

Radiopharmaceutical Therapy: Agent/Protocol-Specific Procedure I-131 Sodium Iodide for Hyperthyroidism

Radiopharmaceutical Agent:	I-131 Sodium Iodide I-131 sodium iodide is available as a stabilized aqueous solution or solid capsule form for oral administration. I-131 decays by beta emission (~90% of local irradiation) and associated gamma emission (~10% of local irradiation), with a physical half-life of 8.04 days. Sodium iodide is readily absorbed from the gastrointestinal tract. Following absorption, it is distributed primarily within the extracellular fluid of the body. It is concentrated and organified by the thyroid, and trapped but not organified by the stomach and salivary glands. It is promptly excreted by the kidneys.
Drug Information Source:	FDA approved for hyperthyroidism and carcinoma of the thyroid. For additional information regarding this agent, consult package insert or other standard references
Applicability of Worksheet:	Clinical use of commercial product; standard of care
Target Patient Process:	Patient's with hyperthyroidism including Graves Disease, multiple hyperfunctioning nodules, solitary autonomous nodule, and subclinical hyperthyroidism.
Written Directive and Validation:	Authorized User will determine the appropriateness of the therapy based on the thyroid uptake, perform the necessary calculations, and complete the written directive as instructed on the Radiopharmaceutical Therapy Dose Documentation Form . Section B on the Radiopharmaceutical Therapy Dose Documentation Form "Patient Information/Education Verification" will be completed by the Authorized User prior to forwarding the Radiopharmaceutical Therapy Dose Documentation Form to Nuclear Pharmacy staff for drug procurement/preparation.
Administration/Treatment Schedule:	<p>Patient Prep: A 24 hour uptake is usually scheduled for a diagnostic I-131 sodium iodide dose administration 24 hours prior to therapy. If a thyroid uptake has been done within 3 months, that result may be acceptable if approved by the Authorized User. Both uptake and therapy appointments should be made only for the morning unless otherwise agreed to by the Authorized User. For the therapy, allow 90 minutes, which includes physician consultation. For patients who are suspected of having a solitary toxic thyroid nodule or in whom there is difficulty in clinically deciding between nodular and Graves' disease, a Tc99m-pertechnetate thyroid scan is recommended. See the Department of Radiology Nuclear Medicine Division Thyroid Uptake and Thyroid Scan Protocols for details regarding these procedures.</p> <p>Patients should be off of propylthiouracil (PTU) for between 3-5 days (not less than 3 days or more than 5 days), prior to thyroid uptake and/or therapy.</p> <p>Female Patients (Age 10 to 55 years): Patients must have a pregnant test performed no greater than 24 hours prior to the administration. Patients must not be breast feeding or have ceased breast feeding 3 to 6 months prior to therapy.</p> <p>The uptake and therapy are affected by certain medications, iodine agents (eg. contrast dyes) and foods (eg. seaweed, kelp, sushi, miso soup, carrageen thickeners, and alginate wound care agents). See Radioactive Iodine Uptake Interactions document and Iodine Containing Foods document attached to the</p>

Department of Radiology Nuclear Medicine Division Thyroid Uptake Protocol for detailed lists.

Patients must complete a thyroid questionnaire upon arrival to Nuclear Medicine.

Treatment:

A Nuclear Medicine physician will interpret the thyroid uptake and scan (if performed) and decide whether or not there is sufficient clinical indication for the therapy. If not, the Nuclear Medicine resident or faculty physician of the day will speak with the patient and/or referring physician as needed.

Prior to administration, the Nuclear Medicine physician will obtain written informed consent, and explain the treatment options to the patient. They must determine that the patient understands these options and implications, and advise the patient about the incidence of re-treatment and the incidence of early and late hypothyroidism. The Nuclear Medicine physician will educate the patient regarding radiation safety issues associated with I-131 sodium iodide treatment. The Nuclear Medicine Physician will discuss the planned treatment with the administering clinician.

Administering clinicians must comply with the Department of Radiology Nuclear Medicine Division Personnel Bioassay Thyroid Counts policy.

