U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH

DRAFT REGULATORY GUIDE

June 1994
Division 8
Task DG-8015

Contact: S. Schneider (301) 415-6225

DRAFT REGULATORY GUIDE DG-8015

RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS

A. INTRODUCTION

NRC is proposing to amend the patient release criteria in 10 CFR Part 35, "Medical Use of Byproduct Material." The proposed Section 35.75 reads as follows:

> (a) A licensee may authorize release from licensee control any patient administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to an individual from exposure to the released patient is not likely to exceed 5 millisieverts (0.5 rem) in any one year.
> (b) If the total effective dose equivalent to any individual other than the patient is likely to exceed 1 millisievert (0.1 rem) in a year from a single administration, upon release the licensee shall:
>
> > (1) Provide the patient with written instructions on how to maintain doses to other individuals as low as reasonably achievable; and
> > (2) Maintain, for three years, a record of the released patient and the calculated total effective dose equivalent to the individual likely to receive the highest dose.

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Regulatory Publications Branch, DFIPS, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by August 29, 1994.

Requests for single copies of draft guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Office of Administration, Distribution and Mail Services Section.

This guide is being developed to provide guidance on determining the potential doses to an individual likely to receive the highest dose from exposure to the patient, to establish appropriate activities and dose rates for release, to provide guidance on instructions for patients on how to maintain doses to other individuals as low as reasonably achievable, and to describe recordkeeping requirements. For summaries, Table 1 lists the gamma ray constants and half-lives of commonly administered radionuclides, and Table 2 lists activities above which records and instructions should be prepared and the does rates below which patients may be released.

Regulatory guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with regulatory guides is not required. Regulatory guides are issued in draft form for public comment to involve the public in the early stages of developing the regulatory positions. Draft regulatory guides have not received complete staff review and do not represent official NRC staff positions.

The information collections contained in this draft regulatory guide are covered by the requirements in the proposed 10 CFR 35.75, which have been submitted to the Office of Management and Budget for review and approval.

B. DISCUSSION

This guide lists activities for commonly used radionuclides and their corresponding dose rates with which a patient may be released in compliance with the dose limits in the proposed Section 35.75.

The activities were calculated by using, as a starting point, the method discussed in 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).

Table 1

Gamma Ray Constants and Half-Lives of Commonly Administered Radionuclides

Radionuclide	Half-Life (days)[1]	Specific Gamma Ray Constant ($R \cdot cm^2/mCi \cdot h$)	Radionuclide	Half-Life (days)[1]	Specific Gamma Ray Constant ($R \cdot cm^2/mCi \cdot h$)
Ag-111	7.5	0.2[1]	Re-188	0.7	0.26[4]
Au-198	2.697	2.3[1]	Sc-47	3.43	0.56[1]
Cu-64	0.53	1.2[1]	Sm-153	1.95	0.447[5]
I-125	60.2	1.11[2]	Sr-89	52.7	NA[6]
I-131	8.05	2.2[1]	Tc-99m	0.25	0.607[7]
Pd-103	17.	0.86[3]	Yb-169	31.8	2.38[8]
Re-186	3.7	0.2[4]			

[1]From Reference 2.
[2]From Reference 3. The constant given is a dose rate constant that takes into account the attenuation of gamma rays within the implant capsule itself.
[3]From Reference 4. The constant given is a dose rate constant that takes into account the attenuation of gamma rays within the implant capsule itself.
[4]From Reference 5.
[5]Calculated by Radiation Internal Dose Information Center, Oak Ridge Associated Universities, Oak Ridge, Tennessee.
[6]From Reference 2. Not applicable (NA), 0.91 MeV gamma (0.009%, with Y-89m).
[7]From Reference 6.
[8]From Reference 7.

