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*Current Practice for the Release of Patients
Administered Radioactive Materials*

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CURRENT PRACTICE FOR THE RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS

STATEMENT OF OBJECTIVES

The purpose of this continuing education lesson is to increase the reader's knowledge and understanding of the newly adopted Nuclear Regulatory Commission guidelines for the release of patients who have been administered radioactive material.

On completion of this material, the reader should be able to:

1. Describe the 1997 NRC regulations for the diagnostic and therapeutic uses of radionuclides in accordance with release criteria as stated in 10 CFR 35.75.
2. Describe methods for demonstrating compliance with 10 CFR 35.75 regulations.
3. Discuss advantages/disadvantages of the new "dose-based" limits.
4. Discuss the four criteria used in the release of patients administered radioactive materials.
5. Describe and discuss calculation methods and assumptions for the release of patients based on administered radioactivity and patient specific dose calculations.
6. Describe and discuss four criteria for instructions.
7. Describe and discuss content of written instructions.
8. Describe and discuss records of release and minimum information required.

COURSE OUTLINE

I. INTRODUCTION

II. THE CHANGING REGULATORY CLIMATE

III. NRC REVISED REGULATION 10 CFR 35.75

IV. HOW LICENSEES CAN IMPLEMENT THE NEW REGULATIONS

- A. Criteria Used for the Release of Patients Administered Radioactive Material

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By:

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INTRODUCTION

Radiopharmaceuticals are unique among therapeutic agents in that they do not limit their effects to the patient undergoing treatment, but may directly affect the health and safety of individuals who associate with the patient. For example, a patient being treated with radioiodine for thyroid carcinoma may expose family members, friends, coworkers and other members of the public to both gamma radiation and to radioactive contamination that is excreted in urine, perspiration and saliva. For many years, treatment with radiopharmaceuticals required hospitalization of the patient until the retained radioactivity decreased to certain acceptable levels. In 1997, new risk-informed rules were implemented by the United States Nuclear Regulatory Commission (NRC), which significantly modified the conditions under which patients were required to remain in medical isolation.

Because radiopharmacists and other nuclear medicine professionals will be involved in counseling patients and families with regard to the precautions that are suggested following release from medical isolation, it is important that they become familiar with the rationale for the precautions, and the ways in which they are implemented. In this lesson, we will (a) review the regulatory basis for the release of patients, (b) review the ways in which the NRC expects licensees

to comply with the new regulatory guidance, (c) demonstrate ways in which licensees can comply with the requirements and (d) present evidence that the new release regulations are effective in reducing radiation exposure to individuals to acceptable levels.

THE CHANGING REGULATORY CLIMATE

Regulations governing the release of patients who receive radiopharmaceuticals from medical isolation or confinement were implemented because of concerns regarding stochastic radiogenic risks for those individuals exposed to such patients. These risks include carcinogenesis and germ cell mutagenesis. These regulations, which remained in effect until 1997, established the retained-activity limit for patient release for ^{131}I of 30 mCi (or a maximum dose rate of 5 mrem per hour at one meter) in the United States.

The development of new radiopharmaceuticals for therapy, along with the goal of optimizing clinical efficacy, cost-effectiveness and accessibility, led to an effort to develop regulations based on sound dosimetric and radiobiological principles. The original 30 mCi limit for ^{131}I proved to be a reasonable value based on actual measurements of exposure rates in the proximity of hyperthyroid patients following ^{131}I treatment. These measurements indicated that an average retained activity of 29 mCi yields an effective dose of 0.5 rem to family members.¹⁻³ This result was based on an assumption of complete in vivo physical decay with no biological elimination of the radioactivity. Although these assumptions may be appropriate for patients who have an intact thyroid, they are not valid in post-thyroidectomy patients being treated for metastatic thyroid cancer, who characteristically have relatively low retained activities. Their external exposure rates, normalized to administered activity, are considerably lower than those encountered in benign thyroid disease

patients. Estimates of retained activities of up to 200 mCi resulted in estimates of effective dose of 0.5 rem to the family members of thyroid cancer patients treated with ¹³¹I.^{2,3}

In May 1997, the NRC amended its regulations with regards to the release of patients administered radioactive material, specifically 10 CFR 35.75.⁴ This new ruling established release criteria based on the potential effective dose equivalent to individuals exposed to the radioactive patient, rather than the patient's retained activity or the dose rate at one meter. This permitted consideration of patient-specific kinetic and dosimetric data. The new regulation stipulates that the anticipated dose to individuals exposed to patients administered radioactive materials must be less than 0.5 rem. This dose-based limit better expresses the NRC's concerns with the health and safety of individuals who may be exposed to the patient. This is reflected in guidance provided by the NRC's Regulatory Guide 8.39 entitled "Release of Patients Administered Radioactive Materials."⁵

Regulatory analysis concluded that the new dose-based limit is acceptable according to current radiation protection principles.⁶ Anticipated benefits from the change included an improvement in the patients' quality of life, a decrease in the number of required hospital admissions and ultimately a contribution toward the minimization of national health care costs.

NRC REVISED REGULATION 10 CFR PART 35.75

The revised 10 CFR Part 35.75 applies to patients containing radioactive material in the form of permanent implants and radiopharmaceuticals. This revision allows the license holder to release a patient from its control when the total effective dose equivalent (TEDE) to exposed individuals as a consequence of the release is less than 5 mSv (500 mrem).

In implementing this regulatory requirement, the NRC regulations stipulate that three guidelines be observed. First, a licensee may authorize the release from its control any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the TEDE to any person from exposure to the released patient is not likely to exceed 5 mSv (500 mrem).

