DMC
HEALTH CARE CENTERS
WOODLAND

QUALITY MANAGEMENT PROGRAM

WOODLAND HEALTH CARE CENTER

January 2, 1992

1. Objective

". . . to provide high confidence that by product material will be administered as directed by the authorized user."

2. Responsibility, Authority, and Audit

The responsibility and authority to establish and implement the Quality Management (QM) Program shall be given to Harold J. Daitch, M.D.

3. Elements for Medical Use-
Radiopharmaceutical Therapies and Nal 1-125 or 1-131 >30 uCi

A. Prior to administration, a written directive will be prepared for:

i. any therapeutic administration of a radiopharmaceutical and
ii. any administration of Nal 1-125 or I-131 greater than 30 uCi.

With regard to diagnostic and therapeutic radiopharmaceuticals "A written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, containing the following information.

patient name
patient identification number, if available
radiopharmaceutical
dosage
route of administration
the type of procedure desired

B. Prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive by the person administering the radiopharmaceutical.

1. The patient shall be called by name.
2. The patient shall be asked to spell their name.
3. The patient shall be asked to state their birth date.
4. The patient shall be asked to state their Social Security Number.

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5. The patient shall be asked for some identification such as driver's license.
6. The in-patient's wrist band shall be checked.

If the information obtained from both of any two of these methods do not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive verification that this procedure is intended for this patient is obtained.

C. Each administration is in accordance with the written directive.

The technologist shall read the written directive before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear to the technologist, they shall contact an authorized user for clarification. The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the technologist. If the technologist preparing the dose is different from the technologist administering the dose, both technologists shall read and understand the written directive.

The technologist shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration) are in accordance with the written directive. The actual dose calibrator assay shall be verified with the dosage listed on the written directive.

A procedure manual shall be available and shall contain protocols for all radiopharmaceutical procedures performed which require written directives. A procedure which requires a written directive shall not be initiated until a written protocol approved by an authorized user is available.

The technologists shall be familiar with the contents of the manual. They shall be instructed to refer to the manual before proceeding with non-routine procedures or in any case where the protocol is not completely familiar to them.

The protocols shall contain the following elements:
--pharmaceutical
--radionuclide
--routine dosage
--route of administration
--indications
--contraindications

Each change in protocol shall be approved by an authorized user before the change is implemented and before the change is incorporated into the procedure manual. Each technologist shall be instructed in the change before it is inplemented or incorporated into the procedure manual.

D. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

Upon identification of an unintended deviation, an investigation of the incident shall be made. The cause of the incident shall be determined and, if appropriate, corrective procedures will be implemented. Documenting and reporting of the unintended deviation shall be in accordance with the reporting rules of Part 35.

lw:106.3

INFORMED CONSENT TO ROUTINE NUCLEAR MEDICINE THERAPEUTIC PROCEDURE

WARNING: PATIENT MUST NOT BE EITHER PREGNANT OR BREAST FEEDING.

OTHER TREATMENTS

1. **SURGERY.**
2. **ANTITHYROID DRUGS.**

POSSIBLE SIDE-EFFECTS

1. **SLIGHT NAUSEA.**
2. **MINOR NECK SWELLING AND/OR SORE THROAT.**

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 percent. It is the responsibility of the physicians to prevent this complication by:

a. Treat underlying illness prior to Iodine-131 therapy.
b. Bedrest 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 antithyroid 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 within 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. Postradiation 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 the onset probability of 50-60 percent within the first six (6) years.

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 to cells to TSH. These results stem from the follow-up of over 18,000 patients within the US.

GENETIC DAMAGE - There has been no evidence of an increase of congenital abnormalities, prematurity, birth mishaps, 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 percent rather than 4.0 percent, 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 six (6) months to one (1) year post therapy in case retreatment is required.

TITLE: **PROCEDURE: IODINE - 131 THERAPY 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. Patient Complications

PROCEDURE:

A. RESPONSIBILITY

Medical Responsibility: Nuclear Medicine Physician to Attending Physician

Radiation Safety Responsibility:

Radiation Safety Committee

Radiation Safety Officer

Nuclear Medicine Physician (Pregnancy Status) (Informed Consent)

Nuclear Medicine Supervisor (Dose Administration)

Nuclear Medicine Technologist (NMT)

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

Other Treatments: Surgery, Antithyroid drugs (PTU)

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 **"Radioactive Iodine-131 Patient Instructions"** for the dose level administered either > or < 12 mCi.

B. WRITTEN DIRECTIVE - PATIENT IDENTIFICATION

Prior to administration of Radioactive Iodine, a written directive or an order in writing will be prepared, 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

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

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 identification, i.e. drivers license

If the information obtained from the above noted checks do 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.

D. DOSE ADMINISTRATION

Administration of Radioactive Iodine in capsule form will require special attention to avoid possible contamination or spillage. This dose should be administered to the patient in their private room. 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 as possible. 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 the injection room in Nuclear Medicine. 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 1 10 percent of script.
Two (2) 10 cc syringes with COLD "Sterile Water for Irrigation" and labeled.
Three (3) 23 gauge 1" needles
One (1) administration set (Straw and Needle setup).
Two (2) cups of "Sterile Water for Irrigation".
Gloves.
Requisition.
Informed Consent - Hyperthyroidism.
"Radioactive Iodine - 131 Patient Instructions - For < 12 mCi - Nuclear Pharmacy Rack.

