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Response to Apparent Violation in Inspection Report No 030-30130 / 2014001(DNMS); EA-14-115

Radioactive Materials License #24-25816-01 (Truman Medical Center; 2301 Holmes Street; Kansas City, MO 64108)

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August 14, 2014

Andrew Bramnik, Health Physicist
Division of Nuclear Materials Safety
Nuclear Regulatory Commission-
Region III
2443 Warrenville RD. Suite 210
Lisle, IL 6053204352

Subject: Response to Apparent Violation in Inspection Report No 030-30130 / 2014001(DNMS); EA-14-115

Dear Mr. Bramnik,

This correspondence is in Response to Apparent Violation regarding the inspection of our Radioactive Materials
License #24-25816-01 (Truman Medical Center; 2301 Holmes Street; Kansas City, MO 64108).

Apparent Violation Item:
10 CFR 35.75(a).-A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem)

Contrary to the above, the apparent violation concerned the release from Truman Medical Center's (TMC) control of two individuals who had been administered byproduct material and the total effective dose equivalent to any other individual from exposure to the released individuals was likely to exceed 5 milliSievert, as prohibited by 10 CFR 35.75(a)

Reason for Apparent Violation: Specifically, on June 27, 2011 and November 30, 2012, TMC administered a 70.0 mCi and a 69.3 mCi of I-131 Sodium Iodide to patients (respectively) and released the individuals from our control as outpatients. Both Written Directives indicated that the patients had intact thyroids; therefore, neither patient should have been released as outpatients based on the general calculations. Specifically, the violation occurred due to the administration of Sodium Iodide in amounts greater than TMC protocol for outpatient administration. This deviance from established protocol was not detected by TMC's contracted health physicist during the quarterly audits.

Corrective actions, which have been taken by you and the results achieved:
TMC immediately recognized the seriousness of the infraction during the NRC survey of May 22 and 23, 2014. Truman Medical Center took immediate action to comply with 10 CFR 35.75(1) which included:

1. May 30, 2014, TMC adapted a new Patient Release Policy and Procedures, Written Directive and Quality Management Program (QMP) and with corresponding forms and records system. All technologists were immediately educated on the revised release policies as well as the Quality Management Program. These documents included a corrected calculation of the maximum Sodium Iodide dose for outpatients as well as a requirement for survey with documentation of results with patients scheduled to be released following dosing.

These new Policies and Procedures will assure that no outpatients are discharged from TMC without survey record of an acceptable level to prevent radiation exposure of other individuals.

We have discussed the importance of review of our patient care in dosing and release our contractual audits with our Health Physicist consulting group and have made them aware of our mandate for heightened scrutiny of our program.

2. As discussed, TMC has changed its maximum outpatient I-131 Sodium Iodide administrations for Post- Thyroidectomy limits to 178 mCi and for Hyperthyroidism to 53 mCi. As an added mandatory precaution, all patients are now measured with a suitable survey instrument at one (1) meter prior to being released as outpatients with the results of the survey documented in the medical record. This will confirm that patients considered for Immediate Release who are:

Hyperthyroid Patients
Administered Activity <53 mCi have a Dose Rate of <11.7mrem/hr at 1 meter

Post-Thyroidectomy Patients
Administered Activity <178 mCi have a Dose Rate of <38.2mrem/hr at 1 meter

3. On June 20, 2014, a mandatory in-service was provided to all Approved Technologists and members of the Radiology Administration and TMC Hospital Administration by our contracted Health Physicist consultant group. This training included the review and discussion of policies and related forms. An I-131 Sodium Iodide Therapy Training Exam was administered to each Approved Technologist to assess knowledge of the I-131 Sodium Iodide Therapy Program. Therapists were required to pass this written examination with a score of 90% in order to continue administering Sodium Iodide. We have attached the following policies and forms for your review;

Exhibit I
The Policies and Procedures for Administrations Requiring a Written Directive -Policy 10(A).
- Form 116A-Reporting a Medical Event;
- Form 116B-Written Directive

Exhibit II
The Policies and Procedures for Iodine-131 Therapy for Hyperthyroidism and Post- Thyroidectomy Requiring Hospitalization-Policy 18(A).

Exhibit III
The Policies and Procedures for Release of Patients Administered Radioactive Materials in Nuclear Medicine-Policy 18(B).

Exhibit IV
- Table-4; Section 18B-Release of Patients Administered Radioactive Materials in Nuclear Medicine; page #16

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Exhibit V
- Form 123C-Record of Release Survey Record;

Exhibit VI
- Form 123D and Form 123E-Release Determination for Hyperthyroidism and Written
Instructions;

Exhibit VII
- Form 123 F and Form 123G-Release Determination for
Post- Thyroidectomy and Release Instructions.

Corrective actions, which will be taken to avoid further Apparent Violation:
Each completed I-131 Sodium Iodide Therapy administration and corresponding forms will be reviewed by a supervisor prior to discharge of the respective patient from the facility. The document will be recorded in the patient's medical record.
These completed records will also be reviewed by our Health Physicist consulting group on a quarterly basis. A summary of all administrations will be documented in the quarterly audit and reported to the Radiation Safety Committee.

Date of full compliance: May 28, 2014
These policies were in place before the next patient was dosed on June 5, 2014.

We sincerely appreciate the collaborative survey of Andrew Bramnick, Health Physicist of the NRC. We have taken this event very seriously and have implemented aggressive procedural changes which will ensure that we are exceeding standards in the care of patients receiving Sodium Iodide. Thank you.

Sincerely,

Carole Jones
Director of Radiology

Lawrence Ricci, D.O.
Radiation Safety Officer

SECTION 10.0(A)

NUCLEAR MEDICINE
Procedures for Administrations Requiring A Written Directive

A. Purpose and Criteria

Regulations require medical use licenses to develop, maintain, and implement written procedures to provide high confidence that licensed material is administered as directed by authorized users.

B. NRC References

10 CFR §35.40, 10 CFR §35.41, 10 CFR §35.2040 (or Your Specific Regulatory Regulations)

C. Procedure

1. Written directive (WD) (see Form 116B) means an authorized user's (AU) written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject.

2. Written directive is required if the administrative involves:

   a. 30 μCi or greater of I-131 and /or I-125 sodium iodide

   b. Any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material

3. An AU must prepare, date, and sign a WD prior to the administration of any dose or dosage. A radiopharmaceutical prescription is acceptable.

