

## **Procedure: I-131 Tx for Hyperthyroidism**

**PURPOSE:** To provide a pathway to successfully and safely deliver a prescribed dose of Iodine - 131 to a patient diagnosed with Hyperthyroidism.

**SCOPE:** The stipulation of this procedure shall apply to all Nuclear Medicine Professional and Technical personnel.

- CONTENTS:**
- A. Responsibility
  - B. Patient Education
  - C. Written Directive - Patient Identification
  - D. Dose Administration
  - E. Out Patient Release
  - F. Bioassay
  - G. Patient Complications

### **PROCEDURE**

#### **A. RESPONSIBILITY**

Medical Responsibility: Nuclear Medicine Physician to Attending Physician

Radiation Safety Responsibility:

Radiation Safety Officer	(Patient Education)
Nuclear Medicine Physician	(Pregnancy Status)
	(Informed Consent)
	(Written Directive)
Nuclear Medicine Technologist	(Dose Administration)
	(Written Directive)

#### **B. PATIENT EDUCATION**

Each patient will be given the "**Informed Consent to Routine Nuclear Medicine Therapeutic Procedure**" for Hyperthyroidism which contains the following warnings, possible side effects, future health risks and other treatments which are available other than Iodine-131 Therapy by the Nuclear Medicine Physician. The Nuclear Medicine Technologist(NMT) will insure that this process is complete **prior** to administering Iodine-131 to the patient.

#### **INFORMED CONSENT CONTENTS**

Warning: Patient must **not** be either pregnant as confirmed by **serum** pregnancy test or breast feeding.

Possible Side Effects: Slight nausea, minor neck swelling and/or sore throat.

Future Health Risks: Hypothyroidism - 50-60% chance within 6 months

Other Treatments: Surgery, Anti-thyroid drugs(PTU).

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**Prior** to administration of radioactive iodine the NMT will be responsible for insuring that compliance for the warning is achieved. The NMT will check that the patient has an understanding of the contents of the consent form and that the Nuclear Medicine Physician has signed the bottom of the consent form that instruction has taken place. Actual signing of the consent form by the patient and witnesses is the responsibility of the NMT. Additionally each out patient must have in their possession and have read and understood to the best of their abilities the instructions noted on "**Radiation Safety Instructions for Iodine-131 Hyperthyroid Patients and Family**" for the dose level administered.

### **C. WRITTEN DIRECTIVE - PATIENT IDENTIFICATION**

Prior to administration of Radioactive Iodine a written directive will be dated and signed by an authorized user. The written directive will at least contain the following information:

- a. Patient Name
- b. Patient Identification Number (If applicable)
- c. Radiopharmaceutical, i.e. Sodium Iodide-131 liquid or capsule
- d. Dosage
- e. Route of administration (Always Oral due to pyrogenicity)
- f. Type of procedure / therapy desired
- g. Authorized User Signature and Date

Prior to administration of Radioactive Iodine, the patient's identity will be verified by the following methods as the individual named in the written directive noted above. The individual that will actually administer the radiopharmaceutical will conduct this verification process.

- a. Patient shall be called by name
- b. Patient shall be asked to spell their name.
- c. Patient shall be asked their date of birth
- d. Patient shall be asked their Social Security Number
- e. Patient shall be asked to produce ID, i.e. driver's license
- f. In-Patient's wrist band shall be checked

If the information obtained from the above noted checks does not correspond to the written directive, the radiopharmaceutical **will not** be administered until conclusive verification can be obtained.

The technologist administering the radiopharmaceutical shall read the written directive completely prior to dose administration and patient identification. If any part of the written directive is unclear the technologist will ask for clarification prior to proceeding. The technologist shall take all reasonable measures (i.e. read the label and note the dose calibrator assay) possible to verify that the radiopharmaceutical delivered is in accordance with the written directive.

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### **D. DOSE ADMINISTRATION**

Administration of Radioactive Iodine in **capsule form** will require special attention to avoid possible contamination. This dose should be administered to the patient in their private room or within a restricted area in Nuclear Medicine (i.e. hot lab).. The employment of tongs and extra cups for dose handling should be used. The patient should be involved as much as possible in the dispensing of capsules. This will have to be evaluated on a case by case basis.

Administration of Radioactive Iodine in **liquid form** must be performed with the utmost caution and care within a restricted area in Nuclear Medicine (i.e. hot lab). The following list of items required and step by step procedure is on the "**Liquid Iodine-131 Administration Procedure - Hyperthyroid Therapy**" sheet.

#### **ITEMS REQUIRED**

- Iodine - 131 dose Assayed to within +/- 10% of script.
- Two (2) 10cc syringes with cold water and labeled (**Liquid Only**)
- Three (3) 23 gauge 1" needles (**Liquid Only**)
- One (1) administration set (Straw and Needle setup) (**Liquid Only**)
- Two (2) cups of water
- Gloves
- Requisition
- Informed Consent - Hyperthyroidism
- Radiation Safety Instructions for Iodine-131 Hyperthyroid Patients and Family

#### **PROCEDURE**

1. Note pregnancy status of patient - consult with Nuc. Med. Physician.
2. Fully explain procedure to patient.
3. Have patient sign consent form.
4. Put on gloves !!
5. Carefully remove lead shield top and place sponge side up

#### **CAPSULE**

6. Have patient swallow cap(s) from medicine cup with water.

#### **LIQUID ONLY**

6. Insert one (1) 23 gauge needle into I-131 vial septum.
7. Insert administration set needle into vial septum.
8. **SLOWLY** inject 7 - 10 cc of water at full arms length into the vial.
9. Have patient lean over vial and drink Iodine - 131 through the straw of admin. set.
10. Repeat steps 8 & 9, prevent droplet movement within the straw.
11. Have patient swish and swallow 2 cups of water.
12. Put vial assembly into glove & assay residual activity. (<200 $\mu$ Ci - OK)
13. Compute net administered activity and note on dose slip.
14. Dispose of all materials check Pb container and top for contamination.
15. Record administered dose

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### **E. OUT PATIENT RELEASE**

The Nuclear Regulatory Commission allows the release of patients treated for Hyperthyroidism with Iodine-131 to be immediately released as out patients.

