

Gallagher, Carol

Subject: FW: Docket ID NRC-2015-0020
Attachments: Nuclear Medicine Thyroid Cancer Radioiodine Treatment.docx; Nuclear Medicine Thyroid Therapy Checklist.docx; OP I131 screening.doc; Thyroid Cancer Ablation Dosing Worksheet-3.docx; PH I-131 Thyroid Cancer Therapy.doc; Pt Ablation Restrictions 2013.doc; Max Exposure Calc.xlsNEW.xls; Dose form Therapy I131(tan)-1.doc

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From: Aaring, Dixie [mailto:DAaring@peacehealth.org]
Sent: Monday, February 15, 2016 3:33 PM
To: Gallagher, Carol <Carol.Gallagher@nrc.gov>
Subject: [External_Sender] Docket ID NRC-2015-0020

11/16/2015
80 FR 70843

Hi Carol,
I am attaching the procedure and documents used (at Sacred Heart MC RiverBend, Springfield, Oregon) to schedule patients for I-131 imaging and therapy, as well as the screening worksheet for inpatient versus outpatient treatment, patient restrictions to be followed patient following therapy treatment, copy of dose worksheet used to determine dosing for patient therapy, worksheet used by physician and technologist on day of dosing to assure informed consent, etc. We have a mix of inpatient and outpatient treatment based on living situation, dose administered, and uptake fraction. The screening is done by a NM technologist at the time scheduling. The referring physician prior to sending a referral to Nuclear Medicine discusses the use of radioiodine therapy to treat thyroid cancer including information regarding inpatient versus outpatient treatment and the patient restrictions that will need to be performed following treatment. This information is again reviewed by both the NM technologist and the NM physician on the day of dosing (for pre-ablation imaging as well as therapy). Patients receive a copy of their schedule, low-iodine diet recommendations, and the post dosing/therapy restrictions in the mail (or email-if desired). Patient are encourage to call with questions to either Nuclear Medicine or their referring physician. If you have any questions, feel free to contact me,
Dixie

Dixie Aaring CNMT, NCT, ARRT(CT) | NM Manager | Nuclear Medicine
PeaceHealth | 3311 RiverBend Drive | Springfield, OR 97477
office 541-222-2710 | fax 541-222-2780 | cell 541-214-0532



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RULES AND DIRECTIVES
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SUNSI Review Complete
Template = ADM - 013
E-RIDS= ADM-03
Add= D-B- Howe (abh)

1. Referring provider will evaluate patient to determine appropriate treatment including discussion of timing for treatment and imaging with radioiodine (I-131) for residual and metastatic thyroid tissue. Referring provider and Nuclear Medicine physician will determine the appropriate dose of I-131 radioiodine to be given. Important to determine whether radioiodine treatment is to be done while patient is on thyroid hormone and Thyrogen OR while patient is withdrawn from thyroid hormone.
2. When ready to proceed with I-131 radioiodine therapy, referring provider will complete NM Thyroid Cancer order form (may include desired dates for treatment) with prior authorization information which is then faxed to Nuclear Medicine at 541-222-2780.
3. When Nuclear Medicine receives and reviews the order, NM will contact the patient to schedule as well as to screen for outpatient versus inpatient treatment status. The patient's living situation will determine whether they can be treated with the I-131 radioiodine as an outpatient or they will need to be admitted and treated as an inpatient. To be treated as an outpatient:
 - Patient must be able to take care of their own personal needs (does not have a caregiver)
 - Patient must have their own bedroom and sleep alone for 7 nights
 - Patient must have sole use of bathroom for 4 days
 - Patient must minimize time around children and pregnant women for 4 days
 - Patient must not have any travel plans for 4-7 days post treatment
 - Patient can **NOT** go live in hotel for 7-10 days post treatment
4. Nuclear Medicine will notify/confirm with the referring provider's office the scheduled dates and OP vs IP treatment status.
5. Referring provider will arrange for necessary lab work (HCG, Thyroglobulin, and possible TSH) and schedule Thyrogen injections (if needed) with the Infusion Center (541-335-2800). Please send a copy of labs to Nuclear Medicine.
6. If patient must be treated as inpatient, referring provider will obtain current history and physical (within 2 weeks of admission). This H&P along with signed admission orders should be sent to Nuclear Medicine. Inpatient treatment generally involves a one night stay (occasionally two nights) in the hospital.
7. If patient is treated as outpatient, the I-131 radioiodine dose will be given in the Nuclear Medicine department after counseling patient about the necessary precautions and restrictions regarding radiation exposure to others. Patient will then be allowed to go home.
8. All patients will return 7 days later to the Nuclear Medicine department for whole body imaging.

