GREENWICH HOSPITAL
YALE NEW HAVEN HEALTH

July 1, 2010

United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

RE: License No. 06-09522-01

Dear Ms. Nguyen:

I have enclosed the revised "Policy and Procedures for Out Patient Treatment with I-131.

If you have any additional questions regarding this correspondence, please contact me at 203-863-3036 or ralph.scambato@greenhospital.org.

Sincerely:

Ralph Scambato
Program Director Radiology

Enclosure (1)

5 Perryridge Road
Greenwich, CT 06830-4697
(203) 863-3000

Greenwich Hospital Greenwich, Connecticut 06830	DEPARTMENT OF RADIOLOGY POLICY & PROCEDURES		
Title: **OUT PATIENT TREATMENT WITH I-131**			Policy #: **RS - 35**
Date Issued: July, 2010	Date Reviewed/Revised:	Approved By: Radiology Program Director	Page 1 of 2
Contact: **Radiation Safety Officer**			

PURPOSE: To determine the eligibility of outpatient I-131 Therapy with a dose of over 32 mCi.

POLICY: To document that the Total Effective Dose Equivalent to members of the general public will be below 500 mrem.

PROCEDURE:

1. Prior to scheduling an I-131 treatment a nuclear medicine technologist shall conduct an interview with the patient. The technologist will ask the patient the questions contained in "Radiation Safety Checklist for outpatient consideration for Iodine-131 Radiopharmaceutical Therapy", and answer any questions regarding the written patient instructions.

2. The technologist shall determine if the patient is an isolated (occupancy = 0.125), typical (occupancy =0.25) or extensive care (occupancy = 0.5) patient. The technologist shall contact the medical physicist for prescribed doses above 33 mCi for hyperthyroid therapy and for dosages above 175 mCi for thyroid cancer therapy. The medical physicist may conduct a second interview to determine if the patient qualifies as an isolated patient.

Expected dosages are as follows:

Clinical Indication	Isolated	Typical	Extended Care
Hyperthyroidism	65 mCi	32 mCi	16 mCi
Thyroid Cancer	200 mCi	100 mCi	50 mCi

3. Prior to releasing the patient the technologist or medical physicist shall complete the "Release of Patient Administered I-131" to document that the Total Effective Dose Equivalent to members of the general public will be below 500 mrem. If the calculated public dose exceeds the limit DO NOT PROCEED.

4. The patient shall be provided a copy of the written "Patient Instructions".

RESPONSIBILITY: The Nuclear Medicine technologist will assume responsibility of carrying out these responsibilities.

REFERENCES: NRC Regulation 10 CFR 35.75. The method of calculation was adopted from NUREG 1556 vol. 9 Rev 2.

Greenwich Hospital Greenwich, Connecticut 06830	**DEPARTMENT OF RADIOLOGY POLICY & PROCEDURES**		
Title: **OUT PATIENT TREATMENT WITH I-131**			Policy #: **RS - 35**
Date Issued: July, 2010	Date Reviewed/Revised:	Approved By: Radiology Program Director	Page 2 of 2
Contact: **Radiation Safety Officer**			

RELATED POLICIES:

RS-28 Review Package for Group 1V and V Therapy Procedure

RS-12 instructions to OutPatients During Therapy Treatment with Iodine 131

Greenwich Hospital

RELEASE OF PATIENTS ADMINISTERED I-131 FOR THYROID CANCER

The following information is intended to provide verification of dose limits from patients administered radioactive materials in accordance with 10 CFR 35.75. The method of calculation was adopted from NUREG 1556 vol. 9 Rev. 2.

For Thyroid Cancer patients receiving greater than 33 mCi, a calculation of the effective dose to any other individual is required. The exposure to any other individual shall not exceed 5 millisieverts (0.5 rem).

Patient Name _____

Does the patient meet the criteria of a TYPICAL patient as determined by the Radiation Safety Checklist for Outpatient I131 Therapy? **YES** **NO**

If **NO**, contact the medical physicist.

Was the patient treated in the 12 months? **YES** **NO**

If **YES**, contact the medical physicist, and what was the previous I-131 D_t _____ or dosage _____ mCi

Does the patient have an uptake greater than 10%? **YES** **NO**

If **YES**, contact the medical physicist.

External Dose for occupancy factor of 0.25

$$D(\infty) = 34.6(2.2)(Q_0)/(100cm)^2 [(0.75)(8.04)(0.8)(1-e^{-0.693(0.33)/(8.04)}) + (0.25)(0.95)(0.32)\, e^{-0.693(0.33)/(8.04)} + (0.25)(0.05)(7.3)\, e^{-0.693(0.33)/(8.04))}]$$

$D(\infty)=$ $0.002267(Q_0)$

$D(\infty)=$ $0.002267($ _____ mCi)

$D(\infty)=$ _____ REM

Internal Dose

$D_i =$ $Q(10\text{-}5)\,(DCF)$

$D_i =$ $0.00053($ _____ mCi)

$D_i =$ _____ REM

Total Dose

$D_t =$ $D(\infty) + D_i$

$D_t =$ _____ REM ******Dose must be less than 0.5 REM******

Is the dose less than 0.5 REM? **YES** **NO**

If **NO**, contact the medical physicist

_____ _____

Name Date

Greenwich Hospital

RELEASE OF PATIENTS ADMINISTERED I-131 FOR HYPERTHYROID CASES

The following information is intended to provide verification of dose limits from patients administered radioactive materials in accordance with 10 CFR 35.75. The method of calculation was adopted from NUREG 1556 vol. 9 Rev. 2.