Second, a licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to exposed individuals as low as reasonably achievable (the ALARA concept). These instructions are to be given to individuals if the TEDE to any exposed individual has the potential to exceed 1 mSv (100 mrem). If the individual is breast-feeding, and if the dose to her child due to uninterrupted nursing could exceed 1 mSv (100 mrem), then special instructions must be issued.

Third, each licensee is required to maintain a record, for three years after the date of release, of the basis for authorizing the release of an individual if the TEDE is calculated using patient-specific parameters such as effective half-life and consideration of tissue shielding. The licensee is also required to maintain a record documenting that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 5 mSv (500 mrem).

HOW LICENSEES CAN IMPLEMENT THE NEW REGULATIONS

According to Regulatory Guide 8.39 "Release of Patients Administered Radioactive Material," patients may be released based on any of the following criteria:

- Administered radioactivity,
- Retained radioactivity,
- Measured dose rate, and
- Patient-specific dose calculation.

The most straightforward method employs the administered or retained radioactivity as the basis for the release. Assumptions include a point-source patient geometry, no attenuation by tissue or other shielding, an occupancy factor of 1.0 (at a distance of 1 meter) if the physical half-life of the radionuclide is less than one day and 0.25 if the half-life is greater than one day, and no biological elimination. Licensees can use a “default” table provided in Regulatory Guide 8.39, a portion of which is reproduced in Table 1. For example, an

Licensees may release patients with radioactivity or dose rates greater than those listed in Regulatory Guide 8.39 if a case-specific dose calculation is performed. This type of calculation permits the use of patient-specific factors such as tissue attenuation and biological clearance. Utilizing data published in NRC Regulatory Guide 8.39 for uptake fractions and effective half-lives for ¹³¹I thyroid cancer and hyperthyroidism patients, calculations demonstrate that up to 221 mCi of ¹³¹I sodium iodide may be administered for thyroid cancer, and up to 57 mCi

Table 1. Examples of Radionuclide Activities & Dose Rates for Authorizing Patient Release

Radionuclide	Radioactivity at or below which patients may be released		Dose rate @ 1 meter, at or below which patients may be released	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
¹³¹ I	1.2	33	0.07	7
¹⁵³ Sm	26	700	0.3	30
^{99m} Tc	28	760	0.58	58
¹⁹⁸ Au	3.5	93	0.21	21

administered ¹³¹I radioactivity under 33 mCi is acceptable for the release of patients from the licensee’s control. This method may also be employed to release patients from hospitalization when the retained radioactivity has fallen below the tabulated values, regardless of the administered activity. Note that no values are listed in Regulatory Guide 8.39 for pure beta emitters such as phosphorus-32, yttrium-90 or strontium-89. This is due to the very low external radiation hazard posed by patients who have been treated with these radionuclides.

Patients may also be released based on the measured dose rate at one meter. Table 1 gives the dose rates below which patients may be released from medical isolation for selected radionuclides. For example, a patient who has been administered ¹³¹I may be released when the dose rate falls below 7.0 mrem per hour.

may be administered for hyperthyroidism if an occupancy factor of 0.25 is assumed. This method can be applied to other labeled agents, as long as specific biological clearance data are available. Biological clearance data obtained from a group of patients may be applied to individuals, and in those instances for which a case-specific calculation applies to more than one patient release, the calculation need not be performed repeatedly. For example, by applying the formula and parameters found in Regulatory Guide 8.39, all thyroid cancer patients could be released without any calculation if the administered activity is less than 221 mCi or the dose rate at one meter was less than 48.5 mrem/h (assuming an occupancy factor of 0.25). Alternatively, a patient’s specific individual clearance curve, as measured with a tracer dose prior to therapy, may be used to calculate the limiting dose for that patient.

Use of this method should always be applied to research or IND applications for investigational therapeutic radionuclides.

REQUIRED INSTRUCTIONS TO PATIENTS

Written instructions should be specific to the patient's clinical diagnosis, and should not compromise the patient's care or the judgment of the physician. For ¹³¹I patients, written instructions are required if a patient-specific dose calculation is performed, if the dose rate at 1 meter is greater than 2.0 mrem/hr or if the administered activity is greater than 7.0 mCi (see Table 2). Criteria for other radiopharmaceuticals are listed in Regulatory Guide 8.39. The content of the written instructions should include precautions to reduce the spread of contami-

write the proper ALARA patient guidelines to be followed, as well as the length of time for each instruction to be followed.⁸

Additional instructions must be issued to women who are nursing, if the dose to the infant would exceed 1 mSv (100 mrem) if nursing were continued. The administered activities of ¹³¹I and other selected radionuclides that would result in doses to the infant exceeding 1 mSv are listed in Table 3. The instructions to nursing mothers should include guidance on the discontinuation or interruption of breast-feeding, and the potential adverse effects to the infant if the instructions are not followed. For any given radiopharmaceutical, these effects include injury to the blood-forming elements in the bone marrow, the bone surfaces and any tissues

Table 2. Activities and Dose Rates for Selected Radionuclides That Require Instructions

Radionuclide	Radioactivity above which instructions are required		Dose rate @ 1 meter above which instructions are required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
¹³¹ I	0.24	7	0.02	2
¹⁵³ Sm	5.2	140	0.06	6
^{99m} Tc	5.6	150	0.12	12
¹⁹⁸ Au	0.69	19	0.04	4

nation, minimizing time spent in public places including sporting events, shopping centers, theaters and public transportation, the importance of maintenance of distance from others, and the avoidance of sleeping together for a specific time period. The patient must also be instructed in regards to the time period during which these instructions should be observed.