Table 2
Activities for Which Records and Instructions Should Be Prepared, and Dose Rates Below Which Patients May Be Released[1]

Radio-nuclide	Column 1[2] Activity Below Which Patients May Be Released		Column 2[3] Dose Rate at 1 meter at Which Patients May Be Released	Column 3[2] Activity Above Which Instructions to Patients and Records Should Be Prepared		Column 4[3] Dose Rate at 1 meter Above Which Instructions and Records Should Be Prepared
	mCi	GBq	mrem/hr	mCi	GBq	mrem/hr
Ag-111	390	14	8	77	2.9	2
Au-198	93	3.4	21	19	0.69	4
Cu-64	230	8.4	28	45	1.7	5
I-125	8.7	0.32	1	1.7	0.06	0.2
I-131	33	1.2	7	6.5	0.24	1
Pd-103	40	1.5	3	7.9	0.29	0.7
Re-186	780	29	16	160	5.8	3
Re-188	790	29	21	160	5.9	4
Sc-47	300	11	17	60	2.2	3
Sm-153	660	25	30	130	4.9	6
Tc-99m	960	36	58	190	7.1	11
Yb-169	7.6	0.28	2	1.5	0.06	0.4

[1]This table does not include radionuclides not regulated by NRC such as In-111, Tl-201, or Ga-67.
[2]Values have been rounded to two significant figures.
[3]Most values have been rounded to the nearest whole number.

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

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

Where $D(t)$ = accumulated exposure at time t, in roentgens,
Γ = specific gamma ray constant for a point source, R/mCi·h 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, $(1-e^{-0.693t/T_p})$ is set equal to 1.

- It is assumed that 1 roentgen is equal to 1 rem.

- Table 2 assumes, for radionuclides with half-lives greater than 1 day, that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25 percent of the total dose to decay (0.25 in Equation 2) at a distance of 100 centimeters.* For radionuclides with half-lives less than

*Selection of 25 percent of the "reference dose" for estimating the maximal likely exposure is an intuitive judgment based on time-distance combinations believed to occur when instructions to spend as little time as possible to the patient are given. A study by Harbert and Wells (Ref. 8) indicated that actual doses to family members of patients who had been treated for thyroid carcinoma was less than the predicted dose based on 25 percent of the reference dose.

1 day, the factor 1.0 is used in Equation 3 because the assumption that the time that individuals will spend near the patient will be limited is not valid when most of the dose is delivered in a relatively short time.

- The doses are calculated using the physical half-life of the radionuclide as given in Table 1 and do not account for the biological half-life of the radionuclide.

For radionuclides with a half-life greater than 1 day:

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

For radionuclides with a half-life less than 1 day:

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

Equations 2 and 3 calculate the dose from external exposure to gamma radiation. The equations do not account for internal intake by household members and members of the public because the dose from intake by other individuals is normally expected to be small (less than a few percent) relative to the gamma dose.** Further, the table and the methods used do not apply to the release of breast-feeding mothers if they continue to breast-feed. It should be noted that there could be a significant exposure to a breast-fed child.

The gamma ray constants and half-lives for typical radionuclides used in nuclear medicine and brachytherapy procedures are given in Table 1. The gamma ray constants used for iodine-125 (I-125) and palladium-103 (Pd-103) take into account attenuation of gamma rays within the implant capsule itself. All the

---

**There has been only a limited attempt to empirically measure the thyroid burden among family members associated with patients treated for hyperthyroidism or thyroid cancer. Existing information suggests that thyroid doses from contamination leading to internal exposure are likely to be less than external exposures. The addition of such a thyroid dose to the total effective dose equivalent (TEDE) by means of the thyroid weighting factor of 0.03 would, on the average, increase the TEDE by less than 3 percent.

other gamma ray constants in the table assume no attenuation of the gamma rays.

C. REGULATORY POSITION

1. ACTIVITY LEVELS

1.1 Activities for Release of Patients

Licensees may demonstrate compliance with the dose limit in the proposed Section 35.75 for release of patients from licensee control if the amount of the specific radionuclide in the patient's body at the time of release is less than the value in Column 1 of Table 2 or if the dose rate at 1 meter is less than the value in Column 2 of Table 2 for that radionuclide.

If radioactive materials are to be administered to a mother who is currently breast-feeding, several alternatives are available. First, the licensee may determine that the quantity and type of radionuclide administered is not likely to result in a dose to a breast-fed infant exceeding 5 millisieverts (0.5 rem); this is unlikely to be the case for most administrations of radioiodine. A second alternative is for the mother to stop breast-feeding the infant for a predetermined period of time. A third alternative is to postpone the administration until the mother has stopped breast-feeding. References on the transfer of drugs and other chemicals into human milk and the cessation of breast-feeding after administration of radiopharmaceuticals to mothers can be used by licensees to determine whether it is necessary to stop breast-feeding (Refs. 9, 10, and 11).

