University Health Network

Outpatient Iodine-131 Therapy using Greater than 1100 MBq (30mCi)

Policy

Under the Canadian Nuclear Safety Commission (CNSC) Radiation Protection Regulations Section 2.(2)(b), dose limitation **for adult family or friend caregivers** knowingly and willingly exposed to radiation while attending to a therapy patient are not subject to the 1mSv annual dose limit to members of the public.

In accordance with CNSC Licence #12939-2, therapeutic Iodine-131 (I-131) dose administration greater than 1100MBq (30mCi) but less than 7500 MBq (200 mCi) will be performed on an outpatient basis in situations where:

a. a patient has been screened by an authorized physician,
b. patients have been informed of the radiation safety considerations,
c. the patient consents to the treatment mode and,
d. where it is agreed by the Radiation Safety Officer (RSO) and the Nuclear Medicine Physician that radiation exposure to caregivers will not likely exceed 5 mSv and to all other family members and members of the public will not exceed 1 mSv.

Procedure

Limits and Conditions

In addition to the dose limits defined above, outpatient treatment must meet all the following limits and conditions:

a. This policy and procedure is limited to the treatment of Postthyroidectomy for Thyroid cancer. The procedures for all other outpatient uses of Iodine in excess of 1100 MBq (30 mCi) shall be developed and implemented on a case-by-case basis.

b. The patient lives less than 1 hour from Toronto General Hospital.

c. The patient lives with children under the age of 12 who are able to stay away from the home for up to the first 5 days following the administration of the Iodine-131 therapy.

d. The patient does not live with a pregnant or possibly pregnant woman.

e. The patient has a private room for sleeping.

f. The patient has a private bathroom that can be designated exclusively to his/her use.

g. The patient has a private transportation option.

h. The patient understands the potential radiation risks to others.

Patient Screening

The decision on the suitability for treatment shall be assessed on a case-by-case basis. The screening process shall involve:

- Assessment and documentation that the patient's suitability for this treatment mode by estimating the likely exposure and comparing to the above criteria and
- Determining if the patient comprehends the radiation safety considerations and will likely be compliant with instructions such that doses to family and non-occupational home caregivers are as low as reasonably achievable (ALARA).

There must be a reasonable probability that no person will receive an annual effective radiation dose exceeding the regulatory limit of 1mSv. In cases where a family member or a non-occupational friend caregiver is required to provide necessary care of the patient, a target dose constraint of up to 5mSv may be used. The therapy is permitted to proceed only when doses to members of the public (friends, co-workers and children, etc who are not caregivers) are less than 1 mSv.

Only physicians who are authorized by a nuclear medicine physician may only request therapeutic doses of I-131. The requesting physicians are required to have previous training and experience in the administration of therapeutic I-131 and in long-term patient follow-up post therapy.

The screening physician shall use the patient-screening questionnaire attached as Appendix A to document the initial interview. If the patient answers' indicate possible acceptance, then the screening Radiation Safety Officer/Manager will calculate the likely dose to the most exposed caregiver.

Information regarding the length of time and distance the patient will be near this individual for the first three days following the therapy will be used to calculate a maximum expected radiation dose to this individual as described in Appendix B. The calculations can be done by hand, spreadsheet or software provided it indicates all the parameters and assumptions used for the calculation.

Patient Education and Consent

The screening physician shall provide the patient with the treatment mode information both verbally and in written form. Information as per Appendix C will be provided. This includes both general treatment mode information as well as instructions that the patient will be expected to follow. The patient instructions can be modified to suit the quantity of activity being administered.

If the patient is comfortable with the treatment mode and expectations, the screening physician shall obtain written consent as shown in Appendix C.

Copies of the screening questionnaire, calculations, and consent can be emailed or faxed to the Radiation Safety Office for pre-approval, however originals must be signed by the Radiation Safety Officer. If approved by the Radiation Safety Officer and Nuclear Medicine physician signed copies shall be included in the patient's file.

Administration of Treatment

The RSO will review and approve the information that was submitted. The RSO shall screen and provide both verbally and in written form the patient treatment instructions to all patients who have children < 12 years of age residing with them. The Radiation Safety Officer will inform the nuclear medicine physician and the screening physician that the patient is suitable for outpatient therapy. A photocopy of the signed forms will be forwarded to the Nuclear Medicine physician.

The requesting physician must contact the nuclear medicine department to request treatment for a patient who is a candidate for outpatient therapy. The maximum outpatient dose of I-131 authorized under this procedure is 7500 MBq (200 mCi).

Upon final approval by the Nuclear Medicine physician, the patient will be booked for the administration of the therapy in the nuclear medicine department.