At the discretion of the NM Physician the patient may be treated as an **out patient** if patient conforms to **ALL** of the following:

- a. Patient can maintain prudent distance from others for at least two(2) days
- b. Patient can sleep alone in a room for at least first night
- c. Patient will not travel by mass transit or airplane for first day
- d. Patient will not travel with others for a prolonged car trip for two(2) days
- e. Patient will have sole use of bathroom for two(2) days
- f. Patient will drink plenty of fluids for two(2) days

Patients may be released if:

- a) The measured dose rate at 1 meter is at or below 7 mR/hr.
- b) The residual activity in the patient is less than 33 mCi.
- c) Administered activity less than 33 mCi
- d) Calculated dose to others less than 500 mrem

If the administered activity is greater than 7 mCi each patient must receive a copy of “**Radiation Safety Instructions for Iodine-131 Hyperthyroid Patients and Family**” for the dose level administered. The method of release and patient instruction must be documented on the “**<sup>131</sup>Iodine – Record of Patient Release**” form.

### **F. BIOASSAY (INPATIENTS ONLY)**

Due to volatility, whenever radioactive Iodine-131 either capsule or liquid is administered to inpatients, it is required that each individual involved in the actual administration process perform a Bioassay on themselves. In order to access the amount of radioactive Iodine-131 that has been taken up by their thyroid gland the following should be performed.

**APPLICABLE TIME FRAME:** Between 24 and 72 hours post administration

**ACTION LIMITS:** **>1  $\mu$ Ci (0.02)(ALI) - Report to RSO or designate**

- a. Investigate cause & potential for new exposures
- b. If potential exists, restrict your activities until cause is corrected.
- c. Implement corrective action.
- d. Repeat Bioassay in 2 weeks

**>5 mCi (0.1)(ALI) - Report to RSO or designate**

- a. Repeat a - d above.
- b. Medical referral within 2-3 hours of exposure if possible.
- c. Repeat Bioassay every week until <120 nCi.

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### **G. PATIENT COMPLICATIONS**

#### **EARLY COMPLICATIONS**

**THYROID STORM** - A rare complication of Iodine-131 therapy (Incidence 0.34%) due to the rapid outpouring of thyroid hormone due to radiation destruction of the follicles or radiation thyroiditis. This complication generally occurs six(6) days post administration of Iodine - 131 in older patients (>50 yo), with large and nodular glands, but with no specific relationship to the amount of Iodine-131 given. Clinically this complication presents as a fever and tachycardia. Uncontrolled, the fever may be lethal 48 hours after onset, mortality incidence is 25%. It is the responsibility of the physicians to prevent this complication by:

- a. Treat underlying illness prior to Iodine-131 therapy
- b. Bed rest to reduce circulating hormone
- c. Hospitalization of high-risk patients
- d. Possible multiple small doses of I-131 to avoid acute release of thyroid hormone.
- e. Administration of anti-thyroid drugs 2-8 weeks prior to Iodine-131 administration, discontinued 2-4 days prior to dosing.

**RADIATION THYROIDITIS** - Usually manifested as a minor sore throat with in 1-3 days post administration of Iodine -131. Due to the edema formation around the laryngeal nerve partial vocal cord paralysis is a very rare occurrence.

#### **LATE COMPLICATIONS**

**HYPOTHYROIDISM** - Within 14-24 days post dosing thyroid follicles become necrotic, such that within 40 days follicular size and replacement with connective tissue is observed. Post radiation fibrosis in the thyroid progresses over several years. This combined with regeneration of thyroid parenchyma will determine the onset of hypothyroidism. Development of hypothyroidism within the first year post dosing is increasing, such that patients may expect onset probability of 50-60% within the first six(6) months.

**HYPOPARATHYROIDISM** - This is a rare reportable event and autopsy has revealed no morphologic changes observed in the parathyroid glands of the few patients examined. It is anticipated that parathyroid reserve or capacity to recover may be reduced, rather than total and/or continued dysfunction.

**HYPERPARATHYROIDISM** - Spotty reports of this occurrence have been made in the literature but without sound clinical correlation.

**LEUKEMIA, CARCINOGENESIS** - Several studies from U of Mich. and USPHS have concluded that Iodine-131 imposes no risk of development of leukemia or thyroid carcinoma. This is thought to be due to follicle cell destruction that reduces or eliminates the response of cells to TSH. These results stem from the follow-up of over 18,000 patients within the US.

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GENETIC DAMAGE - There has been no evidence of an increase of congenital abnormalities, prematurely, birth mishaps, and demonstration of genetic damage or abnormalities of fertility as a result of Iodine - 131 therapy for either hyperthyroidism or carcinoma. We can via statistics calculate a risk of genetic abnormalities to be 4.004% rather than 4.0%, which is the normal rate of birth defects in the general population. In other words an increase of 4/1000ths of a percent. Although calculable this has not been demonstrated. In keeping with ALARA philosophy however it is advised that conception be delayed for 6 months to one(1) year post therapy in case retreatment is required.