Nuclear Medicine Thyroid Therapy Checklist

Hyperthyroid therapy (≤ 30 mCi I-131)

1. Thyroid imaging with uptake with an elevated 24 hour radioiodine uptake.
2. TSH and FT4 blood levels within 30 days of procedure
3. Serum HCG level for all females 12 to 50 years of age unless surgically unable to become pregnant.
4. Discontinue thyroid replacement medications 4 weeks prior to imaging/treatment. Can taper off using T3 (Cytomel) for two weeks, then off T3 two weeks.
5. Discontinue anti-thyroid medications 3-5 days prior to imaging/treatment.
6. No iodinated contrast agents for 6 weeks prior to imaging/treatment.
7. No iodine supplements (multivitamins (≥ 150 mcg iodine), fish oil, kelp, etc.) for 2 weeks prior to imaging/treatment.
8. No kelp, seaweed, or seafood for 2 weeks prior to imaging/treatment.
9. No Lugol's solution or SSKI for 2 weeks prior to imaging/treatment.
10. No iodine skin preps or ointments for 2 weeks prior to imaging/treatment.
11. No Amiodarone (anti-arrhythmia drug) for 3-6 months. If patient is on this medication, please consult with ordering provider and NM physician before scheduling.
12. Thyroid imaging and uptake study will be used to determine radioiodine treatment dose. (Based on size of thyroid gland and uptake value).

Thyroid Cancer Ablation therapy (100-250 mCi I-131)

1. Imaging and Ablation therapy to be done 6-8 weeks post-surgery
2. Type of thyroid cancer
3. Date of thyroid surgery; Nuclear Medicine will need copy of both surgical and pathology reports
4. Any neck masses or bone tenderness?
5. No iodinated contrast agents for 6 weeks prior to imaging/treatment.
6. No iodine supplements (multivitamins (≥ 150 mcg iodine), fish oil, kelp, etc.) for 2 weeks prior to imaging/treatment.
7. No kelp, seaweed, or seafood for 2 weeks prior to imaging/treatment.
8. No Lugol's solution or SSKI for 2 weeks prior to imaging/treatment.
9. No iodine skin preps or ointments for 2 weeks prior to imaging/treatment.
10. No Amiodarone (anti-arrhythmia drug) for 3-6 months. If patient is on this medication, please consult with ordering provider and NM physician before scheduling.
11. Low-iodine diet for 2 weeks prior to imaging/treatment.
12. Option 1: Discontinue thyroid replacement medications 4 weeks prior to imaging/treatment. Can taper off using T3 (Cytomel) for two weeks, then off T3 two weeks. Labwork required within 3 days of imaging/treatment: TSH level > 30 IU/mL, Thyroglobulin, and serum HCG (females 12-50 yrs).
13. Option 2: Pretreatment with Thyrogen injection (24 and 48 hours) prior to imaging or treatment. Labwork required within 3 days of imaging/treatment: Thyroglobulin and serum HCG (females 12-50 yrs).
14. Living situation of patient – ability to care for self without assistance, presence and age of others in home, single house vs apartment, etc. NM technologist will call patient to interview concerning living situation to determine possibility of outpatient versus inpatient treatment. (Based on living situation, TB uptake value, and radioiodine dose administered).
15. Inpatient treatment – Admitting provider will need to supply Admission orders (Order set is available for use) and recent History and Physical and Discharge patient after release from radiation restrictions.

OUTPATIENT I-131 Treatment > 30 mCi SCREENING

Patient Name _____
MRN _____
Birth Date _____

Date _____ pt

Patient's age _____ Sex M F

Treatment for: Thyroid Cancer

Is Patient pregnant or breastfeeding Y N N/A
If yes, restrictions need to be signed by the patient

Patient Living / Occupancy Situation:

Allowable dwellings:

Single family _____ Apartment/townhouse/duplex _____ (bedroom to outer-wall)

Not allowable dwellings:

Group home _____ Assisted Living _____ City of residence _____

Number of bathrooms: _____

Persons (other than patient) residing in dwelling:

Age	Hours/day		Age	Hours/day

If they will be riding with others in the automobile after treatment, then determine length of time to drive home. If the time is greater than two hours the patient CAN NOT be treated on an outpatient basis and they must be hospitalized.

If the patient is breastfeeding it is recommended that they discontinue a minimum of 3 weeks before being treated.

Check the box next to the statement if patient **can** comply with restriction.

The patient:

- Can attend to their own personal needs and does not require a caregiver?
- Can urinate by themselves and is not incontinent?
- Will have sole use of a bathroom for at least 4 days after treatment?
- Will drink a minimum of 64 ounces of fluid for 2 days after treatment?
- Is NOT the primary caregiver for children under 10 years of age or they can arrange for alternate care for children during the first 4 days after treatment?
- Will the patient maintain a distance of 6 feet from others for at least 4 days after treatment?
- Will the patient sleep alone in a room for at least 7 nights?
- Will NOT travel by airplane or mass transportation for at least 4 days after treatment?
- Will NOT travel on prolonged car trips for at least 4 days after treatment?
- Will limit visits with friends and family for 4 days after treatment?