The NRC has stated that the instructions provided in a pamphlet published by the Society of Nuclear Medicine are sufficient in fulfilling the requirement for written instructions.⁷ Revisions in this pamphlet over the years now require the treating physician to

that might preferentially concentrate the ingested radioactivity. It is noteworthy that the radioactivity values listed in Table 3 fall within the range of administered activities for diagnostic studies as well as therapeutic procedures. In the specific case of ¹³¹I, which accounts for the vast majority of radionuclide therapy procedures, the nursing mother should be advised of the potential for adverse effects to the infant's thyroid gland, including hypothyroidism or the development of thyroid cancer later in life. If the dose to the infant were to exceed 5 mSv, then documentation that instructions were provided must be maintained for at least three years following release.

Table 3. Radiopharmaceutical Activities That Require Instructions and Records When Administered to Patients Who Are Breast-Feeding an Infant or Child

Radiopharmaceutical	Radioactivity above which instructions are required		Radioactivity above which a record is required	
	(MBq)	(mCi)	(MBq)	(mCi)
¹³¹ I Sodium Iodide	0.01	0.0004	0.07	0.02
⁶⁷ Ga Citrate	1	0.04	7	0.2
²⁰¹ Tl Chloride	40	1	200	5
^{99m} Tc Pertechnetate	100	3	600	15

MAINTENANCE OF REQUIRED RECORDS

If the release was based on either patient-specific dose calculation or dose rate, records must be maintained for a minimum of three years. No records are required if the release is based on the administered (or retained) activity, and the activity is less than the levels found in Regulatory Guide 8.39 (33 mCi for ¹³¹I). Records should include a patient identifier, radionuclide, date and time of administration, administered radioactivity, date and time of patient release, estimated dose to exposed individuals and the method employed to calculate the dose. The description of the method should include patient-specific factors such as any changes in occupancy factor (the fraction of a day during which an individual is within one meter of the patient) or biological clearance parameters. Similarly, documentation of required instructions provided to breast-feeding women must be maintained for three years (see Table 3).

COMPUTATION OF DOSE TO EXPOSED INDIVIDUALS

A central tenet of the “dose-based” limit is the requirement that the licensee quantitatively estimate the radiation dose to a person who spends time in proximity to a patient emitting penetrating radiation. The dose to an exposed individual depends upon many factors. These include the exposure

rate constant of the radionuclide (the exposure rate, in roentgens per hour, measured at one centimeter from a source of one millicurie activity), the physical half-life of the radionuclide, the biological clearance of the radiopharmaceutical and its metabolic products, the distance the person is from the patient, and the fraction of the total t time spent at that distance (occupancy factor). In theory, the total dose is the time integral of the dose-rate as measured at the spatial position of the person relative to the patient. Since the spatial position varies unpredictably with time, it would seem that the problem is intractable. In practice, simplifying assumptions can be made which make the computation of the dose to an exposed individual practical.

The factor “34.6” is a product of the conversion of days to hours (24.0) and the total integral of the exponential function (inverse of the natural log of 2.0 = 1.44).

For example, suppose a patient contains 33 millicuries of ¹³¹I, and an exposed individual stands one meter away from the patient for six hours per day, seven days per week for one year. Suppose there is no biological excretion of radioiodine. If the exposure constant for ¹³¹I is 2.2 R / hr per mCi at one cm, what is the total dose to the exposed individual over the one-year period? In this case, E = 0.25, T = 8.06 days, t = 365 days and Q₀ = 33 mCi. Substituting into the above formula, we see that the exponential term

The following formula may be used to calculate potential exposure to exposed individuals, if biological clearance is not taken into account:

$$D(t) = \frac{34.6 \Gamma Q_0 TE (1 - e^{-0.693 t/T})}{r^2}$$

Where D (t) = Accumulated dose to time t, in rems
 T = Physical half-life in days
 E = Occupancy factor that accounts for different occupancy times and distances when individual is near patient. For example, if the individual spends 6 hours per day at 1 meter from the patient, then E = 6 / 24, or 0.25
 Γ = Exposure rate constant for a point source, R / hr per mCi x hr at 1 cm
 Q₀ = Initial activity at the start of time interval
 t = Exposure time in days
 r = Distance in centimeters, 100 cm (1 meter) is usually used

essentially vanishes, since $t \gg T$, and that $D(t) = 0.5$ rem. This is the origin of the 33-millicurie “default” value for ¹³¹I given in Table 1. Other radionuclides will have different exposure rate constants and different physical half-lives. This will result in a wide range of values for permissible retained radioactivity at the time of release; however, all releases would be based on the same maximum permissible radiation dose (0.5 rem). In practice, a licensee would assume that $D(t)$ is 0.5 rem (or some other lower target value) and solve the above equation for Q_0 to obtain the maximum permissible retained activity at release.

The above calculation assumes that the patient is a point source, that there is no biological clearance of radioactivity and that the patient’s tissue is not attenuating the gamma radiation. Because the patient indeed provides some self-shielding, and most radionuclides are subject to biological clearance processes, the above computation is quite conservative. In practice, the actual dose will be lower. For this reason, the NRC has enabled licensees to modify the assumptions underlying the above calculation so that patient-specific factors may be taken into account. The patient-specific calculation of the dose to exposed individuals may incorporate the use of any of four patient-specific

factors including:

1. Retained Radioactivity: May be instead of administered radioactivity.

2. Occupancy or Exposure Factor (E): Assumes individuals will spend variable distance and time in the proximity of the patient. A value of 0.25 may be used without justification. A patient who lives alone and is generally isolated from other people would enable a value of 0.125 to be used with justification. A patient requiring extensive care while at home would require a higher value of the occupancy factor (perhaps 0.50 - 0.75) to account for the increased exposure of the individual providing care.