When the patient arrives, the Nuclear Medicine physician or Charge Technologist will review radiation precautions to be followed with the patient and verify that there have been no significant changes in living arrangements and mode of transport which might lead to a higher than expected radiation exposure to any individual. In particular, the outpatient instructions in Appendix C, and other information brochures will be given to the patient and family explaining precautions to be taken at home.

Patient treatment instructions have been calculated based on the patient I-131 therapy dose administered. Calculations were performed using spreadsheet on patient releasability from medical confinement NCRP No. 155 – Management of Radionuclide Patients and the uptake fractions and effective half lives for the extrathyroidal and thyroidal component for I-131 treatments as described in this procedure.

If there are significant variations, the dose is not to be administered unless specific approval has been obtained from the Radiation Safety Officer. The screening physician will be informed. Any deviations shall be documented.

The Nuclear Medicine Physician or Charge Technologist will verify that the patient instructions and consent form are included with the patient's file.

Informed consent for therapy will be obtained from the patient on the standard consent form.

The patient must be instructed on procedures to follow in the event of an emergency (Appendix C). The patient should make certain that the emergency contact information is readily available.

If requested by the referring physician, an appointment for a nuclear medicine whole body scan, 7 to 10 days post therapy will be given to the patient.

Appendix A - Initial Screening Questionnaire for I-131 Therapy Outpatient Candidates

Other than yourself, how many people live at your place of residence?	
Excluding yourself, what are the approximate ages of each member of your household?	
If you are treated on an outpatient basis, will you be able to avoid contact with pregnant women or children under 12 years old for the next 7 days?	
If there are **children < 12 years** of age in your home are they able to stay outside the home **for up to 5 days**. **Please explain.**	
How many bathrooms are in your residence?	
Is there a bathroom that could be reserved for your exclusive use for 3 days?	
Will you be able to sleep alone in a private room **for up to 14 days**?	
While at home, will you be able to maintain at least a 3 metre distance from all other people for the next 3 days?	
How will you travel from Toronto General Hospital to your home after the treatment?	
Will anyone be traveling with you? If so, will the person be staying with you for the next 3 days?	
How long does it take to travel from Toronto General Hospital to your home?	
After you arrive at home, will you be able to stay there for 3 days?	
Are you planning to initiate a pregnancy within the next 6 months?	

Comments:

Patient's Name

Physician

Date

Radiation Safety Officer

Date

Appendix B - I-131 Patient Release Worksheet (Based on Measured Thyroid Uptake)

The methodology of Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials" is widely recognized as the accepted methodology for releasing patients administered with radioactive materials. The methodology has been written into the United States Code of Federal Regulations. This worksheet provides the basis for patient release as stated in 10 CFR 35.75 (c) for one situation--**release of a patient given more than 33 mCi I-131 sodium iodide for whom the fractional uptake in the thyroid gland is known.**

The following equation shall be used to calculate the patient release criteria.

$$D(\sim) = \frac{34.6(G)(Q_0)}{(100\ \text{cm})^2}\{(0.75)(8.04)(0.8)(1-e^{-0.693(0.33)/8.04}) \ldots(1)$$

$$+\ e^{-0.693(0.33)/8.04}(E2)(F1)(T_{1eff}) \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots(2)$$

$$+\ e^{-0.693\ (0.33)/8.04}(E2)(F2)(T_{2eff})\} \ldots\ldots\ldots\ldots\ldots\ldots\ldots(3)$$

Q_0 = Administered Activity (mCi)
E1 = Occupancy Factor for the first 8 hours
E2 = Occupancy Factor from 8 hours to total decay
F1 = extrathyroidal uptake percentage
F2 = thyroidal compartments uptake percentage
T_{1eff} = Effective Half-Life of extrathyroidal compartment
T_{2eff} = Effective Half-Life of thyroidal compartment
G = Gamma Constant for Iodine-131 (2.2)

The first of the 3 components within the brackets conservatively accounts for the exposure during the first 8 hour after administration, during which time it is assumed that only physical decay occurs and that the maximally exposed person has an occupancy factor of 0.75 @ 1 meter. (The resultant dose due to the first 8 hours is 1.0 mrem per mCi administered to the patient.) The second and third components represent the extrathyroidal and thyroid compartments of the integrated dose for all time after the initial 8 hours. The effective half-lives of I-131 in each of the compartments for thyroid cancer are as follows:

Unless patient specific information is known, the following parameters and equations shall be used. Regulatory Guide 8.39 provides two examples using the methodology. Default values assume patients can follow basic instructions. The examples indicate that 200 mCi will conservatively yield a dose of approximately 5 mSv to the most exposed individual.

$$D(\sim) = \frac{34.6(2.2)(Q_0)}{(100\ cm)^2}\{(0.75)(8.04)(0.8)(1-e^{-0.693(0.33)/8.04}) \ldots(1)$$

$$+\ e^{-0.693(0.33)/8.04}(0.95)(0.20)(0.32)\ \ldots\ldots\ldots\ldots\ldots\ldots(2)$$

$$+\ e^{-0.693\ (0.33)/8.04}(0.05)(0.80)(7.3)\ \}\ \ldots\ldots\ldots\ldots\ldots\ldots(3)$$