If all boxes are checked, then Occupancy factor=0.25; PLUS live alone 2 days, then OF=0.125
If one or more boxes are unchecked then treatment is to be done as an inpatient

Refer to I-131 Max Radiation Exposure worksheet in Nuc Med folder for calculation

Patient Name _____ Referring Provider _____

MRN _____ DOB _____ Age _____ M F

Scheduled Dates: **Patient preparation:** **Withdrawal** **Thyrogen stimulation**

Labs drawn	Thyroglobulin / HCG / TSH		
Pre-Ablation imaging		Ablation therapy (as needed)	
1st Thyrogen injection		1st Thyrogen injection	
2nd Thyrogen injection		2nd Thyrogen injection	
I-131 WB Dose		I-131 Ablation Dose	
I-131 WB Scan		Post-Ablation imaging	

Pathology: Date of Surgery _____

Type: Follicular Papillary Medullary Other _____

Size: _____ cm Margins: Positive Negative

Lymphovascular involvement: Y N

Cervical Lymph nodes at surgery: # positive/# taken: _____

Distant/Extra-thyroid involvement: Y N

Status: OP IP

Ablation dose: _____ mCi

Previous Ablation:

Date _____ Dose _____ mCi

Date _____ Dose _____ mCi

Cumulative Dose _____ mCi

Reviewed by:


Radiologist: _____ Date _____

Endocrinologist: _____ Date _____

Labs:

I-131 Total body imaging results

Date	Lab Test	Value	Normal Range
	Thyroglobulin		0 – 55 ng/mL
	Thyroglobulin Ab		< 40 IU/mL
	TSH **		0.4 – 4.6 uIU/mL
TSH must be >30 for thyroid cancer therapy unless Thyrogen stimulation done			
	HCG (age 12-50)	Positive Negative Not applicable	

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ISOTOPE AND RADIOPHARMACEUTICAL INFORMATION:

Isotope and Radiopharmaceutical	¹³¹ I	Sodium Iodide
Adult Dosage and route of administration	> 30 mCi (> 1110 MBq)	P.O. Capsule
Estimated effective dose and critical organ(s)	24 mSv/MBq 88.8 rems/mCi	Thyroid 351.4 mGy/MBq 1300 rad/mCi
Pediatric Dosage and Minimum Dose	Determined by AU	NA

PRINCIPLE:


A widely accepted therapy is ¹³¹I for patients with differentiated thyroid carcinomas. It has been proven to be a safe and a relatively inexpensive treatment modality. ¹³¹I can lead to complete remission, even in thyroid cancer patients with metastatic disease. Therapeutic doses of ¹³¹I commonly range from 100 to 250 mCi, with the larger activities used to ablate thyroid remnants or to treat metastatic disease in patients with thyroid cancer. After a therapeutic administration of ¹³¹I, the patient becomes a potential radiation hazard to other individuals. Radiation is emitted from radioactivity in the patient, and radioiodine is secreted in body fluids such as sweat and saliva and excreted into urine and feces. Precautions should be taken to limit the radiation exposure of the nuclear medicine physician, nursing personnel, the patient's family, and members of the public with whom a treated patient may come in contact. Recommendations are usually based on measurement of ¹³¹I retention or instantaneous dose rates. Most patients who receive high doses of ¹³¹I are isolated in a private room. The patient is monitored daily, and radiation safety precautions are updated as needed. Nursing care and visitors are limited to non-pregnant adults as necessary. The patients are advised against bringing anything with them that they would be unwilling to leave behind should contamination occur. The patient's radiation exposure is commonly monitored using direct external exposure rate measurements. Outpatient ¹³¹I treatment for thyroid cancer may be considered when patients meet stringent defined criteria.

CLINICAL INDICATIONS:

1. Postoperative ablation of thyroid remnants after thyroidectomy for thyroid cancer.
2. Treat residual thyroid cancer and metastatic disease after partial or complete thyroidectomy or thyroid cancer recurrence.

SCHEDULING INFORMATION:

1. Routine patient information including patient's mailing address and phone number
2. Type of thyroid carcinoma and lymph node involvement; obtain copy of pathology report

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3. Total or near-total thyroidectomy? Obtain copy of operative report(s); (minimum 6 weeks after surgery before NM imaging can be done)
4. Reports and films from prior total body thyroid (I-131) imaging
5. X-ray, CT, MRI reports and films showing any abnormalities
6. Any clinical evidence of metastases, neck masses, or bony tenderness
7. Current thyroid medications (See Patient Preparation for instructions)
8. Will Thyrogen be given? (See Patient Prep for instructions)
9. Any other iodine medications or procedures (i.e. contrast agents, vitamins with iodine, kelp, etc)?
What? When? Cannot schedule within 6 weeks of imaging procedure utilizing iodine contrast
10. Recent TSH level. Draw 3-5 days prior to dose. Result must be **greater** than 30 µIU/ml. TSH level not required if patient is to receive Thyrogen.
11. For all patients who have had prior I-131 ablative therapy or suspected metastatic disease, recent thyroglobulin level (within one month) prior to I-131 dose.
12. If patient is female of childbearing age (12-50), need HCG blood test within 3 days of dosing (exception for hysterectomy patients).
13. Does the patient have problems with urination?
14. Does the patient have a caregiver?
15. Does the patient have young children at home? Pets?

PATIENT PREPARATION:


Pre-ablation metastatic whole body imaging with I-131 is routinely done prior to high dose ablation therapy for thyroid cancer. The following restrictions apply.