3. Effective Half-Life (T_{EFF}): Licensees can use a measured T_{EFF} instead of the physical half-life (T_p) of administered radionuclide.

4. Attenuation or Shielding by Tissue: Licensees can use a measured dose rate, since this measurement includes attenuation by the patient’s tissues. In this case, the dose rate, in rem per hour as determined by using a calibrated ion chamber at one meter from the patient, would replace the term $\Gamma Q_0 / r^2$ in the above equation.

The dose limit of 0.5 rem, as set forth in the regulatory criteria, is expressed as TEDE. The TEDE is not a directly measurable physical quantity. It is a weighted

average of the radiation-absorbed doses to a number of tissues that are considered to be significant with regard to genetic effects and the induction of cancer. In order to correctly calculate TEDE, one must know the radiation doses due to (1) external gamma radiation emitted by the released patient and (2) internally deposited radionuclides that are a consequence of ingestion of contamination derived from the urine, saliva and perspiration of the released patient. A rigorous computation of TEDE is very difficult, and requires mathematical techniques not readily available to most licensees. However, the NRC permits licensees to use simplifying assumptions when computing the TEDE. First, the contribution to TEDE from external radiation may be derived from a single measurement of the dose rate, taking into account the physical or effective half-life, using a suitably calibrated ion chamber at a point one meter from the patient. This will result in an overestimation of the external component, since the target individual's muscle and adipose tissue will reduce the radiation dose to bone marrow, lung, gonads and other biologically significant tissues through attenuation. Although not strictly correct, this "point measurement" approximation of the TEDE will result in a conservative estimate of the dose to exposed individuals. Second, the contribution to TEDE due to the internalization of contamination may be neglected if its estimated contribution to the total dose is less than 10% of

the external dose estimate, according to Regulatory Guide 8.39. This is based on observations of low thyroid uptake of ¹³¹I in family members of patients treated for hyperthyroidism or thyroid cancer with radioiodine and released. Therefore, licensees can usually use the measured dose rate at 1 meter from the patient, in conjunction with the physical or effective half-life, as the sole basis for the computation of TEDE.

Appendix B of Regulatory Guide 8.39 demonstrates how licensees may calculate the external radiation dose to exposed individuals from patients who have been treated with ¹³¹I sodium iodide for hyperthyroidism and metastatic thyroid carcinoma. A three-component model (Equation B-5, Appendix B), which accounts for radioactivity retained during an initial non-void period, clearance via urinary and gastrointestinal routes and retention by intact thyroid gland or thyroid remnants, is used to estimate the total dose to an exposed individual from the time of administration to total decay. The parameters of the model include the effective half-time and fractional uptake of each component, which are tabulated in Table B-1 of Appendix B. Using the maximum permissible dose of 0.5 rem, Equation B-5 may be solved for the maximum permissible administered activity or maximum permissible exposure rate at one meter. Table 4 below shows the results of such calculations assuming three different occupancy factors.

Table 4. Computation of Maximum Administered ¹³¹I Activity and Initial Dose Rate at 1 Meter for Different Occupancy Factors

Occupancy factor	Thyroid Carcinoma		Hyperthyroidism	
	Maximum activity at release (mCi)	Dose rate at 1 meter (mrem/hr)	Maximum activity at release (mCi)	Dose rate at 1 meter (mrem/hr)
0.125	304	66.8	101.4	22.3
0.25	221	48.6	57	12.4
0.50	143	31.4	30.0	6.6

PRACTICAL APPLICATION OF THE CRITERIA

Application of these new criteria may seem complicated, especially with regard to the provision of “customized” instructions to individual patients. However, it is possible to use look-up tables, spreadsheets, databases or Internet-based applications to streamline the procedure.^{9,10} In addition, Zanzonico and co-workers have done extensive work to develop a generalized algorithm for determining the time of release and the duration of precautions for radionuclide therapy patients and their families.¹¹ Application of such algorithms will provide an improved basis for release times and consistency to the post-release instructions.

A straightforward procedure using a questionnaire and a template set of instructions is presented below. This procedure reflects the practice of one of the authors (SGM) and colleagues at the Ohio State University Medical Center.

1. Patient identified by his/her physician as a candidate for radionuclide therapy.

2. Physician indicates the radionuclide and radioactivity to be administered.

3. Prior to scheduling the radionuclide therapy, patient is asked to complete a two page questionnaire (see Figure 1) which solicits information regarding the individual's general health, family members presently at home, sleeping arrangements, pregnancy status for any individuals sharing the home, type of work performed, medical conditions which may require extensive medical care and travel arrangements for returning home.

4. Medical physicist reviews questionnaire and determines if patient is candidate for treatment as an outpatient. If patient is eligible for release as outlined in 10 CFR Part 35.75, a dose estimate is performed to ensure no individual receives a dose greater than 0.5 rem from exposure to the patient.

5. Prior to the administration of the

radiopharmaceutical, the patient is asked to review written instructions (see Figure 2) for the purpose of ensuring the radiation dose to exposed individuals is less than 0.5 rem.

6. Patient is asked to sign the written instructions and a copy provided.

7. After the patient receives the radiopharmaceutical, the patient is surveyed with an ion chamber and the results recorded on a patient release form.

