Applying Nuclear Regulatory Commission Guidelines to the Release of Patients Treated with Sodium Iodine-131

William K. Tuttle, III, and Paul H. Brown

Imaging Service, VA Medical Center and Department of Diagnostic Radiology, Oregon Health Sciences University, Portland, Oregon

Objective: This article presents a brief synopsis of the 1997 regulations from the Nuclear Regulatory Commission concerning the release from the hospital of patients treated for thyroid disease with ^{131}I. A simplified checklist is provided to demonstrate the instructions to patients and the new conditions for release of patients containing a higher level of ^{131}I radioactivity than was allowed under the older regulations.

Key Words: iodine-131; thyroid therapy; NRC regulations; patient release regulations

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The Nuclear Regulatory Commission (NRC) revised Title 10 of the Code of Federal Regulations (10 CFR 35.75) in 1997 to allow the release of patients on a solely dose-based basis (*1*). This change permits a patient to be released from the hospital provided the total effective dose equivalent to any individual (other than the treated patient) will not exceed 500 mrem. Furthermore, in a case where the dose could exceed 100 mrem, the patient also is to be provided with instructions on how to maintain doses to others as low as reasonably achievable (ALARA). This rule was adopted to remove the inconsistency that existed with the promulgation of a 100-mrem public dose limit in Part 20 in 1991, with the previous administered radioactivity-based limit in the pre-1977 10 CFR 35.75. The guidance for implementation was published as *NRC Regulatory Guide 8.39* (*2*). Note that this applies only to NRC licensees, however. Persons working in agreement states must check with their particular state regulators to ascertain whether their state has adopted the NRC's new guidelines.

This article provides the reader with a simple worksheet for releasing patients treated with Na^{131}I. We first summarize the key points presented in *NRC Regulatory Guide 8.39* and then provide some sample worksheets. We consider only patients administered Na^{131}I either for treatment of hyperthyroidism or post-thyroidectomy for thyroid cancer. For other cases and for the extra considerations required for patients who are nursing an infant or child, please refer to the *Regulatory Guide* (*2*).

As shown in Table 1 (which is a synopsis of Table 4 from the *Regulatory Guide*), there are 4 bases for the release of patients: administered activity, retained activity, measured dose rate, and patient-specific dose calculations.

The first, second, and fourth bases in Table 1 apply an equation from NCRP Report No. 37 (*3*) to calculate the exposure to persons from the released patient. Using this equation, with the ^{131}I physical half-life (8 d), an occupancy factor of 0.25 at 1 m, and assuming no shielding, an administered activity of $\leqq$ 33 mCi Na^{131}I will result in an exposure of $\leqq$ 500 mrem. However, using the same model, the revised NRC regulations now require that instructions on ''actions to maintain doses to other individuals as low as reasonably achievable'' be given to patients released with greater than 7 mCi. This is because the exposure to any other individual from the released patient could exceed the ALARA limit of 100 mrem for administered activity of ^{131}I as small as 7 mCi. Thus (basis 1 in Table 1), one may always release a patient administered 33 mCi or less of Na^{131}I; however, instructions must be provided to the patient if he or she gives more than 7 mCi.

We will not discuss release bases 1–3 any further, because these are very similar to the older regulations (pre-1997) and probably very similar to the state regulations that apply for licensees in agreement states that have not as yet adopted the new NRC regulations. We presume that the major interest of the reader is to easily calculate the considerably higher levels of ^{131}I (i.e., $>$ 33 mCi) that now permit release of the patient under the patient-specific dosimetry (basis 4 in Table 1), so we now review the NRC guidelines for patient-specific dose calculations and, lastly, provide some simplified checklists.