4. Prior to administering a dose or dosage, the patient's or human research subject's identity will be verified as the individual named in the WD. **Two additional forms of identification must also be checked.** Examples of patient identity verification include the patient's ID bracelet, hospital ID card, driver's license or social security card.

5. Before administering the dose or dosage, the specific details of the administration will be verified in accordance with the WD. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the **qualified** person administering the dose or dosage to verify agreement with the WD.

6. Appropriate verification methods include measuring activity in the dose calibrator (**must** be within ±20% of the prescribed dose and **should** be within ±10% of the prescribed dose), checking the serial number of the sealed source behind an appropriate shield, using color-coded vials or sealed sources, or using clearly marked storage locations. The verification will be performed by at least one **qualified** person (e.g., authorized medical physicist (AMP) or a nuclear medicine technologist) preferably other than the individual who prepared the dose or dosage or the treatment plan. **The qualified individual must also sign the WD when they verify the patient identifiers, radiopharmaceutical and dosage. (Please see Section C of Form 116B.) As a final step, the A.U. will review all aspects of the W.D. (Sections A, B, and C), The A.U. will then sign Sections B *(If not already completed)* & D of Form 116B.**

7. All workers will be instructed to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have questions about what to do or how it should be done, prior to administration, rather than continuing a procedure when there is any doubt.

8. Exceptions to the written directive:

   a. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

   b. Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.

   c. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in the patient's record and a written directive is prepared with 48 hours of the oral directive.

9. Management Review

   a. Annual reviews of administrations requiring WD's must be performed. (See Form 101B),

b. The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each treatment modality performed in the institution, e.g., radiopharmaceutical, teletherapy, brachytherapy and gamma stereotactic radiosurgery.

For example, using the acceptance sampling tables of 10 CFR §32.110 and assuming an error rate (or lot tolerance percent defective) of 2%:

Lot Size	Sample Size	Acceptance No. *
1 to 75	All	0
76 to 100	70	0
101 to 200	85	0
201 to 300	95	0
301 to 400	100	0
401 to 600	105	0
601 to 800	110	0
801 to 4000	115	0

**** Acceptance No. of 0 means no errors in WD are exempt from reporting a medical event***

c. In order to eliminate any bias in the sample, the patient cases to be reviewed should be selected randomly. If the number of errors in the sample does not exceed the acceptance number in the appropriate Sampling Table, the lot should be accepted. For each patient's case, a comparison should be made between what was administered versus what was prescribed in the WD. If the difference between what was administered and what was prescribed exceeds the criteria for a medical event, that comparison is unacceptable. The number of unacceptable comparisons allowed for each sample size and lot tolerance percent defective is provided in the acceptance sampling tables.

If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. The licensee or designee should regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

For each patient case reviewed, the licensee shall determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable. For each patient case reviewed, the licensee should identify deviations from the WD, the cause of each deviation, and the action required to prevent recurrence. For each patient case reviewed, the licenses should verify the patients identification by at least two means. (i.e. Name, DOB, Driver's License, etc)

10. Medical Event Report and Notification

a. A licensee shall report any event (Form 116A), except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in:

1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

i) The total dose delivered differs from the prescribed dose by 20% or more;
ii) The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or
iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.

2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

i) An administration of a wrong radioactive drug containing byproduct material;
ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;
iii) An administration of a dose or dosage to the wrong individual or human research subject;
iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or
v) A leaking sealed source,

3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

b. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

c. The licensee shall notify by telephone the governing Regulatory Agency no later than the next calendar day **(within 24 hours)** after discovery of the medical event.

d. The licensee shall submit a written report to the governing Regulatory Agency within 15 days after discovery of the medical event.

1) The written report must include:

i) The licensee's name;
ii) The name of the prescribing physician;
iii) A brief description of the event;
iv) Why the event occurred;
v) The effect, if any, on the individual(s) who received the administration;
vi) What actions, if any, have been taken or are planned to prevent recurrence; and
vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

e. The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later that 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgement, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate

medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

f. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

g. A licensee shall:

1) Annotate a copy of the report provided to the governing Regulatory Agency with the:

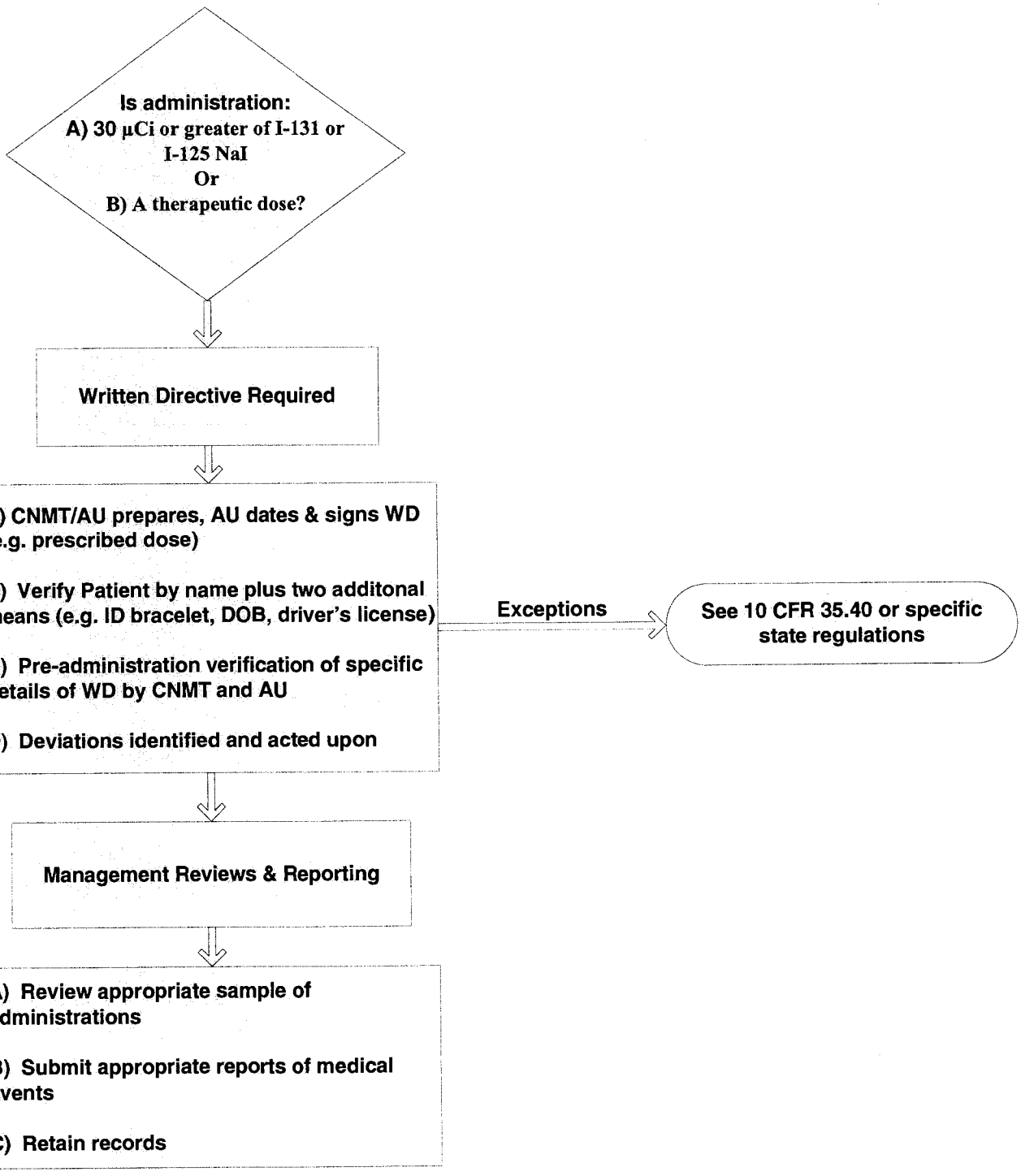
i) Name of the individual who is the subject of the event; and
ii) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