The radionuclides currently used in medical diagnosis and treatment deliver the majority of their dose through an external dose pathway (e.g., radiation from the patient's body that exposes someone standing nearby). If a radionuclide is, for example, a beta emitter, other pathways of exposure may need to be considered. The values in Table 2 do not take these other pathways into account, and licensees should refer to Regulatory Position 1.3 for further information.

1.2 Activities Requiring Instructions and Records

Licensees may use the values in Column 3 or Column 4 of Table 2 to determine when instructions should be given to patients and when records should be kept in accordance with the proposed Section 35.75(b). Column 3 provides activities above which an individual could receive a dose of 1 millisievert (0.1 rem) or more. Column 4 provides corresponding dose rates at 1 meter, based on the activities in Column 3.

1.3 Calculations Based on Case-Specific Factors

Licensees may calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis to account for factors specific to a patient. In such cases, licensees may be able to release a patient with radioactive material in excess of the activity listed in Table 2 and still demonstrate compliance with the annual dose limit. Licensees may take into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case.

If the activity administered exceeds the activity listed in Table 2 for recordkeeping, but a case-specific calculation indicates a dose less than 1 millisievert (0.1 rem) that appears to not need a record, a record should still be maintained to ensure compliance with the proposed Section 35.75. The record should clearly identify the specific assumptions used in the calculation.

For case-specific calculations, written instructions should specifically address the case-specific factors that were assumed in calculating the dose to an individual.

Appendix A provides procedures for performing case-specific dose calculations, and it describes how various factors may be considered in the calculations.

1.4 Multiple Administrations

To prevent a dose in excess of 5 millisieverts (0.5 rem) in any 1 year to an individual as a result of exposure to a patient containing radioactive material, licensees should sum the doses from all administrations of all

radionuclides to the patient in the year for which the record is maintained. (The proposed Section 35.75(b) would require a record of the released patient if, for a single administration, the dose to any individual other than the released patient is likely to exceed 1 millisievert (0.1 rem) in a year.)

2. INSTRUCTIONS FOR PATIENTS TO BE RELEASED

If the total effective dose equivalent to an individual exposed to a patient is likely to exceed 1 millisievert (0.1 rem) in a year from a single administration, the proposed Section 35.75(b)(1) would require that the released patient be given instructions on how to maintain doses to other individuals as low as reasonably achievable.

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, or they may include additional information for individual situations. The instructions should include a contact and phone number in case the patient has any questions. Instructions should include, as appropriate, the need for

- Maintaining distance from individuals, including sleeping arrangements and avoiding public transportation,
- Stopping breast-feeding if appropriate,
- Avoiding public places (e.g., grocery stores, shopping centers, theaters, restaurants, and sporting events),
- Maintaining good hygiene, and
- The length of time precautions should be taken.

Not all these precautions are necessary for every patient; patients should be given specific instructions that are applicable to their particular situation.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine (Ref. 12). This pamphlet was prepared jointly by the Society of Nuclear Medicine and the NRC. The NRC considers the instructions in this pamphlet to be acceptable instructions for patients, provided specific information is given to patients regarding any case-specific factors. However, licensees may

develop their own instructions, addressing the items discussed in the above paragraph as appropriate.

Sample instructions for patients who have received permanent implants are given in Appendix B.

3. RECORDS

If the total effective dose equivalent from a single administration, upon the patient's release, to any individual other than the patient is likely to exceed 1 millisievert (0.1 rem) in a year, the licensee must maintain for 3 years a record of the released patient and the calculated total effective dose equivalent to the individual likely to receive the highest dose.

For example, if a patient is administered 185 megabecquerels (5 millicuries) of iodine-131 (I-131), the maximum dose to another individual is not likely to exceed 1 millisievert (0.1 rem). Column 3 of Table 2 lists an activity of 240 megabecquerels (6.5 millicuries) or more as the activity corresponding to a dose at which a record should be kept and instructions should be given to the patient. However, if the patient is administered 555 megabecquerels (15 millicuries) of iodine-131, the dose to another individual is considered likely to exceed 1 millisievert (0.1 rem). In this case, the licensee is required to maintain a record of the dose and provide the patient with instructions.

Records should include (1) the patient's name, (2) the radioactive material, (3) the administered activity, (4) the date and time of administration, (5) the date and time of release, (6) the estimated dose to an individual exposed to the patient, and (7) whether instructions were given to the patient. If the dose to the individual most likely to receive the highest dose from exposure to the patient is determined by using Table 2 in this guide, the licensee should so state in the record and should state whether the activity or the dose rate from the table was used. If the dose was determined by a case-specific calculation, the licensee should maintain a record of the calculation, including the assumptions used in calculating the dose.