Procedure:

1. Written directive is completed and dose is prepared and administered as directed on the **Radiopharmaceutical Therapy Dose Documentation Form**.
2. Oral dose is given to patient in either capsule or liquid form. The Nuclear Medicine Faculty must be available when the dose is administered.
3. If a liquid form is given, the administration vessel in the lead pig should be sitting on a solid, sturdy surface for administration. Prior to administration, the Administering Clinician may add enough tap water to increase the volume so the glass tube is approximately half full. Water should be added with care to avoid overfilling. After the patient drinks the dose, water should be added two more times to rinse the vessel and ensure the entire dose was administered. The patient should keep their mouth on the straw, and the straw in the glass tube while the water is added to avoid any dripping of I-131 sodium iodide solution.
4. The following will be surveyed with a GM counter and disposed of appropriately by the Administering Clinician: (includes, but is not limited to) gloves, chucks, paper towels, sterile fields.
5. Dispose of contaminated supplies in a long lived isotope waste container.
6. The administration area and will be surveyed with a GM counter after the patient is discharged from area/department.

Exposure Calculations/Release Criteria: Calculations must be completed as directed on the **Radiopharmaceutical Therapy Dose Documentation Form** in Section E: "I-131 Therapy Calculation & Justification Record for Exposure from the Patient". The Administering Clinician should perform calculations and complete the form where indicated before the patient is released. Final dose calibrator assay should be used for all calculations. Estimated maximum dose to an individual exposed to the patient must not exceed 500 mrem (0.5 rem or 5 mSv).

A. Doses Less Than or Equal to 33 mCi

(Reference: WisReg 1556, Vol 9, Table 22: "WI Chapter 157 – Radiation Protection Regulatory Guide")

Exposure will be less than 500 mrem (5 mSv) with any administered activity less than or equal to 33mCi.

Calculate the estimated exposure based on the following equation extrapolated from Table 22:

$$Exposure (mrem) = 15.15 mrem \times Administered Activity (mCi)$$

B. Patient Specific Dose Calculations for Doses Greater than 33 mCi

(Reference: "NRC Regulatory Guide 8.39 – Release of Patients Administered Radioactive Materials", Equation B-5 – used per State of Wisconsin Regulations HFS 157.62.8)

Doses greater than 33 mCi may be given in some cases. Patient specific exposure calculations must be done by the Authorized User, before the patient is released, using the following equation:

$$\text{Exposure(rem)} = \frac{34.6\Gamma Q_o}{(100\text{cm})^2} \{ E_1 T_p (0.8)(1 - e^{-0.693(0.33)/T_p}) + e^{-0.693(0.33)/T_p} E_2 F_1 T_{1\text{eff}} + e^{-0.693(0.33)/T_p} E_2 F_2 T_{2\text{eff}} \}$$

Patient Specific Characteristics:

F₁ (Extra-thyroid uptake fraction) = measured

F₂ (Thyroid uptake fraction) = measured

Constants:

Conversion Factor = 34.6

Γ (Gamma Ray Constant for I-131) = 2.2

T_p (Physical Half-life for I-131) = 8.04 days

Assumptions:

T_{1eff} (Extra-thyroid effective half-life) = 0.32 days

T_{2eff} (Thyroid effective half-life) = 5.2 days

E₁ (Occupancy factor for first 8 hours) = 0.75

E₂ (Occupancy factor from 8 hours to total decay) = 0.25

A spreadsheet may be used to aid in the calculation of this equation. Available at: J:\Nuclear\Nuclear Pharmacy\NRC & Safety & Dosimetry\I131 Exposure\I-131 Hyperthyroidism Exposure Calculation.xls

Dose Range:

Adult Desired Dose Delivered to Thyroid Gland (μCi/gram):

Graves Disease	80-100 μCi/gram
with multiple hyperfunctioning nodules	150-200 μCi/gram
with nontoxic multinodular goiter	100-200 μCi/gram

Pediatric Desired Dose Delivered to Thyroid Gland (μCi/gram):

150 μCi/gram (Higher dose due to resistance of the thyroid gland to therapy)

The prescribed dose is calculated by multiplying the estimated thyroid mass (estimated by palpation) in grams by the desired dose, divided by the 24-hour uptake x 100%.

$$\text{Prescribed Dose (}\mu\text{Ci)} = \frac{\text{Mass of Gland (g)} \times \text{Desired Dose (}\mu\text{Ci/g)}}{\text{Uptake at 24 hours}} \times 100\%$$

For a toxic hot nodule, provided there is suppression of the rest of the gland, a suggested empiric dose is 15 mCi. Alternatively, one can use the thyroid uptake result and give 10 mCi to the autonomous thyroid tissue. All doses are subject to adjustment based on the prescribing physician's clinical judgment.