Figure 1 is an example of the type of questionnaire that would be filled out by the authorized nuclear medicine physician, the radiation safety officer or other appropriately designated personnel while interviewing the patient. The questionnaire depicted in Figure 1 is used by one of the authors (SGM) at the Ohio State University Medical Center. The information collected is useful in assisting the physician and radiation safety officer in making a general assessment of the patient's suitability for release, selecting the appropriate occupancy factors for use in estimating the dose to exposed individuals, and in providing additional guidance to the patient when reviewing the written instructions.

The sample post-discharge instructions shown in Figure 2 are also used at the Ohio State University Medical Center. They provide the patients with ways in which they can modify their normal interactions with friends, colleagues and family members so that the radiation exposure to others is minimized. This set of instructions is specific to ¹³¹I, which is the radionuclide used in virtually all the therapeutic procedures performed in the United States for which written instructions are required. This institution-specific set of instructions is similar to that found in the pamphlet published by the Society of Nuclear Medicine⁷ mentioned earlier. The medical physicist as identified in the “Special Instructions” section would provide the lengths of time that the patient should avoid certain interactions with others.

Figure 1. Radiopharmaceutical Therapy Patient Questionnaire

Patient Name: _____ Identification Number: _____
Radiopharmaceutical: _____
Activity to be administered: _____ mCi

1. Number of individuals living in home: less than 2 years of age: _____
2 to 12 years of age: _____ greater than 12 years of age: _____
2. If there are children less than 12 years of age living at home, can arrangements be made for them to stay with another family member or friend for 3 days (4 days for greater than 150 mCi) following administration?

Yes	No	
NA		
3. Are there any pregnant individuals living in your home?

Yes	No	NA
-----	----	----
4. Can the pregnant individual arrange to stay with another family member or friend for 3-4 days following the administration of the radiopharmaceutical?

Yes	No	NA
-----	----	----
5. Do you have a separate bathroom that could be used exclusively by you for 3-4 days following administration of the radiopharmaceutical?

Yes	No	NA
-----	----	----
6. Can you arrange to sleep in a separate room from your spouse for 3 days (4 days for greater than 150 mCi) following administration?

Yes	No	NA
-----	----	----
7. Do you have any problems with bladder control that require you to wear a shield (e.g., Depends™)?

Yes	No	NA
-----	----	----

8. Do you have any physical problems that require extensive care by others?

Yes

No

If yes, describe the problem and estimate the number of hours per day that extensive care by others is required.

9. Describe your work: _____ Not employed.
(If "Not Employed," skip to next question)

9.a. About how many hours per day do you spend within 3 feet of a co-worker: _____?

9.b. Can you arrange to be off work for at least 3 days following the administration?

Yes

No

10. How will you return home following administration?

Private auto Taxi Bus Airplane

Other*

(describe) _____

How long will it take for you to get home? _____ minutes/hours?

(Contact the radiation safety staff if private auto travel time is greater than 16 hours.)

11. Are there any reasons you may need to spend time close to other people following administration?

Yes

No

If yes, describe reason:

Height: _____

Weight: _____

Completed by: _____ Date: _____

Figure 2. Radiopharmaceutical Therapy Patient Instructions.

Patient: _____
Scheduling Physician: _____
Radionuclide Administered: _____
Radioactivity: _____

For the next two (2) days, you will be excreting large amounts of ^{131}I (radioactive iodine) primarily in your urine. Smaller amounts may be present in your saliva, perspiration, blood and other body fluids. Your body will be giving off radiation, much like a radiator gives off heat. The amount of this emitted radiation will decrease rapidly during the first two days and then more slowly after that. Unlike the heat from a radiator, you and others will not be able to feel, smell or hear this radiation. Consequently, it is important that you observe the following instructions regarding your behavior for the duration time specified. These times have been calculated to ensure the safety of your family, friends and co-workers. Please keep in mind, you need the radiation---others do not. We want you to practice the concept of ALARA or maintaining the radiation exposures of others AS LOW AS REASONABLY ACHIEVABLE.

In general, you should keep the following concepts in mind:

- **DISTANCE:** The greater the distance you are from others, the less radiation they will receive.
- **TIME:** The less time that you spend with others, the less radiation they will receive.
- **HYGEINE:** Good personal hygiene habits reduce the possibility of transferring radiation to others.

TREAT OTHERS AS IF YOU HAVE A BAD CASE OF THE FLU!

Other instructions that must be followed

- Avoid dairy products and citrus juices for the first four hours after dosing.
- Avoid eating solid food for one hour after dosing.
- Stop all breast-feeding.
- Prevent pregnancy for at least 12 months.
- **After receiving the radioactive dose**, you should go directly home. The following instructions must be observed for the time frame given, unless otherwise indicated in the "Special Instructions" section of this form. If you believe you are unable to meet the requirements, please inform a member of the Office of Radiation Safety staff

and/or a member of the Nuclear Pharmacy or Division of Nuclear Medicine staff before signing this document.