h. Medical event records must be maintained for three years.

i. Written directive procedures must be maintained for the duration of the license.

Nuclear Medicine
Written Directive (WD) Flow Chart



NUCLEAR MEDICINE
MEDICAL EVENT FORM
WRITTEN REPORT

1. Licensee Name: _____ Date: _____

   Address: _____
   _____
   _____

   Phone Number: _____

2. Prescribing Physician's Name:

3. Allied Health Personnel (e.g., Nuclear Medicine Technologist):

4. Patient's Referring Physician:

5. Patient Medical Record Number:

6. Brief Description of the Medical Event Form:

   a. Date of Administration: _____

   b. Was this the correct patient? ☐ Yes ☐ No, Explain:

   c. Was the dose to the whole body above 5 Rem? ☐ No ☐ Yes, Explain:

   d. Was the dose to any organ greater than 50 Rem? ☐ No ☐ Yes, Explain:

   e. Was the correct radiopharmaceutical utilized? ☐ Yes ☐ No, Explain:

   f. Was the correct route of administration utilized? ☐ Yes ☐ No, Explain:

   g. Was the administered dosage different from the prescribed dosage by more than 20%? (Note: For NaI I-125 or I-131, the dosage must be greater than 30 microcuries) ☐ No ☐ Yes, Explain:

7. Evaluation on why the medical event occurred:

8. Judgment of the effect on the patient:

9. Was the patient a minor?

☐ Yes Was the patient's responsible relative or guardian notified? If No, Explain:

☐ No See #10 Below.

10. What information was provided to the patient?

☐ None, based on referring physician's medical judgment.

☐ Copy of this report will be provided.

☐ Other. Explain:

11. Identify improvements needed and actions taken to prevent recurrence:

_____ _____

Technologist Date

_____ _____

Radiation Safety Officer Date

WRITTEN DIRECTIVE WORKSHEET (QMP)

Section A: Patient Data

Place sticker here

1. Patient: _____
2. Referring Physician: _____
3. Birthdate: _____
4. MRN# _____
5. Diagnosis: _____
6. □ Inpatient □ Outpatient
   □ Intact □ Thyroidectomy- date: _____

Section B: Authorized User (Licensed Physician)

1. Written Directive:
2. Radiopharmaceutical Prescribed:
3. Prescribed Activity: _____mCi
4. Route of Administration: □ Oral □ I.V. □ Other (Specify): _____
5. Authorized Physician Signature: _____ Date: _____

   Printed Name: _____

Section C: Nuclear Medicine Technologist

1. Patient ID Verification
   a. Must ask patient his/her name and confirm with written directive.
   b. Must confirm patient by comparison with corresponding infom1ation in patient's records. **Check a minimum of *two* of the following:**
      □ Birthdate □ Address □ Medical Record Number □ Name □ ID Bracelet
      □ Name on Hospital ID Card □ Name on Patient Medical Insurance Card
      □ Other, Specify:
2. Verification of Radiopharmaceutical: □ Yes □ No
3. Verification of Prescribed Dose: Dose Calibrator Reading: _____ mCi
4. Is dose within 10% +/- prescribed dose: □ Yes □ No (Refer to Section D)
   Date: _____ Time: _____ Route: _____
   Note: For Beta-emitters (i.e., P-32, Sr-89, Y-90), you may accept supplier calibration.
5. Technologist Signature: _____ Date: _____

   Printed Name: _____

Section D: Review and Verification of Administered Dose

1. □ No Exceptions □ Yes, Exceptions were made.
   Explanation: _____
2. Authorized Physician Signature: _____ Date: _____

   Printed Name: _____

Section 18.0(A)

IODINE-131 THERAPY FOR HYPERTHYROIDISM AND POST-THYROIDECTOMY REQUIRING HOSPITALIZATION

A. Radiation Safety Procedure

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.

2. Prepare the room for the procedure as follows:

   a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, door knobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.

   b. Prepare separate boxes for linen, disposable waste, and nondisposable contaminated items. Place a single large re-sealable plastic bag in each box, or supply several small plastic bags.

   c. Urine will be discarded by release to the sanitary sewer.

   d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.

3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.

4. Supply the nurses with film badges, TLDs, or other monitoring devices.

5. Brief the nurses on Radiation Safety Precautions. See Form 123A (Nursing Instructions for Patients Treated with Phosphorus-32 or Iodine-131). Allow time for questions and answers during the briefing. Leave a written copy of the Radiation Safety Precautions in the patient's chart or at the nurses' station.

6. Brief the patient on Radiation Safety Procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.

7. Only those persons needed for medical, safety, or training purposes should be present during the administration.

8. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.

9. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line", and in the surrounding hallways and adjacent rooms. Exposure rates in hallways and adjacent rooms must be less than 2 mR in any one hour. Record this and any other necessary information on the nursing instructions form or the nurses' dosimeter sign-out form. Post the room with a "Caution - Radioactive Material" sign.