For Hyperthyroid patients receiving greater than 33 mCi, a calculation of the effective dose to any other individual is required. The exposure to any other individual shall not exceed 5 millisieverts (0.5 rem).

Patient Name _____

Does the patient meet the criteria of a TYPICAL patient as determined by the Radiation Safety Checklist for Outpatient I131 Therapy? **YES** **NO**

If **NO**, contact the medical physicist.

Was the patient treated in the last 12 months? **YES** **NO**

If **YES**, contact the medical physicist, and what was the previous I-131 D_t _____ or dosage _____ mCi

Does the patient have an uptake greater than 10%? **YES** **NO**

If **YES**, contact the medical physicist.

External Dose for occupancy factor of 0.25

$$D(\infty) = 34.6(2.2)(Q_0)/(100cm)^2\ [(0.75)(8.04)(0.8)(1-e^{-0.693(0.33)/(8.04)}) + (0.25)(0.20)(0.32)\ e^{-0.693(0.33)/(8.04)} + (0.25)(0.8)(5.2)\ e^{-0.693(0.33)/(8.04)}]$$

$D(\infty)=$ $0.008837(Q_0)$

$D(\infty)=$ $0.008837($ _____ mCi)

$D(\infty)=$ _____ REM ***Dose must be less than 0.5 REM***

Internal Dose

$D_i =$ $Q(10\text{-}5)\ (DCF)$

$D_i =$ $0.00053($ _____ mCi)

$D_i =$ _____ REM

Total Dose

$D_t =$ $D(\infty) + D_i$

$D_t =$ _____ REM ***Dose must be less than 0.5 REM***

Is the dose less than 0.5 REM? **YES** **NO**

If **NO**, contact the medical physicist

_____ _____

Name Date

GREENWICH HOSPITAL

RADIATION SAFETY CHECKLIST FOR OUTPATIENT CONSIDERATION FOR Iodine-131 RADIOPHARMACEUTICAL THERAPY

Patient Name:_____
I-131 Prescribed Dosage:_____

Record Yes/No responses and comments for the following questions:

1. Does the patient live alone? _____Yes _____No

Notes/comments:_____

_____

2. Can the patient drive themselves home ? _____Yes _____No

Notes/comments:_____

_____

3. Is the patient self-sufficient - can he/she care for themselves without assistance from another individual? _____Yes _____No

Notes/comments:_____

_____

4. Can the patient isolate themselves in their own bedroom (sleep alone) ?

_____Yes _____No

Notes/comments:_____

_____

5. Can the patient use a separate bathroom from other family members?

_____Yes _____No

Notes/comments:_____

_____

6. Are there any minors living at home (less than 18 years old) ?

_____Yes _____No

Notes/comments:_____

_____

RADIATION SAFETY CHECKLIST FOR OUTPATIENT CONSIDERATION FOR Iodine-131 RADIOPHARMACEUTICAL THERAPY

7. If yes to question 6, can arrangements be made such that the children will spend a limited amount of time with the patient? _____Yes _____No _____N/A

Notes/comments:_____

_____

8. Can young children (less than 13) be relocated with a family freind or relative during the treatment? _____Yes _____No _____N/A

Notes/comments:_____

_____

Based upon the above responses, classify the patient accordingly:

_____***Isolated Patient:*** Patient lives alone and can take care of themselves.
Yes answer to questions 1 to 5, No to question 6, and N/A to questions 7 & 8.

_____***Typical Patient:*** Patient lives at home with other family members, but can care for themselves, and can minimize their time with other family members.
No answer to question 1, Yes answer to all other questions;

_____***Extensive Care Patient:*** Patient is unable to care for themselves. They require assistance from family members and/or visiting nurse.
No answer to question 3 regardless of all other responses.

Below are the maximum I-131 dosage that can be administered to an outpatient:

Clinical Indication	Isolated Patient	Typical Patient	Extensive Care Pt.
Hyperthyroidism	65 mCi	32 mCi	16 mCi
Thyroid Cancer	200 mCi	100 mCi	50 mCi

GREENWICH HOSPITAL
NUCLEAR MEDICINE

I-131 NAI THERAPY
DOSE GREATER THAN 32 mCi

PATIENT INSTRUCTIONS – REDUCING EXTERNAL EXPOSURE

Dear Patient

The main source of radiation exposure to other individuals from the radioactive medicine remaining in your body is from radiation given off as the medicine changes to a non-radioactive form. The radiation is similar to an x-ray. The number of "x-rays" emitted will decrease with time and eventually will be gone. You can reduce the exposure to other individuals by increasing your distance from them and decreasing the time spent close to them.

Observing the following precautions for the days listed will help reduce the exposure to others.

INSTRUCTIONS	DURATION (DAYS)
To reduce the external exposure of others, you shall:	
• Sleep in a separate room (7 foot separation)	5
• Refrain from sexual activity	5
• Avoid prolonged close contact with children and Pregnant women	5
• Maintain a prudent distance from others (3 feet)	3
• Drink plenty of liquids (e.g., water and juices)	3
• Delay return to work	3
• Stay at home	3
• Do not travel by airplane or mass transportation	3
• Do not travel on a prolonged automobile trip with others	3

Revised 02/11/2009