- **For at least seven (7) days**, avoid sexual intercourse and kissing. No close contact (less than 3 feet) for children under the age of 12 or pregnant individuals. Separately launder bath towels, bed linens and underclothing. If you do not have a washer & dryer, wash these items by hand and thoroughly rinse them in a basin or tub afterward. Avoid preparing food for other individuals. Use separate or disposable eating utensils and wash them separately.
- **For three (3) days and dosages between 33 mCi and 150 mCi**, stay off work. Make arrangements for children under the age of 12 and pregnant individuals to stay outside your home. Sleep alone in a separate room if available. Use separate bathroom facilities if available and flush the toilet 2-3 times after each use. Males are encouraged to sit down while urinating. Use separate towels/linens from other members of the household and rinse the tub and sink thoroughly after each use. Wash your hands with soap and plenty of water frequently. Avoid close, prolonged contact (less than 3 feet and limit the time to 15-20 minutes/day) with other adults. Avoid traveling and public places (restaurants, grocery stores, theaters, hotels, public transportation, etc.). Drink plenty of fluids.
- **For four (4) days and dosages greater than 150 mCi**, wash your hands with soap and plenty of water frequently. Avoid close, prolonged contact (less than 3 feet and limit the time to 15-20 minutes/day) with other adults. Avoid traveling and public places (restaurants, grocery stores, theaters, hotels, public transportation, etc.). Drink plenty of fluids.

SPECIAL INSTRUCTIONS:

I have received, understand and agree to follow the above instructions.

NAME: _____ DATE: _____

Specific Patient Dose Calculations: _____ mrem

Body Frame: Small/Large/Normal Living Conditions: Normal/Alone/Extended

Office of Radiation Safety Contact Person:

Steven G. Marsh Phone: _____

Robert E. Peterson, Jr. Phone: _____

Patient Signature: _____

An alternative approach to generating the required instructions and documentation involves the use of an on-line form accessed via the Internet. Radiation safety personnel can enter the required patient-specific information, dates, exposure rates and effective half-lives via radio buttons, text boxes and check boxes. This information is electronically submitted to a Web server, which computes the expected radiation dose to exposed individuals and the lengths of time the patient should observe certain

precautions. These values are used to produce a suitable post-discharge instructions document that can be printed from the Web browser. Similarly, the program can generate the required documentation of the expected dose and the method of calculation. This approach is used by one of the authors (RER) at Duke University Medical Center. A portion of Duke's on-line form, which includes textboxes, radio buttons and checkboxes used for data entry, is depicted in Figure 3.

Figure 3. A Portion of Duke University's Online Form

Activity Administered (mCi): <input type="text"/>	Activity at Time of Release (mCi): <input type="text"/>	Release Exp. Rate (mR/hr): <input type="text"/>	*Effective half-life (days): <input type="text"/>	**Thyroid Uptake Value (%): <input type="text"/>
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*Patient-specific; required only for anti-lymphoma antibody treatments.

**Patient-specific; required only for hyperthyroidism treatments.

Household Information

Type of Dwelling: Single-Family Multi-Family Apartment Dormitory

Is anyone in the household: Pregnant Breastfeeding

Enter Data on Household Members:

PATIENT: <input type="radio"/> Male <input checked="" type="radio"/> Female <input type="text"/> Age	Household Member 2: <input type="radio"/> Male <input checked="" type="radio"/> Female <input type="text"/> Age	Household Member 3: <input type="radio"/> Male <input checked="" type="radio"/> Female <input type="text"/> Age	Household Member 4: <input type="radio"/> Male <input checked="" type="radio"/> Female <input type="text"/> Age
Household Member 5: <input type="radio"/> Male <input checked="" type="radio"/> Female <input type="text"/> Age	Household Member 6: <input type="radio"/> Male <input checked="" type="radio"/> Female <input type="text"/> Age	Household Member 7: <input type="radio"/> Male <input checked="" type="radio"/> Female <input type="text"/> Age	Household Member 8: <input type="radio"/> Male <input checked="" type="radio"/> Female <input type="text"/> Age

Transportation/Visitors/Work/School Information

Transportation Home: <input type="radio"/> Private Car, Alone <input checked="" type="radio"/> Private Car, Shared (less than 50 miles) <input type="radio"/> Private Car, Shared (50-200 miles) <input type="radio"/> Private Car, Shared (over 200 miles) <input type="radio"/> Public Conveyance (airplane, bus, train)	Visitors (check all that apply): Regular <input type="checkbox"/> Children <input type="checkbox"/> Pregnant <input type="checkbox"/> Breast-feeding <input type="checkbox"/>
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EXAMPLES

To illustrate the principles outlined above, we present three examples of how they may be implemented to release patients and provide them with appropriate home-going instructions.

(1) A 47-year-old man is treated for lymphoma with a monoclonal antibody labeled with ^{131}I . He lives with his wife and a 19-year-old daughter. Despite his illness,

greater than the default 7.0 mrem per hour (see Table 1), then the release must be documented, and the documentation maintained for at least three years. Because the dose rate exceeds 2 mrem per hour (see Table 2), the patient must be supplied with written post-discharge instructions (see Figure 2), a copy of which must be maintained for three years along with the dosimetry documentation.

The estimated dose to exposed individuals for this patient due to external gamma radiation is given by:

$$D_E = 34.6 \times (10.0 \text{ mrem/hr}) \times [0.97 \times (3.0 \text{ d} \times 0.25) + 0.03 \times (8.04 \text{ d}) \times 0.75]$$
$$D_E = 314 \text{ mrem}$$

he is active and continues to work as a park ranger. Measurement of the clearance of antibody with a small test dose demonstrated a single-exponential clearance with an effective half-life of 3.0 days in this patient. Immediately after administration of the therapy dose, the medical physicist measures the dose rate at a distance of 1 meter from the patient and determines it to be 10.0 mrem per hour. What will be the expected TEDE for individuals exposed to this patient? Is he a candidate for immediate release?

This patient is capable of self-care and has simple home and employment situations. Therefore, the default occupancy factor of 0.25 may be used for the single-exponential component in the dose calculation. In addition, it is assumed that the patient does not void for the first eight hours following administration. This requires inclusion of a second component in which the only clearance is by physical decay. For this component, an occupancy factor of 0.75 is recommended. (see Regulatory Guide 8.39).