10. Set the patient up in bed or a chair and take several readings at 1 meter, perpendicular to the patient with the ion chamber. Record the reading. This baseline reading will be used to determine the remaining activity on subsequent days.

11. For patients treated with liquid or gelatin-capsuled I-131, measure the thyroid burden of all personnel who were present for the administration within 6 to 72 hours **(IA 24 to 96 hrs-ideal is 24 hrs; see section 8)**. Also consider a thyroid bioassay for patient care personnel if intake is suspected. Make a record of the worker's name, amount of I-131 activity in the worker's thyroid, the calculated committed dose equivalent (CDE) of the thyroid, and date.

12. As the therapy proceeds, pick up waste for transfer to a decay-in-storage area.

13. Do not release any patient until either the exposure rate from the patient is less than 7 millirem per hour at 1 meter or the retained radioactivity is less than 33 millicuries. If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing, or if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

14. The patient will be given Radiation Safety Discharge Instructions for Hyperthyroidism or Post-Thyroidectomy. Refer to Forms 123D and 123E.

15. Use Form 123C as an internal record to document the specific release criteria that was utilized for each patient. Check the appropriate type of release utilized. Record the instrument used, and the (1) one meter reading in mR/hr.

16. Before using the room for general occupancy, it must be surveyed and wipe tested. (decontaminated if necessary).

17.

a. Remove all absorbent paper, and place it in the appropriate container.

b. Transfer all containers to a decay-in-storage or decontamination area.

c. Use a radiation detection survey meter to check for room contamination. Perform swipes and clean contaminated areas until removable contamination is less than 200 dpm/100 cm^2. See Form 123B (Iodine-131 Therapy Activity Calculations/Wipe Test).

d. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

Section 18 (B)

RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS IN NUCLEAR MEDICINE

A. Introduction

The regulations permit licensees to release from their control any individual who has been administered radiopharmaceuticals if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).

Further, the regulations require that the licensee provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were not interruption of breast-feeding, the instructions shall also include (1) guidance on the interruption or discontinuation of breast-feeding and (2) information on the consequences of failure to follow the guidance.

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

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

B. Release of Patients That Require No Instructions or Release Records

Only patients who are not breast-feeding and that are administered activities less than or equal to the Table 2, Column I activities may be released without instructions or release records. For patients who are breast-feeding, the administered activities must be less than or equal to Table 3, Column I.

C. Instructions to Patients (Forms 123E, 123G, and 123H)

According to the Summary Table, some released patients must be given instructions on how to maintain doses to other individuals as low as is reasonably achievable after the patients are released. Table 2 provides activities and dose rates above which instructions should be given. The patient should sign the release instructions and a copy kept for your records.

D. Record of Patient Release (Form 123C)

There is no requirement for record keeping on the release of patients who were released in accordance with administered **activity** being less then that shown in Column 1 of Table 1. If the release of the patient is based on a dose calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by the regulations. This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information:

1. For Immediate Release of a Patient Based on Measured Dose Rate

   The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.

2. For Delayed Release of a Patient Based on Measured Dose Rate

   The results of the survey meter measurement, the specific survey instruments used, and the name of the individual performing the survey.

3. For Immediate Release of a Patient Based on a Patient-Specific or Case-Specific Calculation

   The equation used, including the patient-specific factors and the bases used in calculating the dose to the person from exposure to the patient, and the calculated dose. The patient-specific factors include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record. (See Form 123C)

4. For Delayed Release of a Patient Based on Radioactive Decay Calculation

   The time of the administration, date and time of release, and the results of the decay calculation. See form 123H

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

E. Records of Instructions for Breast-Feeding Patients

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

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

F. Iodine-131 Treatments for Hyperthyroidism and Post-Thyroidectomy

Regulatory guidance defines acceptable values for uptake fractions and effective half-lives for the extra-thyroidal and thyroidal components associated with hyperthyroidism and post-thyroidectomy. Substituting these values into the equation to calculate the maximum likely dose to an individual exposed to the patient yields the release values in Table 4.

All treatments require:

1. Patient Questionnaire and Release Determination **(Form 123D or 123F)**; and

2. Record of Release of Patient **(Form 123C)**; and

3. Written Instructions to Patient **(Form 123E, 123G, or 123H)**.

Note that release determinations and written instructions are based on activities up to the maximum releasable activities. Please see the following case-specific calculations for immediate release.

G. Thyroid Ablation Delayed Release Patient Retention Times for Iodine -131 Doses >178 mCi.

If a patient is being treated for thyroid C.A. and the prescribed dose is in excess of 178 mCi, the patient must be held in the department for a specific time period. The patient retention time period is based on the administered dose and the Occupancy Factor of 0.25. Please see the required retention times table on page 10 section 18 (B).

After the patient has been retained for the required time period, acquire a (1) one meter reading with an ion chamber and complete Form 123C.

For the "Written Release Instructions", please complete **Form 123H**.

Note: Because of the amount of activity that was administered, care should be taken to ensure that the patient can adhere to all of the requirements listed on Form123H. If the patient can not full-fill each and every requirement listed on Form 123H, the patient should be hospitalized.

I-131 Therapy
Case-specific Calculations Required for Immediate Release

Patient Release Criteria Summary

Based upon governing Regulatory Agencies requirements , regarding the release of patients administered radioactivity, Radiation Safety has determined the following criteria for immediate release of I-131 patients[1];

Hyperthyroid Patients

Immediate release: Administered Activity < 53 millicuries **OR**
Patient Dose Rate at 1 meter < 11.7 mrem/hr

Thyroid Cancer Patients

Immediate release[2]: Administered Activity < 178 millicuries **OR**
Patient Dose Rate at 1 meter < 38.2 mrem/hr

Administered Activity > 178 millicuries the patient must be retained
See Form 123H or Table "Release Limits for Post-thyroidectomy Patients" in Section 18(b) page 10.

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1 All patient release criteria based on an occupancy factor of 0.75 for the first 8 hours after administration and 0.25 after 8 hours.

2 Patient release criteria has been determined for thyroid cancer patients that exceed the "immediate release" criteria.

Release Criteria for I-131 Therapy Patients

PURPOSE

The purpose of this analysis is to document the case-specific calculations used to release I-131 patients from the hospital in accordance with State and Federal Regulations. For this analysis the following I-131 therapies will be evaluated;

a) Hyperthyroidism

b) Post-thyroidectomy Therapy;

i) Ablation following thyroidectomy

ii) Therapeutic doses for suspected residual, recurrent or metastatic disease

For each of these protocols case-specific release criteria will be determined. Assumptions will be stated as appropriate.

