10 millicuries (0.37 gigabecquerel) or 10 millirems (0.1 millisievert) per hour are rounded to one significant figure.

2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following.

- Maintaining distance from other persons, including separate sleeping arrangements.
- Minimizing time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Precautions to reduce the spread of radioactive contamination.
- The length of time each of the precautions should be in effect.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine (Ref. 4). This pamphlet was prepared jointly by the Society of Nuclear Medicine and the US Nuclear Regulatory Commission. The pamphlet contains blanks for the physician to fill in the length of time that each instruction should be followed. While this pamphlet was written for the release of patients to whom less than 30 millicuries (1,110 Megabecquerels) of Iodine-131 had been administered, IDPH still considers the instructions in this pamphlet to be an acceptable method for meeting the requirements of 41.2(39) provided the times filled in the blanks are appropriate for the activity and the medical condition.

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. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breast-feeding. The consequences should be explained so that the patient will understand that, in some cases, breast-feeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving Iodine-131 is that continued breast-feeding could harm the child's thyroid. Most diagnostic procedures involve radionuclides other than radioiodine and there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the child from breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding a child, the pamphlet should be supplemented with guidance on the interruption or discontinuation of breast-feeding and information on consequences of failure to follow the guidance.

The requirement for written instructions to patients who could be breast-feeding does not in any way interfere with the discretion and judgment of the physician in specifying the detailed instructions and recommendations.

2.3.2 Instructions Regarding Permanent Implants

For patients who have received permanent implants, additional instructions may include the following:

> A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for _____days.
>
> - Stay at a distance of _____ feet from _____.
> - Maintain separate sleeping arrangements.
> - Minimize time with children and pregnant women.
> - Do not hold or cuddle children.
> - Avoid public transportation.

- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
- If you find a seed or pellet that falls out:
  - Do not handle it with your fingers.
  - Use something like a spoon or tweezers to place it in a container that you can close with a lid.
  - Place the container with the seed or pellet in a location away from people.
  - Notify one of the persons listed in this instruction.

3. RECORDS

3.1 Records of Release

There is no requirement for record keeping 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. 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 half-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.

Table 2. Activities and Dose Rates above Which Instructions Should Be Given When Authorizing Patient Release*				
Radionuclide	COLUMN 1 Activity above which instructions are required		COLUMN 2 Dose rate at 1 meter above which instructions are required	
	(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	0.011	0.3	0.002	0.2
P-32	**	**	**	**
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	**	**	**	**
Tc-99m	5.6	150	0.12	12
Tl-201	3.1	85	0.04	4
Y-90	**	**	**	**
Yb-169	0.073	2	0.004	0.4

* The activity values were computed based on 0.1 rem (1 millisievert) total effective dose equivalent.

** 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 10 millicuries (0.37 gigabecquerel) or 10 millirems (0.1 millisievert) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492 (Ref.2).

Table 3. Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who Are Breast-Feeding					
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*
	(MBq)	(mCi)	(MBq)	(mCi)	
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this child)
I-123 NaI	20	0.5	100	3	
I-123 OIH	100	4	700	20	
I-123 mIBG	70	2	400	10	24 hr for 10 mCi (370 MBq) 12 hr for 4mCi (150 MBq)
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.30	60	1.5	
Tc-99m DTPA	1,000	30	6,000	150	
Tc-99m Pertechnetate	50	1.3	200	6.5	12.6 hr for 30 mCi (150 MBq)
Tc-99m Pertechnetate	100	3	600	15	24 hr for 30 mCi (1,100 MBq) 12 hr for 12mCi (440 MBq)
Tc-99m DISIDA	1,000	30	6,000	150	
Tc-99m Glucoheptonate	1,000	30	6,000	170	
Tc-99m HAM	400	10	2,000	50	
Tc-99m MIBI	1,000	30	6,000	150	
Tc-99m MDP	1,000	30	6,000	150	
Tc-99m PYP	900	25	4,000	120	
Tc-99m Red Blood Cell *In Vivo* Labeling	400	10	2,000	50	6 hr for 20 mCi (740 MBq)
Tc-99m Red Blood Cell *In Vitro* Labeling	1,000	30	6,000	150	
Tc-99m Sulfur Colloid	300	7	1,000	35	6 hr for 12mCi (440 MBq)
Tc-99m DTPA Aerosol	1,000	30	6,000	150	
Tc-99 MAG3	1,000	30	6,000	150	
Tc-99m White Blood Cells	100	4	600	15	24 hr for 5mCi (1,100 MBq) 12 hr for 2mCi (440 MBq)

Table 3 (continued). Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who Are Breast-Feeding

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*
	(MBq)	(mCi)	(MBq)	(mCi)	
Ga-67 Citrate	1	0.04	7	0.2	1 month for 4mCi (150 MBq) 2 weeks for 1.3 mCi (50 MBq) 1 week for 0.2 mCi (7 MBq)
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells	10	0.2	40	1	1 week for 0.5 mCi (20 MBq)
TI-201 Chloride	40	1	200	5	2 weeks for 3 mCi (110 MBq)

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

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).