Because the calculated TEDE is less than 0.5 rem, this patient is a candidate for immediate release. Since the release is based on an effective half-life rather than the default physical half-life, and a dose rate

(2) A 28-year-old woman is being evaluated for a possible recurrence of Hodgkin lymphoma. She is given 4.0 millicuries of ^{67}Ga -gallium citrate intravenously and told to return in 48 hours for an imaging procedure. Following administration of the radiopharmaceutical, she tells the technologist how much she enjoys nursing her 3-month-old infant. What instructions should she be given?

In general, it should be determined if the patient is nursing or pregnant before administering radioactive material, to permit an informed decision as to whether or not to defer the procedure. In this case, the administered activity of ^{67}Ga is well above the level for which instructions to nursing mothers must be supplied (0.2 millicuries; see Table 3). Nursing should be interrupted until the retained activity is less than 0.04 mCi (Regulatory Guide 8.39, Table 3, Column 1). This patient should be instructed to discontinue breast-feeding her child for at least one month, and documentation of this event should be maintained for at least three years.

(3) A 75-year-old male patient is being considered for treatment for thyroid cancer with 200 millicuries of ^{131}I sodium iodide following total thyroidectomy. He is

incontinent of urine and requires extensive home nursing care from his daughter. Two children, aged 10 and 12, also live with him. Is this patient a candidate for immediate release? If not, when could he be released?

In this case, an occupancy factor of 0.25 at 1 meter would not be appropriate, given the requirement for extensive nursing care. A value of 0.50 is chosen instead. According to Table 4, the maximum administered activity for an occupancy factor of 0.50 is 143 millicuries. This patient would not be a candidate for immediate release if a treatment activity of 200 millicuries were used. In addition, this patient's incontinence suggests that the potential for ingestion of contamination may present a significant risk to the daughter and small children in the household. To be conservative, the treating physician and radiation safety officer decide that release at the default dose rate for which instructions are required, but not documentation (2.0 mrem per hour for ^{131}I), is appropriate. In this case written post-discharge instructions should include additional precautions, such as wearing protective gloves when handling disposable diapers or linens.

DISCUSSION

The revised dose-based release criteria have several advantages over the older activity- and dose-rate-based criteria. Most importantly, required hospital stays are reduced, which will help minimize health care costs and may also provide emotional benefits to patients and their families.⁶ The radiation exposure to the occupationally exposed health care workers who care for these patients will be reduced. The primary disadvantage of releasing patients (who have received radioactive material) into the unrestricted environment is the higher exposure to radiation to other individuals than those incurred if the patient remained isolated in an institution. However, with proper instruction, the doses to those people who live with

the patient should remain low. Indeed, Grigsby and colleagues at the Washington University School of Medicine recently followed 65 family members of 30 outpatients who were treated with ^{131}I sodium iodide for thyroid cancer. Despite administered activities between 76 mCi and 151 mCi, the average measured dose to family members was only 0.24 mSv (24 mrem), with a maximum of 1.09 mSv (109 mrem).¹²

A dose-based release criterion has an advantage over the activity-based criteria in that it standardizes the conditions for release among the growing number of radionuclides being used in nuclear medicine practice, particularly for therapy. Patients can now be released from licensee control regardless of the quantity of radioactivity they receive as long as the total dose to an individual is less than 500 mrem. These revised regulations make it possible to perform some radionuclide therapy procedures on an outpatient basis. This should improve the utilization of newer forms of therapy for bone pain palliation and treatment of solid and hematologic cancers.¹³

Authorized users of radioactive materials in the eighteen states under the jurisdiction of the Nuclear Regulatory Commission must follow the new regulations. Users in the 32 Agreement States should verify that their state authorities have amended their regulations to incorporate these changes, and amend their institutional license conditions if required.

As discussed above, the methods of calculating the potential dose to individuals exposed to the patient permitted by the new regulations can be expected to result in an overestimation of absorbed dose due to simplifying assumptions. Sparks and colleagues, using powerful Monte-Carlo dose calculation methods, have demonstrated that the use of a single measurement of dose-rate at 1 meter from the patient overestimates the TEDE by about 60%.¹⁴ It is possible that improvements to the computation of TEDE

can be made to address the issues (including attenuation and variable organ geometry) which lead to overly conservative estimates for the potential radiation dose. Even with-

out such refinements, straightforward applications of the new release criteria provide a much-improved method for patient care, while assuring the safety of the public.

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QUESTIONS

1. Which of the following radionuclides does NOT present a significant EXTERNAL radiation hazard to members of the public?
 - a. Iodine-131
 - b. Iridium-192
 - c. Iodine-125
 - d. Strontium-89
2. Under the patient release criteria adopted by the NRC in 1997, what is the maximum exposure an individual may receive from patients who have been administered radioactive material?
 - a. 5000 mrem
 - b. 5 rem
 - c. 500 mrem
 - d. 100 mrem
3. Based on the release criteria employed PRIOR TO 1997, the licensee could release a patient containing radioactive material under which of the following body burden / dose rate conditions?
 - a. 300 mCi or 50 mrem/hour @ 1 meter
 - b. 3 mCi or 500 mrem/hr @ 1 meter
 - c. 30 mCi or 5 mrem/hr @ 1 meter
 - d. 0.3 mCi or 0.5 mrem/hr @ 1 meter
4. In what section of the Code of Federal Regulations (CFR) is the "Release of Patients Administered Radioactive Material" addressed?
 - a. 10 CFR 20.1902
 - b. 10 CFR 35.75
 - c. 10 CFR2
 - d. 10 CFR 35.900
5. Which of the following phrases does the acronym "ALARA" represent?
 - a. As Long As Required by Administrators
 - b. As Limits And Records Agree
 - c. As Low As Reasonably Achievable
 - d. As Long As the Regulators aren't Aware
6. Written instructions must be given to individuals whenever the dose (TEDE) to exposed individuals may exceed _____.
 - a. 10000 mrem
 - b. 1 rem
 - c. 10 rem
 - d. 100 mrem
7. Above what dose (TEDE) to an infant or child as a result of breast-feeding should instructions be given to the nursing mother?
 - a. 5000 mrem
 - b. 50 rem
 - c. 100 mrem
 - d. 10 mrem
8. Which of the following is currently NOT a criteria for the release of patients administered radioactive material?
 - a. release based on administered activity
 - b. release based on a patient specific dose calculation
 - c. release based on retained activity
 - d. release based on the total counts obtained from whole body imaging