D. IMPLEMENTATION

The purpose of this section is to provide information about the NRC staff's plans for using this draft regulatory guide.

This draft guide has been released to encourage public participation in its development. Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method to be described in the active guide reflecting public comments will be used in the evaluation of a licensee's compliance with Section 35.75.

REFERENCES

1. National Council on Radiation Protection and Measurements, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," Report No. 37, 1970.

2. Radiological Health Handbook, U.S. Department of Health, Education, and Welfare, Public Health Service, 1970.[1]

3. R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of ^{125}I and ^{192}Ir Interstitial Brachytherapy Sources," Medical Physics, Volume 17, Number 6, November/December 1992.

4. Ravinder Nath, Yale University School of Medicine, letter to Dr. U. Hans Behling dated March 31, 1993.[1]

5. D.E. Barber, J.W. Baum, and C.B. Meinhold, "Radiation Safety Issues Related to Radiolabeled Antibodies," NUREG/CR-4444 (BNL-NUREG-52275), NRC, March 1991.[2]

6. H.E. Johns and J.R. Cunningham, The Physics of Radiology, Third Edition, Charles C. Thomas Publisher, 1978.

---

[1]Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

[2]Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Mail Stop SSOP, Washington, DC 20402-9328, telephone (202)512-2249 or (202)512-2171. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and copying for a fee in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

7. S. Schneider et al., "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492 (Draft report for comment), NRC, May 1994.[3]

8. J.C. Harbert and S.N. Wells, "Radiation Exposure to the Family of Radioactive Patients," Journal of Nuclear Medicine, Volume 15, Number 10, 1974.

9. L.K. Wagner, Editor, Radiation Bioeffects and Management Test and Syllabus, American College of Radiology, 1991.

10. American Academy of Pediatrics, Committee on Drugs, "Transfer of Drugs and Other Chemicals into Human Milk," Pediatrics, Volume 84, Number 5, 1989.

11. United States Pharmacopeial Drug Information, "Drug Information for the Health Care Professional," Volume I, 13th Edition, 1993.

12. "Guidelines for Patients Receiving Radioiodine Treatment," Society of Nuclear Medicine, 1987.[4]

[3]Requests for single copies of drafts should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Distribution and Mail Services Section. Requests for drafts will be filled as long as supplies last. Copies of drafts are also available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC: the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202) 634-3273; fax (202) 634-3343.

[4]This pamphlet may be obtained from the Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016-6760.

APPENDIX A

PROCEDURES FOR CALCULATING DOSES BASED ON CASE-SPECIFIC FACTORS

There may be situations in which a licensee may release a patient with an activity higher than the values listed in Table 2 for a specific radionuclide. Licensees may calculate potential doses to individuals exposed to patients receiving treatment with radioactive material on a case-by-case basis to account for certain factors specific to an individual. Such factors include (1) the effective half-life of the radioactive material, (2) exposure factors, and (3) other factors that may be relevant to the particular case.

The proposed Section 35.75 would require that a record of the release of the patient and the evaluation of the dose to an individual likely to receive the highest dose from a patient be maintained if the dose would exceed 1 millisieverts (0.1 rem).

The following equation may be used to calculate doses based on case-specific factors:

$$D(t) = \frac{34.6\Gamma Q_o T_p E}{(r)^2} \qquad \text{(Equation A-1)}$$

Where $D(t)$ = dose to total decay,
Γ = specific gamma-ray constant,
Q_o = initial activity at the start of the time interval,
T_p = physical half-life,
E = exposure factor that accounts for the different occupancy times and distances when an individual is around a patient. This value is typically 0.25 when the distance is 100 cm.
r = distance. This value is typically 100 cm.

1. EFFECTIVE HALF-LIFE

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits to members

of the public stated in the proposed Section 35.75. The effective half-life is defined as:

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

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

Using the effective half-life, Equation A-1 becomes:

$$D(t) = \frac{34.6\Gamma Q_0 T_{eff}\ (E)}{(r)^2} \qquad \text{(Equation A-3)}$$

with the factors defined as above and T_{eff} is the effective half-life.

