Radiopharmaceutical Therapy: Agent/Protocol-Specific Procedure

I-131 Sodium Iodide for Thyroid Cancer Therapies

Remnant Ablation and Cancer Metastases

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:	Thyroid carcinoma patients in the initial post-thyroidectomy surgery phase, and post-thyroidectomy thyroid carcinoma patients with metastases (lymph node, pulmonary or skeletal)
Written Directive and Validation:	Authorized User will determine the appropriateness of the therapy, 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:	**Patient Prep:** Remnant Ablation: For patients whose thyroidectomy is suspected to be incomplete, a Tc99m-pertechnetate thyroid scan is recommended. See the Department of Radiology Nuclear Medicine Division Thyroid Scan Protocol for details regarding this procedure. If significant thyroid activity is visualized, then consider reducing the dose to prevent radiation tracheitis and esophagitis. Metastatic survey scans are generally not performed prior to the postoperative ablation therapy (thyroid stunning possible after 6 mCi I-131 scan dose). The original histology/ pathology report must be obtained, together with the surgeon's operative report to assess the risk category (low, moderate, high) of the patient. Cancer Metastases: Uptake in identified regions or lesions should be quantitated via a metastatic survey scan. See the Department of Radiology Nuclear Medicine Division Metastatic Survey Scan Protocol for details regarding this procedure All Patients: Thyroid Stimulating Hormone (TSH) greater than 50 international units is preferred. Patients should be off thyroid hormone for at least 3-4 weeks and liothyronine (Cytomel) 2 weeks prior to therapy to ensure this. Note: Patients on Thyrotropin alpha (Thyrogen) do not need to be off of hormone. 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 feed 3 to 6 months prior to therapy.

The therapy is affected by certain medications, iodine agents (e.g. contrast dyes) and foods (e.g. seaweed, kelp, sushi, miso soup, carrageen thickeners, alginate wound care agents. A low iodine diet 10 to 14 days prior to the therapy is to be followed, and the patient should not have received any iodine contrast within the last 6 weeks. See Health Facts For You Low Iodine Diet for list of restrictions and suggested menus. See Radioactive Iodine Uptake Interactions document and Iodine Containing Foods document attached to the Department of Radiology Nuclear Medicine Division Thyroid Uptake Protocol for detailed lists.

Treatment:
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. 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 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 vessel is approximately half full. Water should be added with care to avoid overfilling. Place water in a disposable cup or a syringe and slowly add to glass tube. 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 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. 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 220 mCi in Post-Thyroidectomy Patients:
(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)
Exposure will be less than 0.5 rem (5 mSv) with any administered activity less than or equal to 220 mCi.

Calculate the estimated exposure based on the following equation simplified from Equation B-5:

$$Exposure\ (rem) = 0.00227 \times Administered\ Activity\ (mCi)$$

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:
F_1 (Extra-thyroid uptake fraction) = 0.95
F_2 (Thyroid uptake fraction) = 0.05
T_{1eff} (Extra-thyroid effective half-life) = 0.32 days
T_{2eff} (Thyroid effective half-life) = 7.3 days
E_1 (Occupancy factor for first 8 hours) = 0.75
E_2 (Occupancy factor from 8 hours to total decay) = 0.25

B. Patient Specific Dose Calculations for Doses Greater than 220 mCi in Post-Thyroidectomy Patients:
(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 220 mCi may be given in some cases. Patient specific exposure calculations may done using the following equation:

$$Exposure(rem) = \frac{34.6\Gamma Q_o}{(100cm)^2}\{E_1T_p(0.8)(1-e^{-0.693(0.33)/T_p}) + e^{-0.693(0.33)/T_p}E_2F_1T_{1eff} + e^{-0.693(0.33)/T_P}E_2F_2T_{2eff}\}$$

Patient Specific Characteristics:
F_1 (Extra-thyroid uptake fraction) = measured
F_2 (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) = 7.3 days
E_1 (Occupancy factor for first 8 hours) = 0.75
E_2 (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\Regulatory Safety & Dosimetry\I131 Exposure\ Thyroid Cancer release calculator2008.xls

Dose Range:

Remnant Ablation: (In the initial post-operative period)

Low Risk Cancers:	30 mCi
Moderate Risk Cancers:	50-80 mCi
High Risk Cancers:	100-175 mCi, if no known distant metastases
	150-220 mCi, if known distant metastases

Cancer Metastases: (For follow-up treatment)

Lymph node metastases:	100-150 mCi
Lung metastases:	150-200 mCi
Bone metastases:	175-220 mCi, with possible higher dose, but requires patient specific release calculations.

Ordering Procedures:

Referring clinician will enter an order for **NM Therapy Ablation Thyroid Cancer or Metastasis** 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 of I-131 sodium iodide must comply with the Radiology Department Nuclear Medicine Division Personnel Bioassay Thyroid Counts policy. Individuals that verify the product do not need a bioassay. 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 an outside vendor.

For solution doses prepared in house, all manipulations will occur in a fume hood or SmartFill. The appropriate dose will be drawn up from a stock vial of I-131 sodium iodide and placed in to a 10 mL glass tube with a rubber stopper. The vessel containing the dose will be placed in a lead shield.
For capsules prepared in house, all manipulations will occur in the SmartFill unit.

If a dose needs to be ordered from a Contracted Nuclear Pharmacy, 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 process should be used only under extenuating circumstances due to the increased expense over 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 verify that the dose is dispensed within 10% of the prescribed dose and that the correct isotope is selected on the dose calibrator. If a unit dose was ordered from Cardinal Health, the verification of the product will also include comparison of the assay to the vendor's product 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:	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.

REVIEWED BY: S Perlman, MD, D Fuerbringer, CMNT, S Knishka, RPh

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SCOTT B. PERLMAN, MD, Chief, Nuc Med Section

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Derek E. Fuerbringer, CNMT, Nuclear Medicine Manager

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Scott Knishka, RPh, BCNP, Nuclear Pharmacist

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