A. Patient Off of Thyroid Medication:

1. Discontinue thyroid medication and other iodine 4-6 weeks prior to imaging.
Off Synthroid (Thyroxine; T4; thyroid extract) 4-6 weeks prior to imaging.
OR switch patient to Cytomel (T3) 25 micrograms for 2 weeks, then discontinue 2 weeks prior to test.
Remain off thyroid meds until a determination is made about the need for high-dose I-131 therapy.
2. Start low iodine diet 2-3 weeks prior to test.
3. Have TSH and thyroglobulin levels drawn 3-5 days prior to I-131 dose with results to Nuclear Medicine.

B. Patient On Thyroid medication with PreTreatment with Thyrogen (synthetic TSH)

1. Thyrogen 0.9 mg IM (Buttock) is given at 48 and 24 hours prior to dosing with I-131.
Thyrogen is administered by the referring physician.
2. Patient may remain on thyroid medication
3. Start low iodine diet 2-3 weeks prior to test.
4. Have thyroglobulin level drawn 3-5 days prior to I-131 dose with results to Nuclear Medicine.
TSH level is not required on these patients.

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PROCEDURE:

- A. Follow screening process to determine patient's eligibility for outpatient treatment. (Refer to outpatient screening documents). Patients who are eligible follow outpatient protocol.
- B. Patients who require hospital admission for high-dose ¹³¹I therapy:
Patient is admitted to OHVI 5 into the designated prepared room (see room preparation protocol).

Technologist: Tech Responsibilities

- Prior to administration of I-131 therapy dose:
 - a. Verify dose slip; initial + medical record number
 - b. Identify patient by 2 methods (Name + MR #); initial on "Monitoring and Contamination Survey" form
 - c. Take background survey readings inside and outside patient's room; record readings on "Monitoring and Contamination Survey" form
 - d. Review post-discharge precautions with patient (information sheet on this should be in chart); give to patient to take home with them (generally put with clothing that patient will wear home)


Nuclear Medicine Physician:

1. Prior to administration of the therapy dose, the Nuclear Medicine physician will obtain written informed consent per policy.
2. The Nuclear Medicine physician will instruct the patient concerning radiation safety issues associated with ¹³¹I sodium iodine treatment and re-review the post discharge precautions.
3. After the patient has signed the informed consent, the oral dose in capsule form is given to the patient

Technologist: Tech Responsibilities

1. Immediately after administration of I-131, monitor and record on worksheet the following:
 - a. Patient surface: (place energy-compensated probe of survey meter up to xiphoid area.
 - b. Measure activity approximately 18 inches from patient: ("Bedside" reading on form)
 - c. 1 meter from patient: use meter stick (Place glove on the end of the meter stick and have patient hold meter stick to their sternum)
 - d. 6 feet from patient
 - e. At the entrance to room 5416
 - f. At the nurse's station (this should be background)
 - g. In room 5415: at the bathroom wall nearest 5416 bed location (record 5415 patient's name or MR# on worksheet). Maximum reading should be 2 mR/hr or less.
2. Using the readings obtained in 1b, 1c, and 1d; calculate the maximum nursing time from each of these locations using the following formula:

$$\underline{150 \text{ mR/patient}} = \underline{\hspace{2cm}} \text{ Hours/patient stay}$$

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Dose rate (mR/hr)

Example for 1 meter: $(150 \text{ mR/patient})/50 \text{ mR/hr} = 3 \text{ hours at 1 meter}$

NOTE: If there is reason to believe that the patient will not be discharged in the usual 24 hours, adjust calculation by dividing the 150 mR/patient by the probable number of admitted days then doing the calculation. (Example: Patient to stay 48 hours or approximately 2 days - $(150 \text{ mR/patient})/2 = 75 \text{ mR/patient}$, then use 75 mR/patient divided by dose rate to get hours/patient stay at each distance.

3. Record both the readings and the calculated times on the bright yellow/orange Radiation Warning sheet to be posted on the patient's door.
4. Calculate the Emergency Exposures maximum times for the three categories and write in the appropriate line on the SHMC Radiation Safety Information Sheets. To calculate, divide the allowed/year level by the **maximum surface reading** of the patient (1a). List time units on each line. (Time = Allowable mR/maximum surface reading (mR/hr))
5. Fill in the appropriate values in #6 and #7 on Doctors' Order sheet.
6. Place both the Radiation Safety (Emergency Exposures) sheets and the Doctors Orders signed by NM physician in the physicians' orders section of the patient's chart after attaching patient label to each one.
7. Place the bright yellow/orange Radiation Warning sheet and the Monitoring and Contamination Survey sheet into plastic pocket on the patient's door.
8. Remind patient to wear cotton gloves (if available) when handling non-disposable items, wash hands frequently, males should sit to urinate, flush toilet twice after each use, shower at least once in AM and once in PM, do NOT urinate in shower and rinse shower down after use.
9. Return in approximately 24 – 28 hours post dose to take sternum reading at 1 meter. (see instructions for Patient Monitoring for Release)

C. On day of dosing:


1. Complete data entry in Syntrac
2. Scan dose sheet (both sides) to ImageCast
3. Complete exam and turn into physician for dictation