If there is no recommendation in Column 3 of this table, the maximum activity normally administered is below the activities that require instructions on interpretation or disconnection of breast-feeding.

In some situations, a calculation may be case specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients.

Records should be kept in a manner that ensures the patient's confidentiality, that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These record keeping 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 child more than 0.5 rem (5 millisieverts), a record that instructions were provided is required. 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.

4. Summary Table

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

D. IMPLEMENTATION

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

Except in those cases in which a licensee proposes an acceptable alternative method for complying with 41.2(25), the methods described in this guide will be used in the evaluation of a licensee's compliance.

Table 4. Summary of Released 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	Administered activity	Administered activity ≤ Column 1 of Table 1	Yes - 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	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 child	Records that instructions were provided are required if: Administered activity > Column 2 of Table 3 or Licensee calculated dose from continued breast-feeding > 5 mSv (0.5 rem) to the child

REFERENCES

1. National Council on Radiation Protection and Measurements (NCRP), "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," NCRP Report No. 37, October 1, 1970. (Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095.)

2. S. Schneider and S. A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG1492 (Final Report), NRC, February 1997.'

3. M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine," in *Pediatric Nuclear Medicine,*

Edited by S. Treves, Springer Verlag, New York, 1995.

4. "Guidelines for Patients Receiving Radioiodine Treatment," Society of Nuclear Medicine, 1987. This pamphlet may be obtained from the Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016-6760.

APPENDIX A

Table A-1. Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine

Radionuclides'	Half-life (days)'	Exposure Rate Constant' (R/mCi-h at 1 cm)	Radionuclide'	Half-life (days)'	Exposure Rate Constant' (R/mCi-h at I cm)
Ag-111	7.45	0.150	Pd-103 implant	16.96	0.86[5]
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[6]
I-125 implant	60.14	1.11[4]	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[6]
Ir-192 implant	74.02	4.59[4]	Yb-I69	32.01	1.83
P-32	14.29	NA[6]			

[1] Although non-by-product materials are not regulated by IDPH, information on non-byproduct material is included in this regulatory guide for the convenience of the licensee.

[2] 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.

[3] 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, I-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, USNRC, Washington, DC, 1991. For Ag-111, Ga-67, !-125, Sm-153, Sn-117m, Tc-99m, Tl-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 calculations of the exposure rate constants are shown in Table A.2 of Appendix A of NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," USNRC, February 1997.

[4] R. Nath, A.S. Meigooni, and A.J. Meli, "Dosimetry on Traverse Axis of ^{125}I and ^{192}Ir 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.

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

[6] 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 0.5 rem (5 millisieverts).

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.

The following equation can be used to calculate doses:

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

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_o = 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

B.1 OCCUPANCY FACTOR

B.1.1 Rationale for Occupancy Factors Used To Derive Table I

In Table 1 of this regulatory guide, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members 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 1 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 I 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,
- Drink plenty of fluids for at least the first 2 days.
- E = 0.125 when an effective half-life is greater than one 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 two days,
    - Have few visits by family or friends for at least the first two days.
- In a two-component model (e.g., uptake of Iodine-131 using thyroidal and extra-thyroidal 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 60 millicuries (2,220 Megabecquerels) of Iodine-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.)

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

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.

$$D(\infty) = \frac{34.6\ (2.2\ \text{R- cm}^2/\text{mCi hr})\ (60\ \text{mCi})\ (8.04\ \text{d})\ (0.125)}{(100\ \text{cm})^2}$$

$$D(\infty) = 0.459\ \text{rem}\ (4.59\ \text{millisieverts})$$

Since the dose is less than 0.5 rem (5 millisieverts), the patient may be released, instructions must be given to the patient on maintaining doses to others as low as is reasonably achievable. A record of the calculation must be maintained because an occupancy factor less than 0.25 at 1meter 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 41.2(27). The effective half-life is defined as:

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

Where
T_b = biological half-life of the radionuclide
T_p = physical half-life of the radionuclide.

The behavior of Iodine-131 can be modeled using two components: extra-thyroidal iodide (i.e., existing outside of the thyroid) and thyroidal iodide following uptake by the thyroid. The effective half-lives for the extra-thyroidal and thyroidal fractions (i.e., F_l and F_2, respectively) can be calculated with the following equations.

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

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

Where:
T_{bl} = biological half-life for extra-thyroidal iodide

T_{b2} = biological half-life of iodide following uptake by the thyroid

T_p = physical half-life of iodine- 131.

However, simple exponential excretion models do not account for (a) the time for the Iodine-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 Iodine-131 administered is removed from the body at a rate determined only by the physical half-life of Iodine-131.

Thus, an equation to calculate the dose from a patient administered Iodine-131 may have three components. The first component is the dose for the first 8 hours (0.33-days) 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 extra-thyroidal 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 Iodine-131. The second exponential factor represents the activity from t = 8 hours to total decay based on the effective half-life of the extra-thyroidal 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.