Scheduling Procedures:

Referring clinician will enter an order for NM THERAPY RADIOPHARMACEUTICAL ORAL HYPERTHYROID INITIAL OR RETREATMENT via HealthLink for this therapy. The referring clinic schedulers will call Radiology/Nuclear Medicine schedulers to schedule this order. A Nuclear

Medicine or Radiology resident will protocol the order via the HealthLink Protocol Worklist work que and fill out the I-131 Therapy Consults form. The order and I-131 Therapy Consults form are then review with the Nuclear Medicine staff for approval

Drug Procurement/Preparation:

All individuals involved in the preparation or verification of I-131 sodium iodide must comply with the Radiology Department Nuclear Medicine Division Personnel Bioassay Thyroid Counts policy. Order entry and dose preparation will be documented as instructed on the **Radiopharmaceutical Therapy Dose Documentation Form**.

Upon receipt of the written directive, Nuclear Pharmacy staff will determine whether they choose to prepare the dose in house or order a unit dose from a Contracted Nuclear Pharmacy.

For solution doses prepared in house, all manipulations will occur in a fume hood or SmartFill Unit. The appropriate dose will be drawn up from a stock vial of I-131 sodium iodide and placed in to a test tube or equivalent vessel. Any dilution will be done with water step. The vessel containing the dose will be placed in a lead shield for dispensing

For Capsule doses prepared in house, all manipulations of RAM will occur in a fume hood or SmartFill Unit

Compounding I-131 capsules:

Compound I-131 capsule in SmartFill unit, per protocol (see attached)

Unit doses can be ordered via phone and FAX from:

Cardinal Health
153 East Badger Road
Madison, WI 53713
608-270-2670
FAX 608-270-3572

Nuclear Pharmacy staff will place the order via phone. A time estimate for receipt of the dose will be communicated to the Administering Clinician. This should be used with extenuating circumstances as it is more expensive than in-house compounding.

Pharmacy Product Validation:

As instructed on the **Radiopharmaceutical Therapy Dose Documentation Form**. The verification of the product will include placement of the dose into the dose calibrator, and comparison of the assay to the product label generated at the completion of dose assay, as well as the written directive. If a dose was prepared in house, the administering clinician will confirm that the dose was drawn from an I-131 sodium iodide stock vial in the fume hood, the proper isotope is selected on the dose calibrator, and that the displayed dose is within 10% of the prescribed dose. If a unit dose was ordered from Cardinal Health, the verification of the product will also include comparison of the assay to the Contracted Nuclear Pharmacy's radiopharmaceutical label.

Patient Instructions/Education Validation:

I-131 Sodium Iodide Health Facts For You will be reviewed with and given to the patient as instructed on the **Radiopharmaceutical Therapy Dose Documentation Form**; no additional procedures required

Administration Validation:

Only appropriately trained individuals may administer this product. Complete and document administration as instructed on the **Radiopharmaceutical Therapy Dose Documentation Form**. Administering clinicians must comply with the Department of Radiology Nuclear Medicine Division Personnel Bioassay Thyroid Counts policy.

Other information/instructions:

The uptake and therapy are both reported in the physician dictation. In addition, the report should include if the patient should remain on drug therapy (propranolol) or

restart-PTU (usually 3 days later), and when he or she should be seen in clinic or at the patient's own primary or referring physician's office.

If for any reason the patient must be admitted to UW Hospital within 96 hours of treatment, the **Radiopharmaceutical Therapy: Agent/Protocol-Specific Procedure for I-131 Sodium Iodide for Inpatient Use** should be followed.