D. On day of patient discharge/room decontamination

1. Complete Monitoring and Contamination Survey sheet
2. Scan completed survey sheet and Radiation Warning sheet to Document Management in ImageCast
3. File patient chart in appropriate date slot for follow-up imaging

REFERENCES:

Society of Nuclear Medicine (SNM)

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OUTPATIENT:

Hotlab Technologist:

- Call patient; identify yourself and the purpose of your call.
- Verify with patient that they are interested in having therapy as an outpatient.
- If yes, begin outpatient evaluation process.
- Tell patient, "The questions I ask, including those concerning your living arrangements, are to assure that the radiation we give you will not expose others unnecessarily and will comply with state licensing requirements."
- Fill out Patient Information and Calculation for Radiation Exposure Worksheet.
- If the patient **does not** qualify based on the questions, inform the patient that he/she must be admitted for treatment. Review dates and times for the pre-therapy total body and the admission for therapy.
- Document on TB Thyroid and Ablation Checklist (pink sheet) whether eligible or not eligible,
- Return patient chart to the front desk.
- If the patient **does** qualify for outpatient therapy, inform patient that our physician, based on the information from the pre-therapy total body I-131, makes the final decision. Take the chart to NM physician for review and approval.
- Once approved return patient chart to the front desk.

Outpatient Screening worksheet:

Outpatient I-131 Treatment > 30 mCi Screening Worksheet

Patient Name _____
MRN _____
Birth Date _____

Date _____ pt phone _____

Patient's age _____ Sex M F

Is Patient pregnant or breastfeeding Y N N/A

Treatment for: Thyroid Cancer

Patient Living / Occupancy Situation:

Allowable dwellings:

Single family _____ Apartment/townhouse/duplex _____ (bedroom to outer-wall)


Not allowable dwellings:

Group home _____ Assisted Living _____ City of residence _____

Number of bathrooms: _____

Persons (other than patient) residing in dwelling:

Age	Hours/day	Age	Hours/day
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If they will be riding with others in the automobile after treatment, then determine length of time to drive home. If the time is greater than two hours the patient CAN NOT be treated on an outpatient basis and they must be hospitalized.

If the patient is breastfeeding they must stop after being treated.

Check the box next to the statement if patient **can** comply with restriction.

- The patient can attend to their own personal needs and does not require a caregiver?
- The patient can urinate by himself or herself and is not incontinent?
- The patient will have sole use of a bathroom for at least 4 days after treatment?
- The patient will drink a minimum of 64 ounces of fluid for 2 days after treatment?
- The patient is NOT the primary caregiver for children under 10 years of age or they can arrange for alternate care for children during the first 4 days after treatment?
- Will the patient maintain a distance of 6 feet from others for at least 4 days after treatment?
- Will the patient sleep alone in a room for at least 7 nights?
- The patient will NOT travel by airplane or mass transportation for at least 4 days after treatment?
- The patient will NOT travel on prolonged car trips for at least 4 days after treatment?
- The patient will limit visits with friends and family for 4 days after treatment?


If all boxes are checked continue with outpatient screening.

If one or more boxes are unchecked then treatment is to be done as an inpatient

Refer to I-131 Max Radiation Exposure worksheet for calculation (see below)

Calculation of Maximum Radiation Exposure:

- To determine Occupancy Factor (E2): _____
 If all the boxes on the previous page are checked then an Occupancy factor of 0.25 can be used.
 If all the boxes on the previous page are checked and the patient can live alone for at least 2 days then an Occupancy factor of 0.125 may be used.
- To determine Uptake Fraction (F2): _____
 Use the fraction obtained from the calculated uptake on the dose form for the total body scan. If no uptake fraction available use 0.05.
- To determine the effective half-life (T2eff) of the thyroidal component: _____
 Use 7.3 days for thyroid cancer patients and multinodular goiter.
 Use 5.2 days for patients with hyperthyroidism.

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4. The administered dose is to be determined by the Nuclear Medicine Physician: _____ mCi.

Use the I-131 MAX EXPOSURE CALC sheet to calculate dose (mrem) to another individual.

Dose (mrem) = _____ (< 500 mrem)

Form filled out by: _____ Physician Signature _____

Date ablation dose given _____ Time _____

Radioactive trash saved by patient and brought in to be stored at _____ until decay.


(location to be held)

Technologist _____

Comments: _____

Day of Total Body Dosing:

- When possible, have the hot lab tech who called the patient administer the TB dose.
- Re-ask all the questions from the OP worksheet to verify previous answers. Do a visual evaluation of the patient's cooperativeness and ability to follow instructions.
- Give the Radiation Safety Instructions to the patient and allow the patient time to read them. Review these instructions with the patient and stress the importance of compliance. Ask if the patient feels able to follow these restrictions.
- Explain the garbage collection.
- The exact days for the restrictions will be determined on the day of the Total Body scan.
- Dose patient.
- Do patient uptake immediately after dosing. Record counts on Total Body Dose Order Form.
- Remind patient that the NM doctor will make the final determination about OP therapy after the completion of the total body I-131.
- Return patient chart to the front desk.

