NEW YORK STATE DEPARTMENT OF HEALTH
BUREAU OF ENVIRONMENTAL RADIATION PROTECTION

DRAFT RADIATION GUIDE 10.17

RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS

A. INTRODUCTION

Section 16.123(b) of 10 NYCRR Part 16 requires licensees to assess the radiation exposure to individuals from patients administered radioactive materials and take action, as appropriate, to reduce exposures to other individuals. These requirements apply for both diagnostic and therapeutic uses regardless of the amount administered. Section 16.123(b), Medical uses of radioactive material, states:

- The licensee shall confine patients undergoing procedures authorized by ...until the total effective dose equivalent for the individuals (other than the patient) likely to receive the greatest dose is 5 mSv (500 mrem) or less.

- When the total effective dose equivalent to any individual that could result from the release of a patient is likely to exceed 1 mSv (100 mrem), the licensee shall:

    - provide the patient, or his/her competent representative, written information on risks of radiation and methods for reducing the exposure of individuals; and

    - keep records of such patients release for a period of five years.

This document is designed to provide guidance on determining the potential dose 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 guidelines for instructions to patients on how to reduce exposures to other individuals, to describe recordkeeping requirements, and to inform licensees of other potential problems associated with the release of patients containing radioactive materials.

B. DISCUSSION

The radiation dose to another individual from a patient is highly dependent on a number of factors, including the amount and type of radioactive material administered, the patient's living/working arrangements, ability/willingness to follow instructions, etc. An assessment of potential doses to other individuals requires the collection of detailed patient specific information, the formation of assumptions on time spent with and proximity to other individuals, and the use of appropriate mathematical models. Such calculations may not be practical for most nuclear medicine procedures since it would considerably increase the licensee's workload.

Another approach is to develop a standard model based on realistic, but conservative assumptions regarding the patient-other exposed individual relationship, and derive a list of values based on the isotope and dose limit. This could then be used for all administrations as long as the patient's particular living conditions did not differ greatly from the assumptions used in the model.

A list of activities for commonly used radionuclides and the corresponding dose rates with which a patient may be released in compliance with the dose limits in Section 16.123(b) is listed in Table 2. The activities in Table 2 were calculated based on 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]. Additional assumptions were made, as discussed below.

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

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

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 (from Table 1);

Q_0 = initial activity of the point source in millicuries, i.e., activity remaining in the patient at the time of the release;

T_p = physical half-life in days (from Table 1);

r = distance from the point source to the point of interest, i.e., exposed individual, in centimeters;

t = exposure time in days.

This guide uses the NCRP equation (Equation 1), and makes the following assumptions, in order to calculate the activities at which patients may be released that are listed in Table 2.

- 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 1 rem.

- For radionuclides with half-lives greater than 1 day, 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 total dose to decay (0.25 in Equation 2) at a distance of 100 centimeters.[1] For radionuclides with half-lives less than 1 day, an exposure factor of 1.0 is used (Equation 3) because most of the dose is delivered in a relatively short time and the assumption that the time an individual will spend near the patient will be limited is not valid.

- 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.

- The gamma ray constants listed in Table 1 for iodine-125 (I-125) and palladium-103 (Pd-103) take into account attenuation of gamma rays within the implant capsule itself. All the other gamma ray constants in the table assume no attenuation of the gamma rays.

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

$$D(4) = \frac{34.6 \tilde{A} Q_0 T_p (0.25)}{(100 cm)^2} \qquad \text{(Equation 2)}$$

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

$$D(4) = \frac{34.6 \tilde{A} Q_0 T_p}{(100 cm)^2} \qquad \text{(Equation 3)}$$

Equations 2 and 3 calculate the dose from external exposure to gamma radiation only. 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 external gamma dose.[2] This assumption ***does not*** apply to the release of breast-feeding mothers who continue to breast-feed. It should be noted that there could be a significant internal exposure to a breast-fed child.

[1] Selection of 25 percent of the "reference dose" for estimating the maximum 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 were less than 25 percent of the reference dose.

[2] 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 much 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.

Table 1

Gamma Ray Constants and Half-Lives
of Commonly Administered Radionuclides

Radionuclide	Half-Life (days)[1]	Specific Gamma Ray Constant ($R \cdot cm^2/mCi \cdot h$)
Ag-111	7.5	0.2[1]
Au-198	2.697	2.3[1]
Cu-64	0.53	1.2[1]
I-125	60.2	1.11[2]
I-131	8.05	2.2[1]
In-111	2.8	3.21
Ga-67	3.26	0.792
Pd-103	17.0	0.86[3]
Re-186	3.7	0.24
Re-188	0.7	0.26[4]
Sc-47	3.43	0.56[1]
Sm-153	1.95	0.447[5]
Sr-89	52.7	NA[6]
Tc-99m	0.25	0.607[7]
Tl-201	3.04	0.456
Yb-169	31.8	2.38[8]