CALCULATION OF RELEASE CRITERIA

The regulations permit licensees to authorize the release from its control any individual who has been administered radiopharmaceuticals containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (500 millirem). Guidance on the implementation of patient release is provided in the governing Regulatory Agencies policies. This regulatory guide provides tables with default values authorizing patient release based on administered activities or dose rates 1 meter away from the patient. For I-131, these release values are 33 mCi and 7 mrem/hr. These default values are very conservative in the fact that they are;

- Based upon point source dose rate calculations
- No tissue attenuation is considered in the calculations
- Only use the physical half-life of the radionuclide in determining a total dose
- Calculations based on an occupancy factor of 0.25 at 1 meter (i.e., the maximally exposed individual is assumed to be 1 meter away from the patient 25% of the time).

The governing Regulatory Agency allows the licensee to release patients based upon patient-specific calculations using 1) retained activity rather than administered activities, 2) an occupancy factor less than 0.25

at 1 meter, 3) using the biological or effective half-life, or 4) considering shielding by tissue. The procedure for calculating doses based on patient specific factors can be found in the applicable regulatory guide.

External Dose Contribution

The following equation (equation B-1 in regulatory guide) is used to calculate the external dose to the maximally exposed individual;

$$D(t) = \frac{34.6\,\Gamma\,Q_0\,T\,E\left(1 - e^{\frac{-0.693\,t}{T}}\right)}{r^2} \qquad (Equation\ B\text{-}1)$$

where D(t) = Accumulated dose at time t (mrem)

34.6 = Conversion factor of 24 hrs/day multiplied by the total integration of decay of 1.44

Γ = Gamma ray constant = 2200 mR-cm^2/mCi-hr for I-131

Q_0 = Initial activity at the start of the time interval

T = Half-life being utilized for time interval (e.g., effective half-life, physical half-life)

t = Exposure time (same units as T)

E = Occupancy factor. Regulatory Guide allows E = 0.75 when a physical or effective half-life OR a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day. Otherwise, occupancy factors of 0.25 or 0.125 (for a patient living alone) may be used.

r = Distance in centimeters. Typically 100 cm (1 meter)

To account for the time iodine is absorbed from the stomach to the blood and the holdup of iodine in the urine while in the bladder, the governing Regulatory Agency conservatively assumes that during the first 8 hours after administration, 80% of the administered I-131 is removed from the body at a rate determined only by the physical half-life (i.e., 8.04 days). In accordance with the governing Regulatory Agency assumptions, an occupancy factor of 0.75 should be used during this time interval.

Internal Dose Contribution

Internal dose to the maximally exposed individual from a patient is discussed in the governing Regulatory Agencies regulations. The regulatory guide uses the following equation to get a rough estimate of the maximum likely committed effective dose equivalent (CEDE) from internal exposure;

$$D = Q\ (10^{-5})\ (DCF)$$

where $D =$ Maximum internal CEDE to individual exposed to patient (mrem)

$Q =$ Activity administered to patient (mCi)

$10^{-5} =$ Assumed fraction intake. It should be noted that Regulatory Guide 8.39 indicated that the fraction intake value of 10^{-6} is more realistic (i.e., the equation most likely overestimates the internal dose by a factor of 10).

DCF = Dose conversion factor = 53,000 mrem/mCi for I-131

The Regulatory Guide is not very clear on whether the internal dose contribution should be taken into account when determining the dose to the maximally exposed individual. On one hand, the Regulatory Guide says that internal doses may be ignored in the calculations if they are likely to be less than 10% of the external dose since the internal dose would be significantly less than the uncertainty in the external dose. This would imply that for administered I-131 doses above 85.7 mCi, internal dose should be taken into consideration. On the other hand, the Regulatory Guide goes on to say that "The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP" and then goes on to give an example release calculation for a 200 mCi I-131 administration that does not take into account internal dose. For conservatism, it is decided to use internal dose contribution in all of the patient release calculations for the I-131 protocols addressed in this analysis.

Release Calculations for Hyperthyroidism & Thyroid Cancer

For hyperthyroidism and thyroid cancer, the governing Regulatory Agency provides the following uptake fractions and effective half-lives;

Protocol	Uptake Fraction F_1	Effective Half-life T_{1eff}	Uptake Fraction F_2	Effective Half-life T_{2eff}
Hyperthyroidism	0.20	0.32 days	0.80	5.2 days
Postthyroidectomy (Thyroid Cancer)	0.95	0.32 days	0.05	7.3 days

The total external dose to the maximally exposed individual, D(∞), is given as Equation B-5 in the Regulatory Guide. Adding the contribution from internal exposure and then rearranging this equation gives the following equation that can be used to calculate the administered activity that will result in 500 mrem to the maximally exposed individual;

$$Q_0 = \frac{D}{\left(\frac{34.6\Gamma}{1E4\,cm^2}\right)\left[E_1 T_p (0.8)\left(1 - e^{\frac{(-0.693)(0.33)}{T_p}}\right) + E_2 F_1 T_{1eff}\, e^{\frac{(-0.693)(0.33)}{T_p}} + E_2 F_2 T_{2eff}\, e^{\frac{(-0.693)(0.33)}{T_p}}\right] + 0.53}$$

For both hyperthyroidism and thyroid cancer the following values will be used;

D = Total dose to individual = 500 mrem
Q_0 = Administered activity (mCi)
Γ = Gamma ray constant = 2200 mR-cm^2/mCi-hr for I-131
E_1 = Occupancy factor for the first 8 hours = 0.75
E_2 = Occupancy factor after 8 hours = 0.25
T_p = 8.04 days
$T_{1eff}, T_{2eff}, F_1, F_2$ = Uptake fractions and effective half-lives are given in the above table

To determine the release limits based on a patient's 1 meter exposure reading, the following equation can be used;

$$Dose\,Rate_{1meter} = \frac{500 - 0.53 Q_0}{34.6\left[E_1 T_p (0.8)\left(1 - e^{\frac{(-0.693)(0.33)}{T_p}}\right) + E_2 F_1 T_{1eff}\, e^{\frac{(-0.693)(0.33)}{T_p}} + E_2 F_2 T_{2eff}\, e^{\frac{(-0.693)(0.33)}{T_p}}\right]}$$

where $0.53Q_0$ = Internal exposure due to administered activity (mrem)