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Day of Total Body Imaging


1. The technologist does the TB scan including pinhole per protocol.
2. Do 72 hour I-131 uptake 2 meters from probe. Record and calculate uptake.
3. Have patient return to waiting room while calculations are completed.
4. Scan paper work and send images to ImageCast.
5. Have Nuc Med Physician review TB scan and documents. He determines ablation dose and fills out I-131 Therapy Consent Form with dose amount.
6. In the N-drive, Nuclear Medicine folder, in worksheets find I-131 MAX EXPOSURE CALC sheet. Enter in Dose (*determined by NM doctor*), Uptake fraction, and Occupancy factor (*determined from Patient Information and Calculation for Radiation Exposure Worksheet*). Print results, record the mrem onto 2nd page of Exposure Worksheet do not save. If all occupancy factors are met, and maximum exposure is less than 500 mrem the patient can be treated as an OP. If not, the patient must be treated as an IP.
7. If the patient does not qualify to be done as an OP, based on calculations, inform them of the necessary steps per protocol for IP admission.
8. Return paperwork to front desk staff and proceed with inpatient therapy schedule.
9. If treatment can be done as an OP, have authorized user determine dose. If dose cannot be administered same day, send patient home and have them return to Nuclear Medicine at _____ am the following day for dosing. Review NPO instructions and all other restrictions with patient.
10. Return paperwork to front desk. Inform staff that the patient will follow OP protocol. **Front desk staff** will fax signed dose order sheet to pharmacy; cancel room 5416 with nursing station and admitting; schedule patient for an uptake 3 days following treatment if needed.

Day of I-131 Ablation

1. Have Nuclear Med. Physician review paperwork.
2. Hot lab assay I-131 dose. Place in consult room with water.
3. Give patient radioactive labeled trash bag with I-131 and date marked on it. Also give patient a Ziploc bag of gloves. Instruct patient to keep trash to a minimum and to store it in an area of little or no human traffic. The trash must be returned to Nuclear Medicine on the day of the follow-up Uptake OR post-ablation total body imaging.
4. Instruct patient to wash their dishes and linens separately from other family members; flush all toilet paper and tissue down the toilet. Use plastic wrap on items (remote control, phone, etc) that will be used by others after restrictions are lifted. Do not share these items while under the restrictions.
5. Have authorized user review restrictions with patient and get informed consent.
6. Have Nuclear Medicine physician administer I-131 pill.

Day of Follow-up Monitoring


1. Hot lab technologist monitor patient with survey meter at a distance of one meter. Document.
2. Review how treatment went and document any problems.

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3. Give patient new post Ablation restrictions.
4. Collect trash, monitor, label and store.

Reference:
Oregon Administrative Rules

 PeaceHealth Sacred Heart Medical Center Riverbend	Thyroid Ablation Restrictions (>30mCi I-131)
	Nuclear Medicine Phone: 541-222-2710

**FOLLOW THESE RESTRICTIONS IMMEDIATELY AFTER SWALLOWING I-131
PILL ON _____.**

STOP BREAST FEEDING

Permanently discontinue breast-feeding 3 weeks before treatment to limit radiation going to the breasts and to prevent permanent damage to the infant's thyroid gland.

PREVENT PREGNANCY

Do not get pregnant for 6 months

USE GOOD HYGIENE

Some of the radioactivity will be present in your perspiration and also your urine.

Follow the list of instructions for **4 DAYS** to reduce contamination and avoid exposing others.

- Avoid mouth-to-mouth contact
- Do not share items that contact mouth or saliva (e.g. eating utensils, water/pop bottles/cans)
- Use regular utensils and plates (**Do not** use disposable items), wash separately
- Use separate towels and washcloths, wash separately
- Flush used facial tissue in the toilet
- Wash hands frequently, especially after urination
- Use separate bathroom, flush 2-3 times after each use
- Men need to sit down to urinate
- Shower daily

DISTANCE AND TIME

The greater the distance you are from other people (and pets) and the shorter the time spent near other people the less radiation they will receive. Follow these instructions to reduce exposure to others.

<u>Sleep alone in a separate room for</u>	7 days
<u>Avoid close contact with children and pregnant women for</u>	5 days
<u>Limit time spent in public places for</u>	3 days
<u>Limit private travel with others (> 4hrs) for</u>	3 days
<u>Delay return to work if workplace is shared for</u>	3 days
<u>Do not travel by mass transportation or airplane for</u>	3 days
<u>Maintain a minimum of 6 feet distance from others and have few, short (<30 min) visits for</u>	3 days

DRINK FLUIDS

Drink plenty of fluids. Drink at least 64 ounces per day for the first two (2) days. Urinate often to reduce exposure to your bladder.

USE HARD CANDY

Suck on hard, sour candy to reduce the exposure to your salivary glands for two (2) days following treatment.

TRASH

If instructed, you will need to save your trash for four (4) days. Do not place in the public trash disposal system. You will need to bring the trash back to the Nuclear Medicine Department at the time of your follow up scan.