[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, TN.
[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

Radionuclide	Column 1 Activity Below Which Patients May Be Released		Column 2 Dose Rate at 1 Meter Below Which Patients May Be Released	Column 3[1] Activity Above Which Instructions to Patients and Records are Required		Column 4[2] Dose Rate at 1 Meter Above Which Instructions and Records are Required
	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	0.6	0.2
I-131	33	1.2	7	6.5	0.24	1
In-111	64	2.3	21	13	0.47	4
Ga-67	224	8	17.8	44.8	1.6	3.5
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
Tl-201	417	15	19	83.4	3	3.8
Yb-169	7.6	0.28	2	1.5	0.06	0.4

[1]Values have been rounded to two significant figures.
[2]Most values have been rounded to the nearest whole number.

C. REGULATORY POSITION

1. ACTIVITY LEVELS

1.1 Activities for Release of Patients

Licensees may demonstrate compliance with the dose limits in Section 16.123(b) 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 the dose rate is used, licensees should document the type of instrument used, calibration factor and actual reading).

While use of this table is appropriate for most administrations, licensees need to consider any special circumstances that could increase the dose to another individual. For example, the level of care a patient requires should be considered. The values listed in Table 2 are based on an exposure factor of 0.25 at a distance of 100 centimeters. This assumption may underestimate the dose to a staff member or family member who provides care to a patient.

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 an alpha or 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.

The exposure to an infant from a breast-feeding mother ***can not*** be evaluated based on the values in Table 2. If radioactive materials are to be administered to a mother who is currently breast-feeding, an alternate method of evaluation must be used in order to determine that the quantity and type of radionuclide administered is not likely to result in a dose to the breast-fed infant exceeding 5 mSv (0.5 rem). This is unlikely to be the case for most administrations of radioiodine. Two alternatives to insure that the dose limits are not exceeded are for the mother to stop breast-feeding the infant for a pre-determined period of time or to postpone the administration of radioactive material 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, 11].

1.2 Activities Requiring Instructions and Records

Licensees may use the values in Column 3 and Column 4 of Table 2 to determine when instructions must be given to patients and when records must be kept in accordance with Section 16.123(b). Column 3 provides activities above which an exposed individual could receive a dose of 1 mSv (0.1 rem) or more. Column 4 provides corresponding dose rates at 1 meter based on the activities in Column 3. If the patient exceeds ***either*** Column 3 or Column 4, instructions must be provided to the patient and records must be kept. Further guidance on patient instructions and recordkeeping is contained in Regulatory Position 2 and Regulatory Position 3.

1.3 Calculations Based on Case-Specific Factors

Instead of using the values in Table 2, licensees may calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis in order to account for factors specific to that 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.

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

1.4 Multiple Administrations

If a dose is fractionated, or a patient receives multiple treatments, each case can not be considered separately in order to eliminate the need to confine a patient. To prevent a dose in excess of 5 mSv (0.5 rem) in any l year to an individual as a result of exposure to a patient containing radioactive material, licensees must sum the doses from all administrations of all radionuclides to the patient in that year. Section 16.123(b) requires 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 mSv (0.1 rem) in a year. Therefore, only those doses for which a record is required need to be summed.

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 mSv (0.1 rem) in a year from a single administration, Section 16.123(b) requires that the released patient be given information on risks of radiation exposure and instructions on how to reduce the exposure to other individuals. The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and include additional information for individual situations. For case-specific calculations, written instructions should specifically address the case-specific factors that were assumed in calculating the dose to an individual. The instructions should include a contact and phone number in case the patient has any questions, and the length of time precautions should be taken.

Instructions should include, as appropriate, the need for:

- Maintaining distance from individuals, including sleeping arrangements and avoiding public transportation,
- Stopping breast-feeding,
- Avoiding public places (e.g., grocery stores, shopping centers, theaters, restaurants, and sporting events),
- Maintaining good hygiene,
- Proper handling of waste (i.e. tissues, diapers, etc.), and
- Proper handling of dislodged seeds.

Not all these precautions are necessary for every patient; each patient should be given specific instructions that are applicable to his/her particular situation.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine [Ref. 12]. The department considers the instructions in this pamphlet to be acceptable instructions for patients, provided 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.

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

3. RECORDS

If, upon the patient's release from the hospital, the total effective dose equivalent from a single radioactive materials administration to any individual other than the patient is likely to exceed 1 mSv (0.1 rem) in a year, the licensee must maintain a record of the released patient and the calculated total effective dose equivalent to the individual likely to receive the highest dose. If a case-specific calculation indicates a likely dose of less than 1 mSv (0.1 rem) to an individual, a record must still be maintained if the activity administered exceeds the activity listed in Table 2, Column 3, in order to ensure compliance with Section 16.123(b). The record should clearly identify the specific assumptions used in the calculation. These records must be maintained for 5 years.