For radioiodine, the effective half-life comprises the effective half-life of extrathyroidal iodide and the effective half-life of iodide following uptake by the thyroid. The extrathyroidal and thyroidal fractions of iodide are F_1 and F_2, respectively. The effective half-life for F_1 and F_2 can be calculated with the following equations:

$$T_{1eff} = \frac{T_{b1} \times T_p}{T_{b1} + T_p} \qquad \text{(Equation A-4)}$$

$$T_{2eff} = \frac{T_{b2} \times T_p}{T_{b2} + T_p} \qquad \text{(Equation A-5)}$$

Where T_{b1} = biological half-life for extrathyroidal iodide,
T_{b2} = biological half-life of iodide following uptake by the thyroid,
T_p = physical half-life of iodine-131.

Average values of 5 hours and 68 days may be used for T_{b1} and T_{b2}, respectively, for radioiodine. A maximum daily thyroidal uptake of iodide of

30 percent may be used (Reference A-1). Therefore, the extrathyroidal fraction of iodide is 70 percent.

Example: Calculate the maximum likely dose to an individual exposed to a patient who has been administered 100 millicuries (3,700 megabecquerels) of iodine-131 for the treatment of thyroid cancer.

Solution: In this example, we will account for elimination of iodine-131 from the body by using the biological half-lives appropriate for thyroid cancer to calculate the dose. It will be necessary to consider the different biological half-lives for thyroidal and extrathyroidal iodine. The following assumptions are made in this example:

Physical half-life of Iodine-131, T_p	8.0 days
Extrathyroidal fraction, F_1	0.7
Biological half-life of extrathyroidal fraction, T_{b1}	0.21 day
Effective half-life of extrathyroidal fraction, T_{1eff}	0.2 day
Thyroidal fraction, F_2	0.3
Biological half-life of thyroidal fraction, T_{b2}	68 days
Effective half-life of thyroidal fraction, T_{2eff}	7.2 days
Specific gamma ray constant, Γ	2.2 $R \cdot cm^2/mCi \cdot h$

For the first 24 hours after administration, the effective half-life, T_{eff}, will equal the physical half-life because no correction has been made for loss of iodine from voiding of the bladder.

The dose for the first 24 hours is given by

$$D(t) = \frac{34.6 \Gamma Q_0 T_p (0.25)(1-e^{-0.693t/T_p})}{(100\ cm)^2} \qquad \text{(Equation A-6)}$$

Substituting the values from above gives

$$D(1\ day) = \frac{34.6(2.2 R \cdot cm^2/mCi \cdot h)(100\ mCi)(8d)(0.25)(1-e^{-0.693(1d)/(8d)})}{(100\ cm)^2}$$

therefore,

$$D(1\ day) = 0.126\ rem\ (1.26\ mSv)$$

To calculate the dose from the end of the first day until total decay, it can be assumed that the extrathyroidal iodine has been totally voided and will not contribute to the dose. All the dose after the first day will come from the thyroidal iodine.

It is first necessary to calculate how much thyroidal iodine will be present at the end of the first day. The equation is:

$$Q(1\ day) = Q_0 F_2 e^{-0.693t/T_{2eff}} \qquad \text{(Equation A-7)}$$

If $t = 1$ day and $T_{2eff} = 7.2$ days are substituted into Equation A-7, the activity is

$$Q(1\ day) = 100\ mCi\ (0.3)(0.91)$$
$$= 27.2\ mCi\ (1{,}006\ MBq)$$

The dose from the end of the first day to total decay can now be calculated using Equation A-6 [$(1-e^{-0.693t/T_P})$ is set equal to 1 since the dose is to total decay]:

$$D(1d\text{-}\infty) = \frac{34.6(2.2R\cdot cm^2/mCi\cdot hr)\ (27.2\ mCi)(7.2d)(0.25)}{(100\ cm)^2}$$

$$D(1d\text{-}\infty) = 0.373\ rem\ (3.73\ mSv)$$

Adding the dose of 0.126 rem (1.26 millisieverts) from the first day to the dose of 0.373 rem (3.73 millisieverts) for day 1 to total decay yields a total dose of 0.499 rem (4.99 millisieverts). Thus, the maximum likely dose to an individual exposed to a thyroid cancer patient administered 100 millicuries (3,700 megabecquerels) of iodine-131 is about 0.5 rem (5 millisieverts). Therefore, thyroid cancer patients administered 100 millicuries (3,700 megabecquerels) of iodine-131 or less would not have to be confined and could be released under the proposed Section 35.75, assuming

that there is documentation of the validity of the foregoing assumptions in the individual patient's case and that the patient is given instructions.