PROCEDURE

1. Note pregnancy status of patient-consult with Nuc. Med. Physician.
2. Fully explain procedure to patient.
3. Have patient read instruction sheet and sign consent form.
4. Put on gloves!!
5. Carefully remove lead shield top and place sponge side up.
6. Insert one (1) 23 gauge needle into I-131 vial septum.
7. Insert administration set needle into vial septum.
8. **SLOWLY** injec 7-10 cc of **COLD** Sterile Water at full arms length into the vial.
9. Have patient lean over vial and drink Iodine - 131 through the straw of administration set.
10. Repeat steps 8 & 9, prevent droplet movement within the straw.
11. Have patient swish and drink 2 cups of cold Sterile Water.
12. Place vial assembly into glove and assay for residual activity. (< 2005 Ci-OK)
13. Compute net administered activity and note of Nuc. Pharmacy slip.
14. Properly dispose of all materials; check lead container and top for contamination.
15. Inform Nuc. Med. Physician of net admin. dose - take all paperwork to file room.

F. PATIENT COMPLICATIONS

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RADIOACTIVE IODINE-131 PATIENT INSTRUCTIONS
FOR LESS THAN 12 mCi

You have been referred to the Division of Nuclear Medicine for the following:

_____ Therapeutic Treatment of Hyperthyroidism

_____ Diagnostic Scan for Residual Thyroid Tissue

Radioactive Iodine-131 has been used for each of the above indications since the early 1940s. Once you have swallowed the Radioactive Iodine-131 liquid or capsule, it will accumulate in thyroid tissue in your body. Radioactive Iodine-131 will be leaving your body in large amounts during the next two (2) days primarily in your urine (additional amounts leave through sweat and saliva). The radiation given off by the Radioactive Iodine-131 will be exiting your body at all points without you knowing it. Due to these facts, we would suggest that you follow the instructions noted below because you need the radiation exposure, others don't!!

To reduce radiation exposure to others, there are three (3) basic principles to remember:

1. **DISTANCE** - the greater the distance you are from others, the less radiation they will receive.
2. **TIME** - the less time you spend around others, the less radiation exposure they will receive.
3. **HYGIENE** - good personal hygiene habits are essential to lessen the possibility of unknowingly transferring Radioactive Iodine-131 to others.

SUGGESTED GUIDELINES	**HOW LONG?**
Wait before having a big meal after swallowing Iodine-131	1 hour
Drink plenty of liquids (any liquid) to hasten urinary clearance	2 days
Wash your hands carefully after urination and flush toilet 2-3 times	2 days
Wash eating utensils, bed linens, and underclothing separately	3 days
Absolutely No breast feeding of infants	3 months
Female patients should not have unprotected intercourse	6 months
Avoid contact with others, especially those that are less than 18 years old and those that are pregnant as follows:	
NO CONTACT LESS THAN ONE (1) FOOT	5-7 days
NO CONTACT LESS THAN TWO (2) FEET	2-4 days
NO CONTACT LESS THAN THREE (3) FEET	no restrictions

Other: _____

Radiation Safety Officer
Harold J. Daitch, M.D.

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HYPERTHYROID TREATMENT PROCEDURE

ORAL CAPSULE ADMINISTRATION

1. Note pregnancy status of patient -- consult with Nuclear Medicine Physician.
2. Fully explain procedure to patient.
3. Have patient read instruction sheet and sign consent form.
4. Put on gloves!!
5. Carefully remove lead shield top and remove capsule vial and read dose in dose calibrator (Actual dose shall be rectified with the dosage listed on the written directive.)
6. Patient swallows capsule, is told to go home and follow guideline instructions, and to call department if any further questions arise.

ORAL LIQUID ADMINISTRATION

1. Carefully remove lead shield top and place sponge side up.
2. Insert one (1) 23 gauge needle into I-131 vial septum.
3. Insert administration set needle into vial septum.
4. SLOWLY inject 7-10 cc of COLD Sterile Water at full arms length into the vial.
5. Have patient lean over vial and drink Iodine-131 through the straw of administration set.
6. Repeat steps 8 & 9; prevent droplet movement within the straw.
7. Have patient swish and drink 2 cups of cold Sterile Water.
8. Place vial assembly into glove and assay for residual activity. (<2005 Ci-OK)
9. Compute net administered activity and note of Nuclear Pharmacy slip.
10. Properly dispose of all materials; check lead container and top for contamination.
11. Inform Nuclear Medicine Physician of net administrative dose--take all paperwork to file room.

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THERAPEUTIC AUTHORIZATION

PATIENT NAME _____

FAMILY NO _____

RADIOPHARMACEUTICAL DOSAGE _____ **I-131**

ROUTE OF ADMINISTRATION FOR HYPERTHYROIDISM:

_____ **ORAL CAPSULE**

_____ **ORAL LIQUID**

PHYSICIAN _____

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