For administered activities of Na^{131}I greater than 33 mCi, patient-specific calculations must be performed and documented to allow the release of the patient. Patients may be released, regardless of the administered mCi of ^{131}I, if these patient-specific calculations show a dose to any person, other than the patient, of $<$500 mrem. Incorporated into each patient-specific calculation must be considerations of occupancy factors, effective half-lives, and uptake fractions (based

For correspondence or reprints contact: William K. Tuttle, III, PhD, Radiation Safety Office, P-5-FMS-RSO, Portland VA Medical Center, 3710 SW US Veterans Hospital Rd., PO Box 1034, Portland, OR 97207; Phone 503-220-8252, X55853; E-mail: william.tuttle@med.va.gov.

TABLE 1
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	1. Administered activity	Administered activity of ^{131}I <33 mCi	Yes, if administered ^{131}I >7 mCi	No
	2. Retained activity	Retained activity of ^{131}I <33 mCi	Yes, if retained ^{131}I >7 mCi	Yes, see *Regulatory Guide*
	3. Measured dose rate	Measured dose rate from ^{131}I <7 mrem/h	Yes, if dose rate ^{131}I >2 mrem/h	Yes, see *Regulatory Guide*
	4. Patient-specific calculations	^{131}I calculated dose to other than patient <500 mrem	Yes, if calculated ^{131}I dose >100 mrem	Yes, see *Regulatory Guide,* and discussed below
Patients who are breast-feeding	All the above bases for release		Yes, complex, see *Regulatory Guide*	Yes, complex, see *Regulatory Guide*

*Synopsis of Table 4 from *U.S. Nuclear Regulatory Guide 8.39.*

on a 2-component, extrathyroidal and intrathyroidal model of ^{131}I pharmacokinetics). The formula to be used for the calculation of maximum likely dose to any individual exposed to the released patient (equation B-5 in the *Regulatory Guide*) is:

$$D(\infty) = \{[34.6\Gamma Q_0/(100\ cm^2)]\}\{E_1T_p(0.8)(1 - e^{-0.693(0.33)/T_p}) + E_2F_1T_{1eff}e^{-0.693(0.33)/T_p} + E_2F_1T_{2eff}e^{-0.693(0.33)/T_p}\},$$

where:

- $D(\infty)$ = dose to any person exposed to the patient (rem);
- Γ = the exposure rate constant for ^{131}I = 2.2 (R/mCi-hr at 1 cm);
- Q_o = the administered activity of $Na^{131}I$ (mCi);
- E_1 and E_2 = the occupancy factors for the extrathyroidal and intrathyroidal components, respectively (see below);
- F_1 and F_2 = the uptake fractions for the extrathyroidal and intrathyroidal components, respectively (see below);
- T_P = physical half-life for ^{131}I = 8.04 d;
- T_{1eff} and T_{2eff} = effective half-lives (in days) for the extrathyroidal and intrathyroidal components, respectively (see below).

The uptake fractions and effective half-lives can be measured experimentally for each patient, or alternatively taken from Table 2. The basis for them is explained in *Regulatory Guide 8.39.* Note that if you have an experimental measurement that supports a different value than that shown in Table 2, then you can use that in the equation for calculating $D(\infty)$.

The occupancy factor E is the fraction of time that any other person is considered to be located within 1 m of the patient. What can be used for the occupancy factor E? *Regulatory Guide 8.39* suggests the following:

Use E = 0.75 when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is ≦1 d

or

Use E = 0.25 when an effective half-life is greater than 1 d if the patient has been given instructions, such as the following:

1. Maintain a prudent distance from others for at least the first 2 days;
2. Sleep alone in a room for at least the first night;
3. Do not travel by airplane or mass transportation for at least the first day;
4. No travel on a prolonged auto trip with others for at least the first 2 d;
5. Have sole use of a bathroom for at least the first 2 d; and
6. Drink plenty of fluids for at least the first 2 d.

or

Use E = 0.125 when an effective half-life is greater than 1 d if the patient has been given instructions such as the following:

1. The instructions 1–6 for E = 0.25 above;

TABLE 2
Uptake Fractions and Effective Half-Lives for Iodine-131*

Medical condition	Extrathyroidal component: Uptake fraction F_1	Extrathyroidal component: Effective half-life T_{1eff} (day)	Thyroidal component: Uptake fraction F_2	Thyroidal component: Effective half-life T_{2eff} (day)
Hyperthyroidism	0.20	0.32	0.80	5.2
Post-thyroidectomy for thyroid cancer	0.95	0.32	0.05	7.3

*From Table B-1 in *NRC Regulatory Guide 8.39.*

2. Live alone for at least the first 2 d; and
3. Have few visits by family or friends for at least the first 2 d.

Appendix A is a sample worksheet that can be used to document patient release, basically using the mCi administered to the patient along with the other numeric values as suggested in the *Regulatory Guide* to calculate the dose to any other person, D(∞). If this dose is <500 mrem, the patient may be released (along with appropriate patient instructions and record keeping requirements). Appendix B is a sample form that can be used to document patient and family instructions.

There are 2 final comments. First, there is some useful discussion of patient release that may be reviewed on the Health Physics Society web site (*4*). Second, there was a recent journal article (*5*) that supports the NRC's position that release of patients, using certain criteria, does not exceed the intended exposure limits.

Using the assumptions as stated in the *Regulatory Guide*, patients who are treated with ≦ 56 mCi ^{131}I for hyperthyroidism, or patients treated with ≦ 220 mCi ^{131}I for post-thyroidectomy treatment of cancer may be released from hospital confinement. All you need to do is document your instructions and calculations. Appendices 1 and 2 are examples of forms that can be used for documentation.

REFERENCES

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APPENDIX A
Radioiodine Therapy Outpatient Worksheet

Patient's Name _____ Patient ID Number _____

1. Will the administered activity of ^{131}I exceed 33 mCi?
   - No ➧ The patient may be treated as an outpatient. Ensure that written and oral patient instructions are provided, and a written directive completed.
   - Yes ➧ The patient may require hospitalization for treatment. Continue to Item 2.

2. Determine if the following criteria apply:

Yes	No	
❑	❑	The patient will maintain a prudent distance from others for at least the first 2 days.
❑	❑	The patient will sleep alone in a room for at least the first night.
❑	❑	The patient will not travel by airplane or mass transportation for at least the first day.
❑	❑	The patient will not travel on a prolonged automobile trip with others for at least the first 2 days.
❑	❑	The patient will have sole use of a bathroom for at least the first 2 days.
❑	❑	The patient will drink plenty of fluids for at least the first 2 days.

3. If the answer is No to any one or more of the criteria in Item 2 above, the patient must be hospitalized for treatment if the administered activity exceeds 33 mCi ^{131}I.

4. *If the answer is Yes to all of the criteria in Item 2,* perform the necessary calculations in Item 5, below, to determine whether the patient can be released immediately in accordance with NRC *Regulatory Guide* 8.39, Appendix B, as discussed below.

5. Patient-specific dose calculations (Check 1 of the 3 boxes, whichever applies, and calculate D).

❑ For $Na^{131}I$ treatment of a patient *post-thyroidectomy for thyroid cancer*:

D (mrem) = 2.27 Q_o = _____ mrem,
where D (mrem) is the maximum likely dose to an individual exposed to the patient and Q_o is the administered activity in millicuries (e.g., if you administer 100 mCi to the patient, then D (mrem) = 2.27 ∗ 100 = 227 mrem).

❑ For $Na^{131}I$ treatment of *hyperthyroidism:*

D (mrem) = 8.84 Q_o = _____ mrem,
where D (mrem) is the maximum likely dose to an individual exposed to the patient and Q_o is the administered activity in millicuries.