2. EXPOSURE FACTOR

The distance and the time that other individuals will spend in the proximity of the patient may occasionally be taken into account when determining the dose to an individual. If the patient is living alone, will have few if any visits by family or friends, will not be returning to work immediately, and will be generally isolated from other people, the exposure factor can be decreased by a factor of two (for example, from the general value of 0.25 to 0.125). This would allow an individual to be released with an activity that is higher than that specified in Table 2 in the regulatory guide. On the other hand, if the patient needs extensive care at home, the exposure factor will have to be increased to account for the increased exposure of the individual caring for the patient.

If this option is used in calculating the dose, the licensee should state in the record why a lower exposure factor was justified.

Example: Calculate the maximum likely dose to an individual exposed to a patient who has received 10 millicuries (370 megabecquerels) of iodine-131. The patient lives alone and will not be working.

Solution: The dose is calculated using Equation A-1:

$$D(t) = \frac{34.6\Gamma Q_0 T_p E}{(r)^2}$$

Since the patient lives alone and will not be returning to work, and therefore will not be around the public, the exposure factor can be reduced to 0.125:

$$D(t) = \frac{(34.6)\ (2.22R\cdot cm^2/mCi\cdot hr)\ (10\ mCi)(8.05d)(0.125)}{(100\ cm)^2}$$

$$D = 0.077\ rem\ (0.77\ mSv)$$

Since the dose is less than 1 millisievert (0.1 rem), the patient may be released and instructions to the patient are not required. Because the administered activity would indicate instructions and a record to be maintained based on the values in Table 2, it is recommended that a record of the calculation be maintained to ensure compliance with the dose limits in the proposed Section 35.75.

Example: Calculate the maximum likely dose to an individual exposed to a patient who has received 10 millicuries (370 megabecquerels) of iodine-131. The patient requires extensive care because of other medical conditions.

Solution: Since the patient needs extensive care, the exposure factor will have to be increased to account for the increased time the primary caregiver will spend near the patient. An exposure factor of 0.5 is used in this example:

$$D = \frac{(34.6)\ (2.2R \cdot cm^2/mCi \cdot hr)\ (10\ mCi)(8.05d)(0.5)}{(100\ cm)^2}$$

$$D = 0.304\ rem\ (3.04\ mSv)$$

Since the dose exceeds 1 millisievert (0.1 rem), the licensee must provide the patient with written instructions, and a record of the released patient is required.

3. OTHER FACTORS

3.1 Attenuation of the Radiation in the Body

Licensees may take into account attenuation of the radiation by the patient. The fraction of the dose that results after attenuation by the body may be calculated using the following equation:

$$D = D_0 e^{-\mu x} \qquad \text{(Equation A-8)}$$

Where D = dose after attenuation,
D_0 = dose before attenuation,
μ = linear attenuation coefficient of tissue,
x = thickness of tissue covering the implant.

Also, the dose before attenuation is, from Equation 2 in the guide:

$$D_0 = \frac{34.6 \Gamma Q_0 T_p\ (0.25)}{(100\ \text{cm})^2} \qquad \text{(Equation A-9)}$$

Substituting Equation A-9 for D_0 in Equation A-8, the dose after attenuation becomes

$$D = \frac{34.6 \Gamma Q_0 T_p\ (0.25)(e^{-\mu x})}{(100\ \text{cm})^2} \qquad \text{(Equation A-10)}$$

Example: Calculate the maximum likely dose to an individual exposed to a patient who has received a permanent implant of 60 millicuries (2,220 megabecquerels) of iodine-125. The following factors apply:

Γ = 1.11 R·cm²/mCi·hr,
T_p = 60.2 days,
μ = 0.387/cm (Ref. A-1),
5 HVLs = 9 cm (assume 5 Half Value Layers;
1 Half Value Layer for iodine-125 = 1.8 cm).

There is a significant reduction in the exposure rate from the shielding effects of the source capsule. The Γ of 1.11 R·cm²/mCi·h for iodine-125 already accounts for the reduction in exposure rate from attenuation by the source capsule.

Based on empirical assessment involving patients with implants, tissue shielding for iodine-125 is likely to exceed 5 or more half-value layers.