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Operational Instructions – SmartFill System for compounding I-131

General Notes

- Please refer to the Nuclear Medicine Protocol: Radionuclide Therapy Process and Oversight.
- Always wear gloves when working with or inside the Smart-Fill unit. Assume all contents inside the unit are contaminated.
- Standing order for the bulk I-131 is delivered each Wednesday via Fed-Ex. Standard activity is 250 mCi calibrated for the next Sunday in 0.25 mL. Additional I-131 may be ordered from DraxImage or Cardinal Health Nuclear Pharmacy, as needed.
- When retrieving final capsule from the SmartFill unit, have the “breathing zone” air pump on and the filter by the outside of the left side retrieval door of the SmartFill. RSO reviewing this Jan 2017Rad Safety will replace and count the TEDA cartridge installed by the pump in the interstitial space.
- The magnahellic gauge is set and has a gauge reading of about 0.2. This could go up as the filters become less efficient. It should not go down. The red marker is set over the gauge reading at the time of TEDA cartridge installation to help determine if the air flow is changing. When there is a 20% variance between the actual magnahellic reading and the red marker, change out the TEDA cartridges.
- Remove the TEDA cartridges by reaching through the small side door of the SmartFill unit and unscrewing the filter housing. Place the hot cartridges in a dated plastic bag and store in the decay safe. Replace with new TEDA cartridges screwing the filter housing back onto the exhaust port. Note the direction of airflow to place these cartridges, as noted on the side of the cartridge.

Unit Set up: Done at each installation of new bulk I-131.

- Add the information for the new lot of I-131 to the SmartFill computer.
 - Create a “new lot”
 - Add requested information. NOTE: add the concentration that is listed on the packing list. This is specific to each lot. Even though the lot is “1000 mCi/ml”, the concentration can range from 950 to 1050 mCi/mL. The precision is necessary for accurate dispensing.
- Empty compounding syringe by pressing “Empty Syringe in Stock Vial”.
- Remove old I-131 bulk container and replace original cap. Place in the I-131 fume hood for storage.
- Obtain plastic bag for disposal of contaminated materials
- Holding the bag under the piercing arm, recap and remove the 16 ga needle. Drop directly into the plastic bag.
- Holding the bag under the dispensing arm, recap the 22G spinal needle (3”) and Qosina 0.3 mL needle and drop directly into the plastic bag.
- Install the 22G spinal needle (3”) on the Qosina 0.3 mL syringe.
- Place the syringe in the groove and lock into place by tightening the screw.
- Gently screw the 16G 1.5” needle into the piercing arm.
- Remove needle caps and save caps in back of unit for future use.
- Place the new I-131 bulk container in the unit and replace original lid with the gray pierced lead lid.
- Store the replaced needles in the I-131 fume hood.

Capsule preparation

- Place a size #2 capsule into the bottom half of a size #1 capsule. Set aside the top half of the #1 capsule.
- Obtain a 9 mL Vacuette tube and place in an I-131 dispensing shield.
- Put tube into the designated spot in the SmartFill. Remove cap and attach it to the cap holder.
- On the SmartFill computer screen (dispensing section), enter the activity prescribed and press “calculate volume.”
- Ensuring the spinal needle is inserted into the I-131 bulk vial, pres “draw” button.
- Move dispensing arm over the carousel funnel and lower the arm to the stop. The spinal needle is inside the #2 capsule.
- Dispense the volume into the capsule by pressing “inject.”
- Wait 30 seconds for the phosphate powder to absorb the solution, as indicated by the timer on the computer screen of the SmartFill.
- Using the dispensing arm, return the syringe back to the stock vial.
- Place capsule to be compounded under the staging chute by rotating the carousel to the “Loading/Capping” position.
- Lower the chute over the capsule and insert the half #1 capsule (top) in the chute.
- Push the rod in the chute to snap the cap into place.
- Raise the chute and rotate the carousel counter clockwise 2 steps to the Pick-up position. Using the capsule retrieving arm, remove the capsule from the carousel and place the capsule in the Dose Calibrator to verify the activity.
- Retrieve the capsule from the Dose Calibrator and place the capsule in the Screw/Snap Cap vial. Place the cap on the vial using the capper arm.
- Due to contamination issues on the lead shielding within the SmartFill, transfer the vial with the capsule into a clean shield that can be taken by the technologist. Verify the dose on a calibrated dose calibrator.
- Using NMIS, make capsule to place in inventory, using the inventory used in the SmartFill.
- Enter prescription like usual, and process to create a label.