Using the above equations, the following values can be used for immediate release of a hyperthyroidism or thyroid patient (provided the patient can satisfy the 0.25 occupancy factor requirement);

Release Limits (Immediate Release) for Patients
Occupancy Factor = 0.25

	Hyperthyroidism	Thyroid Cancer
Administered Activity	**53 mCi**	**178 mCi**
Patient Dose Rate @ 1 Meter	**11.7 mrem/hr**	**38.2 mrem/hr**

For certain Post-thyroidectomy procedures (e.g., remnants), it is possible that the patient could be administered more than 178 mCi (e.g., doses of 200 mCi have been administered with a resulting patient 1 meter exposure reading greater than 38.2 mrem/hr). Therefore, for Post-thyroidectomy patients, the following release limits were determined[3] for various waiting times (e.g., time holding the patient before releasing);

Release Limits for Post-thyroidectomy Patients
Occupancy Factor = 0.25

Wait Time	Administered Activity	1 Meter Dose Rate at administration
1 hr	187 mCi	41.6 mR/hr
2 hr	197 mCi	44.4 mR/hr
3 hr	208 mCi	47.5 mR/hr
4 hr	219 mCi	51.0 mR/hr
5 hr	233 mCi	55.1 mR/hr
6 hr	248 mCi	59.9 mR/hr

It should be noted that if an occupancy factor 8 hours after administration of 0.125 is used, the administered activities immediate release limits become 91 mCi and 20.1 mR/hr for hyperthyroidism and 229 mCi and 50.5 mR/hr for Post-thyroidectomy patients.

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[3] To perform this calculation the equations used to determine the immediate release limits are modified by changing the quantity $(1-\exp(-.33\lambda))$ in the denominator to $(\exp(-\lambda t) - \exp(-.33\lambda))$ where t is the time (days) before the patient is released.

Summary Table

Summary of Release Criteria, Required Instructions to Patients, and Records to be Maintained

PATIENT GROUP	BASIS FOR RELEASE	CRITERIA FOR RELEASE	INSTRUCTIONS NEEDED?	RELEASE RECORDS REQUIRED?
All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity ≤ Column 1 of Table 1	Yes - if administered activity > Column 1 of Table 2	No
	Retained activity	Retained activity ≤ Column 1 of Table 1	Yes - if retained activity > Column 1 of Table 2	Yes
	Measured dose rate	Measured dose rate ≤ Column 2 of Table 1	Yes - if dose rate > Column 2 of Table 2	Yes
	Patient-specific calculations	Calculated dose ≤ 5 mSv (0.5 rem)	Yes - if calculated dose > 1 mSv (0.1 rem)	Yes
Patients who are breast-feeding an infant or child	All the above bases for release		Additional instructions required if: Administered activity > Column 1 of Table 3 or Licensee calculated dose from breast-feeding > 1 mSv (0.1 rem) to the infant or child	Records that instructions were provided are required if: Administered activity > Column 2 of Table 3 or Licensee calculated dose from continued breast-feeding > 5 mSv (0.5 rem) to the infant or child

Table 1
Activities and Dose Rates for Authorizing Patient Release[1]
(TEDE = 0.5 rem)

Radionuclide	COLUMN 1 Activity at or Below Which Patients May Be Released (mCi)	COLUMN 2 Dose Rate at 1 meter, at or Below Which Patients May Be Released[2] (mrem/hr)
Ag-111	520	8
Au-198	93	21
Cr-51	130	2
Cu-64	230	27
Cu-67	390	22
Ga-67	240	18
I-123	160	26
I-125	7	1
I-131	33	7
In-111	64	20
P-32	** [3]	** [3]
Re-186	770	15
Re-188	790	20
Sc-47	310	17
Se-75	2	0.5
Sm-153	700	30
Sn-117m	29	4
Sr-89	** [3]	** [3]
Tc-99m	760	58
Tl-201	430	19
Y-90	** [3]	** [3]
Yb-169	10	2

NOTES:

1. The activity values were computed based on 5 millisieverts (0.5 rem) total effect dose equivalent.
2. If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by the regulations because the measurement includes shielding by tissue. See Section D.1. and D.2.
3. Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Table 2
Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release[1]
(TEDE = 0.1 rem)

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required (mCi)	COLUMN 2 Dose Rate at 1 Meter Above Which Instructions Are Required (mrem/hr)
Ag-111	100	2
Au-198	19	4
Cr-51	26	0.4
Cu-64	45	5
Cu-67	77	4
Ga-67	47	4
I-123	33	5
I-125	1	0.2
I-131	7	2
In-111	13	4
P-32	** [2]	** [2]
Re-186	150	3
Re-188	160	4
Sc-47	62	3
Se-75	0.5	0.1
Sm-153	140	6
Sn-117m	6	0.9
Sr-89	** [2]	** [2]
Tc-99m	150	12
Tl-201	85	4
Y-90	** [2]	** [2]
Yb-169	2	0.4

[1] The activity values were computed based on 1 millisieverts (0.1 rem) total effect dose equivalent.

[2] Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Table 3
Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breast-Feeding an Infant or Child (TEDE to Infant = 0.1 rem)

Radiopharmaceutical	COLUMN 1 Activity Above Which Instructions Are Required (mCi)	COLUMN 2 Activity Above Which a Record is Required (mCi)	COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding*
I-131 NaI	0.0004	0.002	Complete cessation (for this infant or child)
I-123 NaI	0.5	3	
I-123 OIH	4	20	
I-123 MIBG	2	10	24 hr for 370 MBq (10 mCi) 12 hr for 150 Mbq (4 mCi)
I-125 OIH	0.08	0.4	
I-131 OIH	0.30	1.5	
Tc-99m DTPA	30	150	
Tc-99m MAA	1.3	6.5	12.6 hr for 150 MBq (4 mCi)
Tc-99m Pertechnetate	3	15	24 hr for 1,100 MBq (30 mCi) 12 hr for 440 MBq (12 mCi)
Tc-99m DISIDA	30	150	
Tc-99m Glucoheptonate	30	170	
Tc-99m HAM	10	50	
Tc-99m MIBI	30	150	3 days for any amount over 1, 100 Mbq (30) mCi.
Tc-99m MDP	30	150	
Tc-99m PYP	25	120	
Tc-99m Red Blood Cell In-Vivo Labeling	10	50	6 hr for 740 MBq (20 mCi)
Tc-99m Red Blood Cell In-Vitro Labeling	30	150	
Tc-99m Sulphur Colloid	7	35	6 hr for 440 MBq (12 mCi)
Tc-99m DTPA Aerosol	30	150	
Tc-99m MAG3	30	150	
Tc-99m White Blood Cells	4	15	24 hr for 1,100 MBq (5 mCi) 12 hr for 440 Mbq (2 mCi)
Ga-67 Citrate	0.04	0.2	1 month for 150 MBq (4 mCi), 2 weeks for 50 MBq (1.3 mCi), 1 week for 7 MBq (0.2 mCi)
Cr-51 EDTA	1.6	8	
In-111 White Blood Cells	0.2	1	1 week for 20 MBq (0.5 mCi)
Tl-201	1	5	2 weeks for 110 MBq (3 mCi)

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

NOTES: Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material". Although non-byproduct materials are not regulated by the NRC, information on non-byproduct material is included in the regulatory guide for the convenience of the licensee.