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 state so in the record. If the dose was determined by a case-specific calculation, the licensee should maintain a record of the calculation. The record should clearly identify the specific assumptions used in the calculation. These records must be maintained for 5 years.

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 mSv (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 mSv (0.1 rem). In this case, the licensee is required to maintain a record of the dose and provide the patient with instructions.

D. OTHER CONSIDERATIONS

Licensees should be aware that patients may be returned to a nursing home or other skilled care facility after undergoing a nuclear medicine procedure. Since these facilities generally do not have radioactive materials licenses, staff may not be aware that patient excreta will be radioactive and that soiled diapers should not be put into the trash. Staff at these facilities should be made aware that a particular patient has had a nuclear medicine procedure and instructions should be given in regard to the handling of patient excreta.

Radioactive patient excreta becomes a problem when it enters the normal waste stream (either regulated medical waste or household trash). Most waste management facilities now have sensitive radiation monitoring capabilities and routinely monitor waste shipments for radioactivity. Since these facilities are not authorized to process radioactive waste, they will refuse to accept any shipment that has elevated radiation readings (in some cases just barely above background). Many times, radiation consultants are called in to identify and isolate the source of the radiation. This generally results in a large expense to either the waste facility, waste hauler, or the licensee who administered the radioactive material. Licensees are advised to instruct patients on storing waste and should be available to provide assistance to patients.

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.

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.

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

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

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

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.

APPENDIX A

PROCEDURES FOR CALCULATING DOSES
BASED ON CASE-SPECIFIC FACTORS

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

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

$$D(t) = \frac{34.6 \tilde{A} Q_0 T_p E}{(r)^2} \qquad \text{(Equation A-l)}$$

Where $D(t)$ = dose to total decay,

$\tilde{A}$ = 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), and

r = distance (this value is typically 100 cm).

l. 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 16.123(b). The effective half-life is defined as:

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

Where T_b = biological half-life of the radionuclide,

T_p = physical half-life of the radionuclide,

T_{eff} = the effective half-life.

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

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

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 each fraction can be calculated with the following equations:

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

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

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 0.21 days (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 (0.3) may be used [Ref. A-1]. Therefore, the extrathyroidal fraction of iodide is 70 percent (0.7). Note that these are average values based on normal thyroid function, and may not accurately reflect a particular individual's situation. Biological half-lives and distribution of the iodine between the thyroid and the rest of the body may be significantly different in individuals with thyroid disease.[3]

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:

[3] Uptake of radioiodine by the thyroid gland ranges from 9 percent to 30 percent in euthyroid individuals, with the average being 17 percent. Hyperthyroid individuals may have an uptake of up to 75 or 80 percent. Biological half-lives range from 21 to 300 or more days in euthyroid individuals. In cases of severe hyperthyroidism, the biological half-life of I-131 may be as little as 7 days [Ref. A-1].

Physical half-life of iodine-131, *Tp* . . . . . 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, Ã . . . . . 2.2 R˙cm^2/mCi˙h

Exposure Factor . . . . . 0.25 at 100 cm

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:

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

Substituting the values from above gives:

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

therefore,

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

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 does not add to the dose. All the dose after the first day will come from the thyroidal iodine, therefore it is necessary to calculate how much thyroidal iodine will be present at the end of the first day.

The equation is:

$$Q(1day) = Q_o F_2 e^{-0.693 t/T2eff} \qquad \text{(Equation A-7)}$$

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

$$Q(1day) = 100 \text{ mCi } (0.3)(0.91)$$

$$Q(1day) = 27.2 \text{ mCi } (1{,}006 \text{ MBq})$$

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

$$D(1d\&4) = \frac{34.6(2.2R/cm^2/mCi/hr)(27.2mCi)(7.2d)(0.25)}{(100cm)^2}$$

$$D(1d\text{-}4) = 0.373 \text{ rem } (3.73 \text{ mSv})$$

Adding the dose of 0.126 rem (1.26 mSv) from the first day to the dose of 0.373 rem (3.73 mSv) for the remaining time until total decay yields total dose of 0.499 rem (4.99 mSv). Thus, the maximum likely dose to an individual exposed to this patient is about 0.5 rem (5 mSv). Therefore, in this case, the patient would not have to be confined and could be released assuming that there is documentation of the validity of the foregoing assumptions and that the patient is given appropriate instructions.