Q_0 = Administered Activity

Uptake Fractions and Effective Half Lives for Iodine-131 Treatments				
	Extrathyroidal Component		**Thyroidal Component**	
Medical Condition	**Uptake Fraction F_1**	**Effective Half-Life T_{1eff} (day)**	**Uptake Fraction F_2**	**Effective Half- Life T_{2eff} (day)**
Postthyroidectomy for Thyroid Cancer	0.95 [2]	0.32 [1]	0.05 [2]	7.3 [1]

[1] International Commission on Radiological Protection (ICRP), "Radiation Dose to Patients from Radiopharmaceuticals", ICRP Publication No. 53, March 1987. (Available for sale from Pergamon Press, Inc., Elmsford, NY 10523). The data in this ICRP document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid and thyroid cancer patients. For thyroid cancer, the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid) as suggested in this ICRP document.

[2]The thyroidal uptake fraction of 0.05 was recommended by Dr. M. Pollycove, M.D., medical visiting fellow, as an upper limit postthyroidectomy for thyroid cancer.

Appendix C - SAMPLE Instructions to be Followed by the I-131 Therapy Outpatient based on I-131 therapy dose of 200mCi.

NOTE: Patient treatment instructions have been calculated based on the patient I-131 therapy dose administered. Calculations were performed using spreadsheet on patient releasability from medical confinement NCRP No. 155 – Management of Radionuclide Patients and the uptake fractions andeffective half lives for the extrathyroidal and thyroidal component for I-131 treatments as described in UHN procedure Outpatient Iodine-131 Therapy Greater than 1100MBq(30mCi).
Nuclear Medicine staff to verify that patient can follow instructions provided and review emergency contact information. Any deviations from the instructions below must be pre-approved by the Radiation Safety Officer/ Manager and referring physician.

When traveling home after treatment, preferably travel alone; if not, maintain as large a distance as possible between yourself and the driver. If you are feeling well enough, you should drive yourself.
If you feel nauseated after the treatment take 50 mg Gravol orally, up to every 6 hours (if needed), for up to two days. If you vomit, call the Emergency Contact numbers provided to you.
If no bowel movement occurs within the first 24 hours post-treatment, take a mild laxative, such as milk of magnesia.
You may spend up to a maximum of 3 hours per day at 1 metre (3.5 feet) from other people, up to a maximum of 12 hours per day at 2 metres (7 feet) from other people. Spend as much time as you like 3 metres (13 feet) from other people. This precaution lasts **3 days** (72 hours) from the time you receive the therapy.
Stay at your home for a minimum of **3 days**.
Drink plenty of liquids starting 90 minutes after you take the dose of Iodine-131 for **3 days**.
Suck on sour candies for the first **2 days** to reduce uptake to your salivary glands.
Avoid alcoholic beverages for **3 days**.
Reserve a bathroom for your personal use for **3 days.** You should be the only person to use this bathroom during this time. Keep the toilet clean by flushing 3 times after each use. Men should sit when urinating to avoid splashing.
Use good hygiene habits. Wash your hands thoroughly after each toilet use.
Take at least 1 shower or bath per day; wash hands frequently for **3 days**.
On the **4th day**, thoroughly clean your entire bathroom. Discard ALL personal toiletry items. This MUST be done prior to allowing anyone else to use your bathroom.
Launder your clothes, bedclothes, towels, etc. separate from the clothes of anyone else for **7 days**.
Do not return to work for **3 days**.
Do not travel on public transit for **3 days**.
Sleep alone for up to **14 days**.
Try to minimize time spent with pregnant women for **7 days.**
Try to minimize time spent with young children. Children **< 12 years** old must be **away from the residence you are staying in** for **up to the first 5 days**. Maintain a 1 meter distance and minimize time spent holding children < 12 years, up to 1 hour per day for the next **7 days**.
Do not become pregnant or father a child after the therapy for **6 months** for women and **2 months** for men. You may wish to discuss contraceptive methods with your physician.

Emergency Contact Information

Should an emergency arise during the first 72 hours post administration of the I-131 therapy, the Radiation Safety Officer and the nuclear medicine department should be informed and will help direct a response. ***In no case should life saving measures be delayed.***

Contacts:	Working hours:	416 340-4801	Radiation Safety Officer
		416 586-4446	Nuclear Medicine Department – Dr. Aaron Hendler or Dr. Marc Freeman
	After hours:	416 340-3155	Radiation Safety Officer
			Nuclear Medicine Physician (via hospital communications dept.)