- **Trash you should save:** toothbrush, gloves used during restrictions, sanitary and incontinent pads used during restrictions
- **Do not use** disposable items, including water bottles, utensils, pop cans or paper towels
- Place small food items in a garbage disposal or down the toilet; avoid eating finger foods

Dose Calculation for I-131 Patient Release Hyperthyroidism

Patient Name:

Please input Necessary Data

Administered Dose = mCi

Occupancy Factor, E =
(0.25 or 0.125)

Uptake Fraction, F2 =
(use either .8 or the patient's measured uptake)

Dose to Total Decay =

0.478	rem
478.00	mrem

The patient specific equation below was used to determine the maximum dose to another individual. Occupancy factor used was selected based on the patients ability to comply with the attached patient instruction sheet.

(Regulatory Guide 8.39, equation B-5)

$$\text{Dose(mrem)} = \{ [34.6 * \text{Gamma} * \text{Activity} / 10000] * \{ E1 * T_p * (0.8) (1 - e^{(-0.693(0.33)/T_p)}) + (E2 * T1_{\text{eff}} * F1 * (e^{(-0.693(0.33)/T_p)}) + (E2 * F2 * T2_{\text{eff}} (e^{(-0.693(0.33)/T_p)}) / T_p) \} \}$$

F1 = 0.2
 T1_{eff} = 0.32
 T2_{eff} = 7.3
 Gamma = 2.2
 T_p = 8.04
 E1 = 0.75
 at 1 meter = 10000
 e(.33) = 0.971956693
 1st 8 hrs = 0.135280912
 extra thy = 0.015551307
 intra thy = 1.419056772

I-131 Dose Calculation Maximum Exposure for OP Ablation Post Thyroidectomy

Patient Name _____
 MRN **Please input Necessary Data** _____
 Birth Date _____

Physician signature _____

Administered Dose = _____ mCi (Calculated by Nuclear Medicine Physician)

Occupancy Factor, E2 = _____ (0.25 or 0.125)

If all the boxes on the OP I-131 Treatment >30mCi Screening Worksheet are checked then an Occupancy factor of 0.25 can be used. If all the boxes are check and the patient can live alone for least 2 days then an Occupancy factor of 0.125 may be used.

Uptake Fraction, F2 = _____

Use the fraction obtained from the calculated uptake on the dose form for the total body scan.
 If no uptake fraction is available use 0.05.

Attention!!

Dose to Total Decay =	0.000 rem	Result has to be less than 500 mrem
	0.00 mrem	

Attention: Scan this document into Imagecast with Ablation treatment

The patient specific equation below was used to determine the maximum dose to another individual. Occupancy factor used was selected based on the patients ability to comply with the patient Radiation Safety Instruction sheet.

(Regulatory Guide 8.39, equation B-5)

$$\text{Dose(mrem)} = \{ [34.6 * \text{Gamma} * \text{Activity} / 10000] \} * \{ E1 * T_p * (0.8) (1 - e^{-0.693(0.33)/T_p}) \} + (E2 * T1_{\text{eff}} * F1 * (e^{-0.693(0.33)/T_p})) + (E2 * F2 * T2_{\text{eff}} (e^{-0.693(0.33)/T_p}))$$

- F1 = 1
- T1_{eff} = 0.32
- T2_{eff} = 7.3
- Gamma = 2.2
- T_p = 8.04
- E1 = 0.75
- at 1 meter = 10000
- e(.33) = 0.9719567
- 1st 8 hrs = 0.1352809
- extra thy = 0
- intra thy = 0

Maximum Administered Activity Allowed for the Release of Sodium I-131 Patients (mCi)

Determine the patients Occupancy Factor (from worksheet) and the Uptake Fraction (if possible) to calculate the maximum amount of I-131 that can be administered to the patient. If the patient's uptake is not available use the NRC suggested Uptake Fraction. The table below is based on Regulatory Guide 8.39, Equation B-5 and a maximum dose of 490 mrem to any individual exposed to the patient.

For Hyper Thyroid and Non-Toxic Goiter

Occupancy Factors	NRC Uptake 80%	Measured Uptake Fraction																	
		10%	20%	25%	30%	35%	40%	45%	50%	55%	60%	65%	70%	75%	80%	85%	90%	95%	100%
0.25	55.4	194.1	143.0	126.3	113.2	102.5	93.7	86.2	79.9	74.4	69.6	65.4	61.7	58.4	55.4	52.7	50.3	48.1	46.0
0.125	99.3	275.7	219.9	199.7	182.9	168.7	156.5	146.0	136.8	128.7	121.5	115.0	109.3	104.0	99.3	94.9	91.0	87.3	83.9

For Post Thyroidectomy / Thyroid Cancer

Occupancy Factor	NRC Uptake 5%	Measured Uptake Fraction													
		1%	2%	3%	4%	5%	6%	7%	8%	9%	10%	15%	20%	25%	30%
0.25	216.1	279.9	260.7	243.9	229.2	216.1	204.5	194.0	184.6	176.0	168.2	137.7	116.6	101.0	89.2
0.125	297.2	352.5	336.8	322.5	309.4	297.2	286.0	275.7	266.0	257.0	248.6	213.6	187.3	166.7	150.2

$$\text{Dose(mrem)} = \{ [34.6 * \text{Gamma} * \text{Activity} / 10000] * \{ E1 * T_p * (0.8) (1 - e^{-0.693(0.33)/T_p}) \} + (E2 * T1_{\text{eff}} * F1 * (e^{-0.693(0.33)/T_p})) + (E2 * F2 * T2_{\text{eff}} (e^{-0.693(0.33)/T_p})) \}$$

F1= 20% #REF! 90% #REF! 80% 75% 70% 65% 60% 55% 50% 45% 40% 35% 30% 25% 20% 15% 10%
 T1eff = 0.32 0.32
 T2eff = 5.2 7.3

Gamma = 2.2
 Tp = 8.04
 E1 = 0.75
 at 1 meter = 10000
 e(.33) = 0.9719567
 1st 8 hrs = 0.1352809
 extra thy = #REF!
 intra thy = #REF!

