
5A.3. REQUIREMENTS FOR OUTPATIENT RELEASE FOLLOWING I-131 THERAPY

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In May 1997, the United States Nuclear Regulatory Commission (NRC) regulations were revised in a way that permits outpatient I-131 therapy for cancer in most situations (NRC 1997). The purpose of this chapter is to explain the NRC release regulations in a way that is directly applicable to clinicians who manage patients with thyroid cancer.

CURRENT NRC REGULATIONS (REVISED IN MAY 1997)

Currently applicable NRC regulations related to the release of patients following I-131 administration are described in the NRC Regulatory Guide 8.39 (April 1997). A copy of this document may be found on the NRC web site. The current link to the actual document is included in the reference list at the end of this chapter.

The major change is that the 1997 revised regulations permit patients to be released from the control of the licensee (usually a hospital) if the Total Effective Dose Equivalent (TEDE) to any person as a result of contact with the treated individual is likely to be no greater than 500 mR. The innovative thing about the TEDE approach is that it takes into account the precautions that patients plan to take during the first few days following I-131 administration (Grigsby 2000). These regulations permit individuals who can isolate themselves from other people to be treated as an outpatient with doses of I-131 that would have required inpatient confinement prior to 1997.

THREE ABSOLUTE CONTRAINDICATIONS TO OUTPATIENT I-131 THERAPY

In our program we find it useful to establish release standards that are not mentioned in NRC regulations. Regardless of TEDE, or patient specific measurements, we do not deliver outpatient I-131 therapy in any of the following situations:

- The patient is unable to care for themselves
- The patient lives in a nursing home or communal living facility
- The patient prefers not to be released after taking I-131

CALCULATING TOTAL EFFECTIVE DOSE EQUIVALENT (TEDE)

NRC regulations permit patients to be released after receiving I-131 if the TEDE to other people is likely to be no greater than 500 mR. To determine if this condition will be met Regulatory Guide 8.39 presents an equation to calculate the expected TEDE to people who may come in contact with the person who has received I-131. The TEDE equation has three variables: The activity of I-131 that will be administered to the patient, the result of a thyroid uptake study, and a factor called the “occupancy factor”, which takes into account the amount of time the treated individual will spend around other people during the first few days after receiving I-131.

Administered I-131 activity: This is the mCi of I-131 administered to the patient. Typical doses for cancer therapy are 50–250 mCi.

Thyroid uptake study: This study is described in a previous chapter. Basically, the patient is given a diagnostic dose of either I-123 or I-131 and then the percent of the activity that is retained in the thyroid bed is recorded at 2–24 hours after radioiodine administration. A typical result following near total thyroidectomy is 0.5–5%.

Occupancy factor: NRC regulations set the occupancy factor as either 0.25 or 0.75. The value to use is determined by how much contact the patient will have with other people during the first two days after receiving I-131. Basically, the occupancy factor is 0.25 when these five requirements are met for 2 days after the patient receives I-131:

- The patient will not use public transportation
- A pregnant woman or a child will not enter the patient’s home
- The patient will not leave their home
- The patient will not touch another person or spend more than a few minutes in the same room with another person
- The patient will have sole use of a bathroom

If it is likely that any one of these requirements will not be met for 2 days after receiving I-131, then the TEDE must be calculated with an occupancy factor of 0.75.

To facilitate and document the evaluation of a patients eligibility for outpatient therapy we fill out a standardized questionnaire at the time of the clinic visit when we discuss the details of I-131 therapy. A version of our questionnaire is included below.

Table 1. Thyroid Uptake Values and I-131 Doses that Meet NRC Requirements for Outpatient Management*.

Thyroid uptake	Occupancy Factor 0.25	Occupancy Factor 0.75
	I-131 dose	I-131 dose
0.5%	295 mCi	165 mCi
1%	285 mCi	155 mCi
2%	265 mCi	138 mCi
3%	245 mCi	125 mCi
4%	230 mCi	113 mCi
5%	220 mCi	105 mCi
6%	208 mCi	97 mCi
7%	197 mCi	90 mCi
8%	187 mCi	84 mCi
9%	178 mCi	79 mCi
10%	171 mCi	74 mCi
11%	163 mCi	70 mCi
12%	157 mCi	67 mCi
13%	151 mCi	63 mCi
14%	145 mCi	60 mCi
15%	140 mCi	57 mCi

* These uptake-dose combinations result in a Total Effective Dose Equivalent of ≤ 500 mR based on the equation presented in NRC Regulatory Guide 8.39.

A TABLE SHOWING THE I-131 DOSES THAT CAN BE DELIVERED AS AN OUTPATIENT

Well in advance of the date of I-131 administration the physician must specify the dose of I-131 and determine if the patient will be treated as an outpatient. To make these decisions it is useful to have a table that shows the combinations of I-131 dose, thyroid uptake value, and occupancy factor that result in a TEDE of ≤ 500 mR using the equation described in NRC Regulatory Guide 8.39. Table 1 provides this information.

WE DO NOT PERMIT A PATIENT TO STAY IN A HOTEL FOR 3 DAYS AFTER RECEIVING I-131

In our practice we encounter the situation where a patient would like to stay in a hotel to meet the requirements for outpatient I-131 therapy. We prohibit patients from staying in a hotel for 3 days after receiving I-131 because it is difficult to control or monitor the people who may come in contact with the linen and objects that may have been contaminated with I-131.