Note: the above 2 calculations use occupancy factors discussed in Appendix B, section B.1.2 of NRC *Regulatory Guide* 8.39, and effective half-lives and uptake components found in Table B-1 of NRC *Regulatory Guide* 8.39. If you use other values, as determined for your specific patient, you must use Equation B-5 of the *Regulatory Guide.* You must write the entire equation below:

❑ D (mrem) =

6. Answer the following:

Yes	No	
❑	❑	The maximum likely dose to an individual exposed to the patient [D (mrem)] is less than 500 millirem?

If yes, the patient may be released. **Keep this worksheet (including any other calculations) and a copy of the patient instructions** for documentation of compliance with 10 CFR 35.75.

7. **Further restrictions apply if the patient is breast-feeding (see *Regulatory Guide*).**

Yes	No	
❑	❑	This patient is breast-feeding an infant or child.

Worksheet completed by _____ Date _____
(Signature)

APPENDIX B
Instructions to Patients Containing More Than 6.9 mCi $Na^{131}I$ Released from the Medical Center

Patient name _____ Patient ID number _____ .
_____ mCi of $Na^{131}I$ was administered orally at _____ am/pm on _____ / _____ / _____ .
Patient released from the medical center at _____ am/pm on _____ / _____ / _____ .

Patient and Family Learning Needs

The patient:

❑ does not have special learning considerations.
❑ has special learning considerations which will change the method of instruction (specify if present).

Patient and Family Instructions

(write additional instructions on the back as needed)

Safe and effective use of medications.

1. Resume previous thyroid medications as follows:

Diet and nutrition.

1. Do not eat for 2 hours following the administration of $Na^{131}I$, however you may drink clear liquids (water, coffee, tea, fruit juices, and/or soft drinks).
2. Drink as much fluid as tolerable for 48 hours following administration.
3. Chew gum, or suck on hard or sour candy, frequently for 48 hours to encourage the flow of saliva.
4. Use disposable cups, plates, and other dishes and tableware for ___ days.

Suggestions to minimize the radiation dose to other people.

1. Avoid sustained close contact with other people for ___ days, especially infants, children, and pregnant women. Remember that radioactive contamination may spread to others through your perspiration, saliva, urine, and feces.
2. Sleep alone for ___ days.
3. Avoid conception for 6 months.

Personal hygiene and grooming.

1. Urinate frequently (every 2 hours if possible) for ___ days. Men need to sit down to urinate during this time.
2. Flush the toilet twice after each use and keep your hands clean for _____ days.
3. Shower daily and use separate towels for ___ days.
4. Wear clothing that can be laundered (not dry cleaned) for ___ days.
5. After ___ days wash your clothing, towels, and bedding separately (put through wash/rinse cycles twice).
6. In the rare chance you should vomit within 2 hours of receiving therapy, use paper towels to soak up the material and flush it down the toilet. Try not to spread the material around, as it will be radioactive. Wash your hands. Inform the nuclear medicine staff as soon as possible at _____ [telephone number].

Special Instructions:

If you experience any of the following symptoms, contact your physician:

Increased shakiness
Rapid heart rate
Shortness of breath
Increasing pain or swelling in the neck over the next 2–3 weeks
Difficulty breathing.

Important Telephone Numbers

After hours urgent calls can be made to the **Medical Center Operator at** _____ and ask the operator to connect you to the **Emergency Care Unit at ext.** _____ .
During normal business hours (8:00 am–4:30 pm) call Nuclear Medicine at _____ .
If you have an **Emergency,** call **911.**

Additional Instructions:

Follow-Up Appointments			
Clinic	**Confirmed date and time**	**Special instructions**	**Initials**

I have reviewed the release instructions with the patient and/or family or caregiver. The patient or caregiver was able to verbalize understanding of the instructions. A copy of these written instructions was given to the patient or caregiver.

Name _____ Date _____ Time _____ am/pm
(Person giving the instructions)

Release instructions have been explained to me and/or my family or caregiver. I have received a copy of the instructions and I understand them.
Name _____ Date _____
Circle one: Patient/Family/Caregiver signature

Place the original in the medical record and give the patient and/or family 1 copy.