2. EXPOSURE FACTOR

The distance and the time that other individuals will spend in proximity to the patient must be taken into account when determining the dose to an individual. The values contained in Table 2 are based on an exposure factor of 0.25 at 100 cm. This exposure factor may be adjusted based on circumstances specific to an individual. For example, if the patient needs extensive care at home or is released to a nursing home, the exposure factor will have to be increased to account for the increased exposure of the individual caring for the patient. On the other hand, the exposure factor may be decreased if the patient is living alone, will have few or no visits by family or friends, will not be returning to work immediately, and will be generally isolated from other people. This would allow an individual to be released with an activity that is higher than that specified in Table 2. 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 requires extensive care because of other medical conditions.

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

$$D(t) = \frac{34.6ÃQ_0T_pE}{(r)^2}$$

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.

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

$$D = 0.304 \text{ rem } (3.04 \text{ mSv})$$

In this case, the dose exceeds 1 mSv (0.1 rem), and the licensee must provide the patient with written instructions and keep a record of the released patient.

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:

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

Since the patient lives alone and will not be returning to work, he will not be around members of the public and the exposure factor can be reduced to 0.125.

$$D(t) = \frac{(34.6)(2.22 R\,cm2/mCi\,hr)(10 mCi)(8.05 d)(0.125)}{(100 cm)^2}$$

$$D = 0.077 \text{ rem } (0.77 \text{ mSv})$$

In this case, the dose is less than 1 mSv (0.l rem), therefore the patient may be released and instructions to the patient are not required. However, because the administered activity is greater than the value in Table 2, Column 3, a record of the calculation should be maintained to ensure compliance with the dose limits in 16.123(b).

3. OTHER FACTORS

3.1 Attenuation of the Radiation in the Body

Licensees may take into account attenuation of the radiation by the patient. This basically applies only to permanent brachytherapy implants. The fraction of the dose that results after attenuation by the body may be calculated using the following equation:

$$D = D_o e^{-Fx} \qquad \text{(Equation A-8)}$$

Where D = dose after attenuation,

D_o = dose before attenuation,

F = linear attenuation coefficient of tissue,

x = thickness of tissue covering the implant.

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

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

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

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

<u>Example</u>: 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:

$\tilde{A}$ = 1.11 R·cm^2/mCi·hr,[4]

T_p = 60.2 days,

μ = 0.387/cm [Ref. A-1],

x = 9 cm (assume 5 Half Value Layers; 1 HVL for iodine-125 = 1.8 cm).[5]

[4] There is a significant reduction in the exposure rate from the shielding effects of the source capsule. The $\tilde{A}$ of 1.11 R·cm^2/mCi·h for iodine-125 already accounts for the reduction in exposure rate from attenuation by the source capsule.

[5] 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:

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

D = 0.107 rem (1.065 mSv)

Therefore, a patient who has received a permanent implant of 60 millicuries (2,220 MBq) of iodine-125 ***may*** 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 alpha or beta emitters which emit few gammas.

One way of evaluating the internal dose is to compare the activity administered to the patient with the annual limit on intake (ALI) value in Appendix 16-C of 10 NYCRR Part 16. The ALI gives the activity of radioactive material that must be taken into the body to result in a total effective dose equivalent of 5 rem. As rule of thumb, it can be assumed that the individual likely to receive the highest dose from exposure to the patient will receive an internal dose from one-millionth of the activity that is in the patient. This rule of thumb was developed for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility [Ref. A-2]. Although this rule of thumb does not specifically apply to cases of intake by an individual exposed to a patient, two studies regarding intakes by individuals exposed to patients administered iodine-131 indicate that internal doses are negligible compared to external doses and that the intakes were of the magnitude of one-millionth of the activity in the patient [Refs. A-3 and A-4]. For additional discussion on the subject, see Reference A-1.

A rough estimate of the effective dose equivalent can be calculated from the following equation:

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

Where D_I = 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 annual limit on intake by inhalation from Appendix 16-C of 10 NYCRR Part 16,

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

10^{-6} = the assumed fractional intake of the patient's activity.

Example: Calculate the internal dose to the individual likely to receive the highest dose from exposure to a patient treated with 30 millicuries (1,110 MBq) of iodine-131.

The following factors apply:

Q = 30,000 microcuries

$ALI_{I\text{-}131}$ = 200 microcuries

Solution: The dose is calculated using Equation A-11:

$$D_I = \frac{5 rems \times 30{,}000 \mu Ci \times 10^{-6}}{200 \mu Ci}$$

$$D_I = 0.00075 \text{ rem } (0.75 \text{ mrem})$$

In this case, the internal dose would be considerably less than 1 percent of the assumed 5 mSv (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 the uncertainty in the external dose is large enough that small contributions from internal dose are insignificant.

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), Nuclear Regulatory Commission, 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 Outpatients: 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.

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 l/3 to l/4 of an inch long, similar in size and shape to a grain of rice. To minimize radiation exposure 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 _____