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

Table 4
Release of Patients by Radionuclide
Summary

Radionuclide	Release		Instructions		Records of Release
	mCi	mrem/hr @ 1 meter	mCi	mrem/hr @ 1 meter	
Tc-99m	760	58	150	12	Required for every administration unless the release was based on administered activity that is less than or equal to Column 1 values.
Cr-51	130	2	26	0.4	
Ga-67	240	18	47	4	
I-131	33	7	7	2	
I-125	7	1	1	0.2	
I-123	160	26	33	5	
In-111	64	20	13	4	
Sm-153	700	30	140	6	
Tl-201	430	19	85	4	
Y-90	Any	Any	N/A	N/A	

NOTE: 1. Does not apply to patients who are breast-feeding an infant or child.

I-131 Therapies

Radionuclide	Release		Instructions		Record of Release
	mCi	mrem/hr @ 1 meter	mCi	mrem/hr @ 1 meter	
I-131Hyperthyroidism [1]	53	11	7	2	Required Form 123 E
I-131Post-thyroidectomy [1]	178 [2]	38	7	2	Required Form 123 G

NOTE:
1. Form 123D or F "Patient Questionnaire and Release Determination" must be completed. Patient-specific calculations must be retained in the records. Calculations for a class of patients are acceptable.
2. If the patient is retained for two (2) hours after administration, up to 200 mCi may be administered.

RECORD OF RELEASE FOLLOWING THERAPEUTIC DOSE

Records of Release are required for every administration unless the release was based on administered activity and that activity is less than or equal to Column 1 of Table 1 (see Section 18(b)) values.

1. Date of Administration: _____

2. Radionuclide: _____ Activity: _____ mCi

3. Patient Name: _____ 4. Patient ID#: _____

5. Additional Information (Check One)

☐ Immediate Release Based on Measured Dose Rate

a. Instrument: _____ S/N: _____
b. mrem/hr at 1 meter - patient: _____
mrem/hr at 1 meter - limit : _____
(Table 4, Release - see Section 18b) _____
c. Name of Individual Performing Survey: _____

☐ Delayed Release Based on Measured Dose Rate

a. Instrument: _____ S/N: _____
b. mrem/hr at 1 meter - patient: _____
mrem/hr at 1 meter - limit (Table 4, Release): _____
c. Name of Individual Performing Survey: _____

☐ Immediate Release Based on Patient-specific or Case-Specific Calculations

a. Patient Information Form Completed.
b. Patient-specific or Case-specific calculations on file.

☐ Delayed Release Based on Radioactive Decay Calculations

a. Date and Time of Administration: _____ at _____ am/pm
b. Date and Time of Release: _____ at _____ am/pm
c. Results of Decay Calculations: _____ mCi
d. mCi Limit (Table 4, Release): _____ mCi

STAFF QUESTIONNAIRE AND RELEASE DETERMINATION
Hyperthyroidism (53 mCi Maximum or 11 mrem/hr at 1 meter)

I. Patient Information

1. Patient Name: _____ MR# _____
2. Date: _____
3. Administered Activity: _____ mCi
4. Sex: Male ☐ Female ☐ Pregnant? Yes ☐ No ☐ Breast-feeding? Yes ☐ No ☐
5. Person Interviewed: Patient ☐ Guardian ☐ Other _____

II. Dwelling Information For Two Weeks After Treatment

1. Type of Dwelling: Single-Family ☐ Multi-Family ☐ Apartment ☐ Other_____
   If not single-family, possible proximity to neighbors: _____ feet
2. Household Members: Sex: a. _____ b. _____ c. _____ d. _____
   Age: a. _____ b. _____ c. _____ d. _____

III. Patient Release Determination (Occupancy Factor = 0.25)

Interview the patient to determine if the patient can accept the following actions based on the activity given:

Action	< 15 mCi	15 to 33 mCi	> 33 to 53 mCi	Circle One
1. Sleep alone for:	2 nights	2 nights	5 nights	Yes No
2. Return to work (if others are NOT in close proximity) for:	1 day	1 day	1 day	Yes No
3. Maintain a prudent distance (≥9 ft) from others for:	1 day	3 days	7 days	Yes No
4. Avoid direct contact with small infants, children and pregnant women for:	3 days	3 days	3 days	Yes No
5. Maintain a distance of 9 ft from infants, children and pregnant women for:	6 days	12 days	16 days	Yes No
6. Maintain sole use of the bathroom for _____. If not possible, keep the toilet especially clean by flushing 3 times after each use. Men should also sit during urination.	2 days	2 days	2 days	Yes No
7. Refrain from traveling by airplane or mass transportation for:	1 day	2 days	5 days	Yes No
8. Refrain from traveling on a prolonged automobile trip (≥6 hrs) with others for:	1 day	4 days	7 days	Yes No
9. Drink plenty of fluids for:	2 days	2 days	2 days	Yes No
10. Washing clothing and eating utensils separately for:	2 days	2 days	2 days	Yes No

The patient can be released if all answers are "Yes". If any answer is "No", the patient may be hospitalized. (Proceed to Section VI)

IV. Instructions

1. Ensure patient receives and understands the instruction sheet.
2. Discuss procedures in case of emergency medical care.

V. Release Record

This patient was released according to federal and state guidelines regarding immediate release based on patient-specific calculations. These calculations are maintained in the Radiation Safety Office. Refer to Form _____.

VI. Signature

☐ This patient was not releasable and therefore hospitalized.

☐ This patient has reviewed all requirements for patient release, was given written instructions and released.

☐ This patient is releasable with exceptions _____.