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0}{(100\ cm)^2} \{E_1\ T_p\ (O.8)\ (1 - e^{-0.693.(0.33)/Tp}) + e^{-0.693(0.33)/Tp} E_2 F_1 T_{1eff} + e^{-0.693(0.33)/Tp} E_2 F_2 T_{2eff}\} \quad \text{(Equation B-5)}$$

F_1 = Extra-thyroidal uptake fraction

F_2 = Thyroidal uptake fraction

E_1 = Occupancy factor from 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_I, 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 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 200 millicuries (7,400 Megabecquerels) of Iodine-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 Iodine-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 I 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 B).

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

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

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

Therefore, thyroid cancer patients administered 200millicuries (7,400megabecquerels) of Iodine-131 or less would not have to remain under licensee control and could be released under 41.2(27), 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 0.5 rem (5 millisieverts).

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 55 millicuries (2,035 Megabecquerels) of Iodine-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 Iodine-131 from the body by using the effective half-lives appropriate for hyperthyroidism. An occupancy factor, E, of O.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

$$D(\infty) = \frac{34.6(2.2)(55)}{(100\text{cm})^2} \{(0.75)(8.04)(0.8)(1-e^{-0.693(0.33)/8.04}\}$$

$$+e^{-0.693(0.33)/8.04}(0.25)(0.20)(0.32)$$

$$+e^{-0.693(0.33)/8.04}(0.25)(0.80)(5.2)\}$$

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

Therefore, hyperthyroid patients administered 55 millicuries (2,035 Megabecquerels) of Iodine-131 would not have to remain under licensee control and could be released 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.

Table B-1. Uptake Fractions and Effective Half-lives for Iodine-131 Treatments				
Medical Condition	Extra-thyroidal Component		Thyroidal Component	
	Uptake Fraction F_1	Effective Half-Life T_{1eff} (day)	Uptake Fraction F_2	Effective half-life T_{2eff} (day)
Hyperthyroidism	0.20[1]	0.32[2]	0.80[1]	5.2[1]
Post Thyroidectomy for Thyroid Cancer	0.95[3]	0.32[2]	0.05[3]	7.3[2]

[1] 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 0.90 was selected as one that is seldom exceeded by the data shown in Figure 1 in this reference document. The effective half-life of 5.2 days for the thyroid 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.

[2] 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 extra-thyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid 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.

[3] The thyroidal uptake fraction of 0.05 was recommended by Dr. M. Pollycove, MD, NRC medical visiting fellow, as an upper limit post Thyroidectomy for thyroid cancer.

B.3 INTERNAL DOSE

For some radionuclides, such as Iodine-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.

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

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 Iodine-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 33 millicuries (1,110 Megabecquerels) of Iodine-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

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

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

In this case, the external dose to the other person would be no greater than 0.5 rem (5 millisieverts), while the internal dose would be about 0.017 rem (0.17 millisievert). 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. S. Schneider and S.A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," USNRC, NUREG-1492, February 1997.'

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.

APPENDIX C

BIOASSAY REQUIREMENTS FOR MEDICAL PERSONNEL WHO ADMINISTER RADIOIODINE TO PATIENTS

Medical personnel who administer substantial doses of radioiodine to patients may inhale or otherwise ingest some of the radioiodine, leading to possible significant thyroid burdens. Historically, bioassays for medical personnel have been required only in cases of administration to hospitalized patients because these are the patients receiving substantial doses of radiopharmaceuticals. This in turn meant that the medical personnel who prepared or administered the dosages to these patients handled substantial amounts of radioactive material, and therefore were at greatest risk for intakes. Patients who did not need to be confined after administration of radiopharmaceuticals were generally those patients who received relatively small dosages of these materials. The preparation or administration of these smaller dosages posed a relatively lower risk to the medical personnel involved.

The change in the criteria for release of patients who have been administered radiopharmaceuticals may involve the administration of relatively large dosages of radioactive materials without requiring patient confinement. Because the bioassay requirement for medical personnel is only applicable in the case of administration to hospitalized patients, it may be possible for medical personnel to prepare or administer substantial doses of radiopharmaceuticals without coming under the bioassay requirements in 641-41.2(39)"a"(8).

Licensees should note that although they may no longer be tied to a bioassay program because of the new patient release criteria, they are still subject to the requirements of 40.37(136C) "Conditions requiring individual monitoring of external and internal occupational dose." This requires the licensee to monitor all occupationally exposed personnel who may receive, in 1 year, an intake in excess of the applicable ALI in Table I, Columns 1 and 2, of Appendix B to Chapter 40.

Licensees are required to review the potential exposures of their employees and to monitor them if there is likelihood that the intake may exceed 10 percent of the limit in the year. Monitoring as it applies to intake means the implementation of a bioassay program designed to monitor and quantify intakes throughout the year. The bioassay program may include one or a combination of whole body or thyroid counting, urine or fecal analysis, or any other form of bioassay depending on the isotope or combination of isotopes handled during the monitoring period. For medical licensees using primarily radioiodine, thyroid monitoring may continue to be the preferable form of bioassay.