THE REQUIREMENT TO GIVE THE PATIENT RADIATION SAFETY INSTRUCTIONS

NRC regulations require that a patient who is released following I-131 therapy be given written instructions on how to limit the dose to other individuals. The instructions that we send patients home with are included below.

YOUR HOSPITAL'S RELEASE REQUIREMENTS MAY BE STRICTER THAN NRC REGULATIONS

The final point to make is that the requirements that we explain in this chapter reflect only the standards presented in the NRC regulations. State governments and local institutions (hospitals) may establish standards that are more restrictive than those of the NRC. The relationship between these three entities is hierarchical- meaning that state regulations must be at least as restrictive as those of the NRC and local policy must be at least as restrictive as both federal and state regulations. For example, NRC regulations currently permit a patient who has received 150 mCi of I-131 to be released from the hospital when the TEDE to other people is likely to be ≤ 500 mR. Some state governments are uncomfortable with the TEDE approach and have established state regulations that prohibit the release of a patient whose total body I-131 activity is > 30 mCi or when the exposure at 1 meter from a patient is > 5 mR/hour. Similarly, some hospitals go beyond the “or” standard by establishing policy that requires that both of these requirements be met to release a patient following I-131 administration. The bottom line is that physicians who deliver I-131 need to know what the release policy is at the institution in which they deliver I-131 because such policy may be more restrictive than NRC or state government regulations.

A related issue that is confusing to people who are not familiar with the regulation of radioactive material is the role of state government in the process. A state may elect to take responsibility for regulating the use of radioactive material or it may leave this responsibility with the NRC. There are political and financial reasons that a state would want to take responsibility for this activity. To regulate the use of radioactive material a state must establish a formal relationship with the NRC in which the state agrees to apply regulations that are at least as restrictive as those of the NRC. States that establish this agreement, and thus regulation the use of I-131 through a state government agency, are called “Agreement States”. Currently there are approximately 33 Agreement States.

QUESTIONNAIRE TO EVALUATE ELIGIBILITY FOR OUTPATIENT I-131 THERAPY

Patient's Name _____ Today's Date _____

Physician prescribing I-131: _____ Treatment Date _____

Dose: _____ mCi of I-131 Thyroid Uptake value _____ %

1. Do you need someone else to help you dress, eat, or go to the bathroom? Y* N
2. Do you live in a nursing home or other communal living facility? Y* N
3. a) Do you live with a pregnant woman? Y N
- b) If yes, can she and you live in separate homes for 2 days after
 you receive I-131 Y N[#]
4. a) Are there children (< 19 years old) living with you? Y N
- b) If yes, can you and the children live in separate homes for 2 days
 after receiving I-131? Y N[#]
5. Can you get home after receiving I-131 without using public
 transportation? Y N[#]
6. Are you able and willing to go straight home and not leave your home
 for 2 days after receiving I-131? Y N[#]
7. Are you able and willing to make it so children and pregnant women
 do not enter the home that you will stay in for 2 days after you
 receive I-131? Y N[#]
8. Are you able and willing to isolate yourself in your home so that you
 spend almost no time in the same room with another person and
 do not touch another person for 2 days after receiving I-131? Y N[#]
9. Are you able and willing to arrange things so that you have sole use
 of a bathroom for 2 days after you receive I-131? Y N[#]
10. Do you prefer to be admitted to the hospital for a few days after
 taking I-131? Y* N

Patient signature _____ Date _____

* If the answer is YES to any of these questions, the patient may not be released until the I-131 activity has dropped below 30 millicuries or the dose rate at 1 meter is less than 500 mR/hr.

If the answer to all of these questions is YES, the Occupancy Factor used to calculate Total Effective Dose Equivalent is 0.25. If the answer to any of these questions is NO, the Occupancy Factor must be 0.75 and it may be appropriate to require inpatient confinement regardless of the TEDE calculation.

RADIATION EXPOSURE TO OTHER PEOPLE AFTER I-131 THERAPY

Patient name: _____ Today's Date: _____

Date of I-131 administration: _____ Dose of I-131 administered: _____

You have received I-131 for treatment of a medical condition. Show this document to anyone who is concerned about your radioactive exposure to other people. For questions contact: Dr. XXXXXXXX or the doctor on-call, Phone XXX-XXX-XXXX

NO RADIATION SAFETY PRECAUTIONS ARE NECESSARY AFTER:

_____, 20_____

- Children and pregnant women should not enter your home for _____days
- Do not leave your home for _____days
- Isolate yourself in your home so that you spend almost no time in the same room with another person for _____days
- Try not to do anything that could transfer your saliva to another person, such as kissing or sharing food, for _____days
- Use disposable eating utensils for _____days
- Wash your bedding, towels, and laundry separately for _____days
- Do not work or volunteer outside the house for _____days
- Do not take public transportation for _____days
- Arrange things so that you have sole use of a bathroom for _____days
- Dispose of all tissues in the toilet for _____days.
- Flush the toilet twice after each use for _____days.
- Do not sleep with, or lay or sit next to, another person for _____days
- Do not have sexual relations with anyone for at least _____days
- Do not get pregnant or get someone pregnant for at least 1 year

REFERENCE

U.S. Nuclear Regulatory Commission Regulatory Guide 8.39. April 1997. Release of Patients Administered Radioactive Materials. This document may be accessed at: <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/occupational-health/active/8-39/08-039.pdf>.