Signature: _____ Date: _____
(Individual completing form)

PATIENT RADIATION SAFETY DISCHARGE INSTRUCTIONS
NUCLEAR MEDICINE - Hyperthyroidism

A. Your release from the hospital is based on State and Federal safety regulations for patients treated with radioactive material.

B. The protective measures that are primarily used to reduce radiation dose to others are:
   1. Decrease the time near the source.
   2. Increase the distance from the source.
   3. Increase the amount of shielding between you and the source

C. The following instructions are designed to maintain radiation doses to other individuals (i.e., family members and the public) to safe levels.

D. Precautions After Discharge (Check Appropriate Column):

Action	☐ < 15 mCi	☐ 15 to 33 mCi	☐ >33 to 53 mCi
1. Sleep alone for:	2 nights	2 nights	5 nights
2. Return to work (if others are in close proximity) for:	1 day	1 day	1 day
3. Maintain a prudent distance (≥9 ft) from others for:	1 day	3 days	7 days
4. Avoid direct contact with small infants, children and pregnant women for:	3 days	3 days	3 days
5. Maintain a distance of 9 ft from infants, children and pregnant women for:	6 days	12 days	16 days
6. Maintain sole use of the bathroom for ____. If not possible, keep the toilet especially clean by flushing 3 times after each use. Men should also sit during urination.	2 days	2 days	2 days
7. Refrain from traveling by airplane or mass transportation for:	1 day	2 days	5 days
8. Refrain from traveling on a prolonged automobile trip (≥6 hrs) for:	1 day	4 days	7 days.
9. Drink plenty of fluids for:	2 days	2 days	2 days
10. Wash clothing and eating utensils separately for:	2 days	2 days	2 days

E. Additional Instructions:

_____

_____

F. I have received and understood the instructions provided:

Signature: _____ Date: _____
(Patient)

STAFF QUESTIONNAIRE AND RELEASE DETERMINATION
Post-Thyroidectomy (178 mCi Maximum or 38 mrem/hr at 1 meter)

I. Patient Information

1. Patient Identifier: _____ 2. Date: _____
3. Administered Activity: _____ mCi
4. Sex: Male ☐ Female ☐ Pregnant? Yes ☐ No ☐ Breast-feeding? Yes ☐ No ☐
5. Person Interviewed: Patient ☐ Guardian ☐ Other _____

II. Dwelling Information For Two Weeks After Treatment

1. Type of Dwelling: Single-Family ☐ Multi-Family ☐ Apartment ☐ Other_____
   If not single-family, possible proximity to neighbors: _____ feet
2. Household Members: Sex: a. _____ b. _____ c. _____ d. _____
   Age: a. _____ b. _____ c. _____ d. _____

III. Patient Release Determination (Occupancy Factor = 0.25)

Interview the patient to determine if the patient can accept the following actions based on the activity given:

Action		< 100 mCi	100 to 150 mCi	>150 to 178 mCi	Circle One
1.	Sleep alone for:	2 nights	2 nights	2 nights	Yes No
2.	Return to work (if others are NOT in close proximity) for:	1 day	1 day	1 day	Yes No
3.	Maintain a prudent distance (≥9 ft) from others for:	1 day	2 days	3 days	Yes No
4.	Avoid direct contact with small infants, children and pregnant women for:	3 days	3 days	3 days	Yes No
5.	Maintain a distance of 9 ft from infants, children and pregnant women for:	4 days	7 days	10 days	Yes No
6.	Maintain sole use of the bathroom for _____. If not possible, keep the toilet especially clean by flushing 3 times after each use. Men should also sit during urination.	2 days	2 days	2 days	Yes No
7.	Refrain from traveling by airplane or mass transportation for:	1 day	2 days	2 days	Yes No
8.	Refrain from traveling on a prolonged automobile trip (≥6 hrs) with others for:	1 day	2 days	2 days	Yes No
9.	Drink plenty of fluids for:	2 days	2 days	2 days	Yes No
10.	Washing clothing and eating utensils separately for:	2 days	2 days	2 days	Yes No

The patient can be released if all answers are "Yes". If any answer is "No", the patient may be hospitalized. (Proceed to Section VI)

IV. Instructions

1. Ensure patient receives and understands the instruction sheet.
2. Discuss procedures in case of emergency medical care.

V. Release Record

This patient was released according to federal and state guidelines regarding immediate release based on patient-specific calculations. These calculations are maintained in the Radiation Safety Office. Refer to Form _____.

VI. Signature

☐ This patient was not releasable and therefore hospitalized.

☐ This patient has reviewed all requirements for patient release, was given written instructions and released.

☐ This patient is releasable with exceptions _____.

Signature: _____ Date: _____
(Individual completing form)

PATIENT RADIATION SAFETY DISCHARGE INSTRUCTIONS
NUCLEAR MEDICINE - Post-Thyroidectomy

A. Your release from the hospital is based on State and Federal safety regulations for patients treated with radioactive material.
B. The protective measures that are primarily used to reduce radiation dose to others are:
   1. Decrease the time near the source.
   2. Increase the distance from the source.
   3. Increase the amount of shielding between you and the source
C. The following instructions are designed to maintain radiation doses to other individuals (i.e., family members and the public) to safe levels.
D. Precautions After Discharge (Check Appropriate Column):

Action	☐ < 100 mCi	☐ 100 to 150 mCi	☐ >150 to 178 mCi
1. Sleep alone for:	2 nights	2 nights	2 nights
2. Return to work (if others are NOT in close proximity) for:	1 day	1 day	1 day
3. Maintain a prudent distance (≥9 ft) from others for:	1 day	2 days	3 days
4. Avoid direct contact with small infants, children and pregnant women for:	3 days	3 days	3 days
5. Maintain a distance of 9 ft from infants, children and pregnant women for:	4 days	7 days	10 days
6. Maintain sole use of the bathroom for ____. If not possible, keep the toilet especially clean by flushing 3 times after each use. Men should also sit during urination.	2 days	2 days	2 days
7. Refrain from traveling by airplane or mass transportation for:	1 day	2 days	2 days
8. Refrain from traveling on a prolonged automobile trip (≥6 hrs) for:	1 day	2 days	2 days
9. Drink plenty of fluids for:	2 days	2 days	2 days
10. Wash clothing and eating utensils separately for:	2 days	2 days	2 days

E. Additional Instructions:
The 1 meter patient measurement must not exceed the 38 mrem/hr from Table 4 of Section 18B.

F. I have received and understood the instructions provided:

Signature: _____ Date: _____
(Patient)