Solution: The dose is calculated using Equation A-10:

$$D = \frac{34.6(1.11R \cdot cm^2/mCi \cdot hr)(60\ mCi)(60.2d)(0.25)(e^{-(0.387/cm)(9\ cm)})}{(100\ cm)^2}$$

$$D = 107\ rem\ (1.065\ mSv)$$

Therefore, a patient who has received a permanent implant of 60 millicuries (2,220 megabecquerels) of iodine-125 may still be authorized for release. The licensee must provide the patient with instructions and maintain a record that documents the validity of the foregoing assumptions in the individual patient's case.

3.2 Internal Dose

Internal dose may be a consideration with certain radiopharmaceuticals now being developed, such as radiolabeled antibodies, or those that are developed in the future. Many of the radionuclides used in radiolabeled antibodies are predominantly beta or alpha emitters, which emit few gammas.

One way of evaluating the internal dose is to compare the internal dose with the annual limit on intake (ALI) value in 10 CFR Part 20. A rule of thumb is to assume that the individual likely to receive the highest dose from exposure to the patient will receive an internal dose of 1-millionth of the activity that is in the patient. This rule of thumb was developed in Reference A-2 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. A-3 and A-4) regarding the intakes of individuals exposed to patients administered iodine-131 indicated that internal doses are negligible compared to external doses and that intakes were of the magnitude of one 1-millionth of the quantity in the patient. For additional discussion on the subject, see Reference A-1.

Thus, a rough estimate of the effective dose equivalent can be calculated from the following equation:

$$D_1 = \frac{5 \text{ rems } Q \ 10^{-6}}{ALI} \qquad \text{(Equation A-11)}$$

Where D_1 = the internal effective dose equivalent to the individual exposed to the patient in rems,

Q = the activity in the patient at time of release in microcuries,

ALI = the occupational inhalation annual limit on intake from Appendix B of Part 20,

5 rems = the dose from an intake of one ALI,

10^{-6} = the assumed fractional intake.

For example, assume that 30 millicuries (30,000 microcuries) iodine-131 was administered to a patient. If 1-millionth of the administered activity is taken in by another individual, the activity would be 0.03 microcuries. The stochastic ALI for iodine-131, 200 microcuries, corresponds to an effective dose equivalent of 50 millisieverts (5 rems). Thus, the individual would receive a dose of about 75 microsieverts (0.75 millirem). In this case, the internal dose would be considerably less than 1 percent of the assumed 5 millisieverts (0.5 rem) 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 they would be significantly less than the uncertainty in the external dose.

REFERENCES FOR APPENDIX A

A-1. S. Schneider et al., "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492 (Draft report for comment), NRC, May 1994.*

A-2. 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.

A-3. R.C.T. Buchanan and J.M. Brindle, "Radioiodine Therapy to Out-patients - The Contamination Hazard," British Journal of Radiology, Volume 43, 1970.

A-4. 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.

*Requests for single copies of drafts should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Distribution and Mail Services Section. Requests for drafts will be filled as long as supplies last. 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.

APPENDIX B

SAMPLE INSTRUCTIONS FOR PATIENTS RECEIVING PERMANENT IMPLANTS

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are 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 and to yourself if the source falls out or comes out, you should do the following:

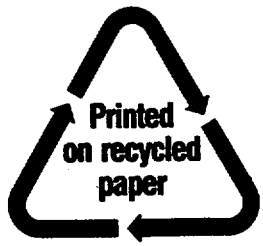
- Stay at a distance of _____ feet from _____ for _____ days/weeks.
- Minimize time with children and pregnant women for _____ days/weeks.
- Do not hold or cuddle children for _____ days/weeks.
- Avoid public transportation for _____ days/weeks.
- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
    - Take the following action if you find a seed or pellet:
        - Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.
        - Place the container with the seed/pellet in a location away from people.
        - Notify _____, at (phone number) for further instructions as soon as possible.

If you have any questions, contact the following individual(s):

Name _____ Phone number _____ Beeper number _____
Name _____ Phone number _____ Beeper number _____

REGULATORY ANALYSIS

"Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (NUREG-1492, S. Schneider et al., 1994), provides the regulatory basis for this guide and examines the costs and benefits. A copy of NUREG-1492 is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW., Washington, DC.



Federal Recycling Program

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300

FIRST CLASS MAIL
POSTAGE AND FEES PAID
USNRC
PERMIT NO. G-67