9. Which of the following doses (TEDE) to the infant or child as a result of continued breast-feeding requires the licensee to maintain records?
 - a. 500 mrem
 - b. 5 rem
 - c. 100 mrem
 - d. 5000 mrem

10. How long must the licensee maintain records which authorizes the release of an individual after the date of release based on the calculated TEDE?
 - a. 10 years
 - b. 1 year
 - c. 3 years
 - d. 3 months

11. Which of the following methods below is NOT acceptable for calculating the TEDE?
 - a. Considering shielding by tissue
 - b. Using the effective or biological half-life
 - c. Using an occupancy factor of less than 0.25 @ 1 meter without justification
 - d. Using an occupancy factor of greater than 0.25 @ 1 meter

12. Adoption of the new dose-based release criteria were based on all the following EXCEPT:
 - a. Comments from interested parties
 - b. Accepted principles of radiation protection
 - c. Vote by a subcommittee of the Senate
 - d. Recommendations of the Advisory Council on the Medical Uses of Isotopes

13. All of the following are DISADVANTAGES of the old activity-based release criteria EXCEPT:
 - a. Were appropriate for ^{131}I only
 - b. Required hospitalization for almost all thyroid cancer patients
 - c. Added to the cost of medical care
 - d. Did not consider stochastic radiogenic risks

14. Which of the following is NOT an advantage of the new dose-based release criteria?
 - a. Fewer patients require hospitalization
 - b. Patients can be released from hospitalization earlier
 - c. NRC has provided dose and activity tables for common radionuclides
 - d. No documentation is required

15. The contents of written instructions to patients should include:
 - a. Measures to reduce the spread of contamination
 - b. Minimizing time spent in public places
 - c. The length of time the patient should follow the precautions
 - d. All of the above

16. Which of the following is the primary reason for giving written instructions to patients who have been released in accordance to 10 CFR Part 35.75?
 - a. Avoiding legal liability by the licensee
 - b. Providing the patient with methods to reduce exposures to members of the general public
 - c. Providing the patient with instructions which would increase exposures above the 500 mrem TEDE
 - d. Helping to increase the effect of the therapeutic radionuclide

17. Which of the following criteria may NOT be used for the release of patients administered radioactive material?
- Release based on an administered activity
 - Release based on a measured dose rate
 - Release based on an estimated dose to individuals exposed to the patient
 - Release based on expiration of the patient's health insurance
18. Model post-release instructions for patients may be found in a pamphlet published by the:
- Justice Department
 - Bureau of Alcohol, Tobacco and Radioactive Materials
 - Society of Nuclear Medicine
 - Nuclear Regulatory Commission
19. According to Regulatory Guide 8.39, the maximum administered (or retained) radioactivity for which a licensee could permit the release of a patient receiving iodine-131, without a dose-rate measurement or patient-specific calculation, is:
- 66 mCi
 - 133 mCi
 - 7 mCi
 - 33 mCi
20. According to Regulatory Guide 8.39, the maximum dose rate at 1 meter for which a licensee could permit the release of a patient receiving iodine-131, without a patient-specific calculation, is:
- 7.0 mrem/hr
 - 10.0 mrem/hr
 - 7.0 mrem/min
 - 1.0 rem/hr
21. How long are records required to be kept after the date of release for patients released based on a measured dose rate or a patient-specific dose calculation?
- 5 years
 - 3 months
 - 6 months
 - 3 years
22. For what minimum period of time are records documenting that instructions were provided to breast-feeding patients required to be kept after the date of release if a child or infant were to receive a TEDE of 500 mrem from the continuation of breast-feeding?
- 3 years
 - 3 months
 - 3 days
 - 3 weeks
23. What piece of information is NOT required to be recorded if the patient is released based on a patient-specific calculation of the anticipated dose to an exposed individual?
- Patient's ethnic background
 - Patient identifier
 - Estimated dose to exposed individuals
 - Radioactive material, activity, date, and time of administration

24. Which of the following calculation methods may be employed, if the patient is released on a patient-specific dose calculation?

- a. Occupancy factor at 1 meter is 1.0, if the physical half-life is less than one day
- b. Consideration of shielding by drywall in the patient's dwelling
- c. Occupancy factor at 1 meter is 0.10, if the physical half-life is greater than one day
- d. Occupancy factor at 1 meter is 0.10, if the physical half-life is greater than eight days

25. The new dose-based criteria reflect the NRC's concern for:

- a. The health and safety of physicians administering radioactive materials
- b. The health and safety of the public
- c. The rising cost of radiopharmaceuticals
- d. The rising cost of regulatory administration