For Hyper Thyroid and Non-Toxic Goiter

	F2	80%	10%	20%	25%	30%	35%	40%	45%	50%	55%	60%	65%	70%	75%	80%	85%	90%	95%	100%	
0.25	33	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720
1st 8 hrs =		0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353
extra thy =		0.0156	0.0700	0.0622	0.0583	0.0544	0.0505	0.0467	0.0428	0.0389	0.0350	0.0311	0.0272	0.0233	0.0194	0.0156	0.0117	0.0078	0.0039	0.0000	0.0000
intra thy =		1.0108	0.1264	0.2527	0.3159	0.3791	0.4422	0.5054	0.5686	0.6318	0.6949	0.7581	0.8213	0.8845	0.9477	1.0108	1.0740	1.1372	1.2004	1.2635	1.2635
0.125	33	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720
1st 8 hrs =		0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353
extra thy =		0.0078	0.0350	0.0311	0.0292	0.0272	0.0253	0.0233	0.0214	0.0194	0.0175	0.0156	0.0136	0.0117	0.0097	0.0078	0.0058	0.0039	0.0019	0.0000	0.0000
intra thy =		0.5054	0.0632	0.1264	0.1579	0.1895	0.2211	0.2527	0.2843	0.3159	0.3475	0.3791	0.4107	0.4422	0.4738	0.5054	0.5370	0.5686	0.6002	0.6318	0.6318

For Post Thyroidectomy / Thyroid Cancer

	F1	95%	99%	98%	97%	96%	95%	94%	93%	92%	91%	90%	85%	80%	75%	70%
	F2	5%	1%	2%	3%	4%	5%	6%	7%	8%	9%	10%	15%	20%	25%	30%
0.25	33	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720
1st 8 hrs =		0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353
extra thy =		0.0739	0.0770	0.0762	0.0754	0.0746	0.0739	0.0731	0.0723	0.0715	0.0708	0.0700	0.0661	0.0622	0.0583	0.0544
intra thy =		0.0887	0.0177	0.0355	0.0532	0.0710	0.0887	0.1064	0.1242	0.1419	0.1596	0.1774	0.2661	0.3548	0.4435	0.5321
0.125	33	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720	0.9720
1st 8 hrs =		0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353	0.1353
extra thy =		0.0369	0.0385	0.0381	0.0377	0.0373	0.0369	0.0365	0.0362	0.0358	0.0354	0.0350	0.0330	0.0311	0.0292	0.0272
intra thy =		0.0443	0.0089	0.0177	0.0266	0.0355	0.0443	0.0532	0.0621	0.0710	0.0798	0.0887	0.1330	0.1774	0.2217	0.2661

I-131 Therapy Consent Form Dose Sheet

Sacred Heart Medical Center Nuclear Medicine
Springfield, OR

Patient Label _____	Verified Name _____ Verified DOB _____	Interpreter Services or Special Accommodations <input type="radio"/> Yes <input type="radio"/> Not needed
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I-131 Therapy:

I-131 Iodine oral capsule _____ mCi @ _____ (Time) on _____ (Date)

Signature _____ (Date) _____ (Last Word #) _____ (Date)
(NM Physician)

RRx _____
 Lot No. _____
 Date _____
 Time _____
 Assay Activity _____
 By _____

Tech _____ LW# _____
 Date _____ Time _____

Notes:

Initials
 _____ I have received a copy of the
 I-131 Thyroid Restrictions.

FEMALES ONLY:
 _____ I am not currently pregnant
 _____ I understand that I must avoid
 pregnancy for 6 months
 _____ I am not currently breastfeeding

Date	Lab Test	Value	Normal Range
	FT4		0.61 - 1.27 ng/dL
	TSH		0.4 - 4.6 uIU/mL
	Thyroglobulin		0 - 55 ng/mL
TSH must be >30 for thyroid cancer therapy unless Thyrogen stimulation done			
	HCG (age 12-50)	Positive Negative Not applicable	

I hereby give Dr. _____ permission to administer a _____ mCi therapeutic dose of I-131 Sodium Iodide to myself for the purpose of treating Thyroid cancer Hyperthyroidism Graves' disease.

Patient (guardian) Signature: _____ Date: _____

Prior to administration of the oral dose of I-131, the procedures regarding avoidance of environmental contamination and exposure of children were discussed. The authorized user's signature documents compliance with pre-administration verification and administration of the above radiopharmaceutical.

Signature _____ Date _____
(NM Physician) (Last Word #)