Fire: In the case of a fire at the patient's residence, the fact that the patient is radioactive should not effect response. The patient should exit the residence as quickly as possible. When safely away from the fire and after the fire department has been called, the patient should attempt to inform the RSO of the situation.

Patient Information:

Clearly Imprint Patient Identification

I-131 therapy dose information:

Date Given (YYYY-MM-DD):	Time Given (24h clock):
Amount of Radioactivity:	Measured Dose Rate at 1 metre:

I have read and understand the above information. I recognize that I have primary responsibility to follow the recommendations of this procedure. I have informed and reviewed these instructions with my family and friend caregivers to ensure that their exposure to radiation is As Low As Reasonably Achievable.

I agree to abide by the above precautions:

Patient's signature _____ Date _____

Witness' signature _____ Date _____

☐ **The Radiation Safety Officer has reviewed the patient treatment instructions for this patient who has children < 12 years of age residing with them.**

Radiation Safety Officer signature _____ Date _____

Patient Information

General Treatment Information

The thyroid gland accumulates the iodine entering your body in foods and uses this iodine to perform its normal functions, which is to make thyroid hormone. The thyroid processes radioiodine in a similar manner. The radiation given off by this form of iodine decreases the function of the thyroid cells and inhibits their ability to grow, which is the desired medical effect. However, some of the radioiodine will leave your body, and individuals who are in close physical contact with you may be exposed to small amounts. There is no evidence that such exposure has caused harm, but efforts should be made to avoid unnecessary exposure to radiation.

Why are you going to receive radioactive treatment?

You are going to receive radioactive iodine treatment because together with your doctor it has been decided that this is the best option for your disease. Most of the radiation emitted by the iodine will be absorbed by your thyroid gland or its remnants, which is located in the anterior part of the neck. This radiation interferes with the function of the residual thyroid cells producing a desired and beneficial effect for your disease. However, small quantities of the radiation present in your body may reach people close to you exposing them to this radiation unnecessarily.

How is radioactive iodine administered and what sort of preparation is required?

You would have received separate instructions from your doctor to stop taking thyroid medication for a minimum of two weeks before radioactive iodine treatment. Radioactive iodine is given orally in variable quantities according to the type of your disease. Your treating doctor together with the physician who will actually administer the treatment determined the dose. According to the administered dose and your condition, it is possible that you should remain isolated for some days. Women must be completely sure that they are not pregnant at the time they receive the treatment. Food should not be ingested in the 2 hours before receiving the treatment and in some cases, a low-iodine diet will be recommended for a few days. You should talk to your doctor to clarify all your doubts in order to organize the activities of you and your family.

For how long does iodine remain in my body?

Radioactive iodine remains in your body just for a few days. Mainly the urine eliminates most of the iodine not retained in your thyroid, within 48 hours. A small quantity will be present in the saliva, sweat and stools. The radioactive iodine that remains in your thyroid gland also decreases quickly. This means that the possibility of unnecessary radiation exposure to other people also decreases in a matter of days.

In which way other people may be exposed to my body's radiation?

Radiation emitted by the radioactive iodine in your body is very similar to the x-rays used in radiological exams. For this reason, people who remain close to you and for prolonged times may be exposed to an unnecessary and avoidable radiation.

Besides the above mentioned radiation, there is the possibility that other people close to you may directly ingest small quantities of radioactive iodine eliminated by your body in the urine, saliva or sweat through contamination.

In which way can I reduce the risk of radiation exposure to other people?

Even though the amount of radioactive iodine present in your body is small, and there is no evidence that the radiation emitted by it may cause problems, it is still advisable to decrease the opportunities to exposure as much as possible. The three basic principles to avoid unnecessary radiation exposure are listed below. You can reduce radiation exposure to others by using the following guidelines (usually two to five days after your treatment). However, your doctor can recommend modifications to these guidelines based on your specific situation. Be sure to discuss your questions and concerns with your doctor.

The three basic principles to remember to reduce radiation exposure to others are:

1. **Distance.** The greater the distance you are from others, the less radiation they will receive. Guidelines are: sleep alone for the first few days after your treatment and avoid kissing or sexual intercourse. Also avoid prolonged physical contact, particularly with children and pregnant women. If you have a baby, be sure to get instructions from your doctor. You can probably do all things necessary to care for your baby, except breastfeeding (see below), but it is preferable not to have the baby too close, such as sitting in your lap, for more than a short time during the first two days after treatment.
2. **Time.** Radiation exposure to others depends on how long you remain in close contact to them. You should minimize the time spent in close contact with others. Drink plenty of fluids, such as water or juices, to help you urinate more frequently. This will help the radioiodine to leave your body more quickly, thus lowering the amount in your body.
3. **Hygiene.** Meticulous hygiene lessens the possibility of contaminating others. Guidelines are wash your hands with soap and plenty of water each time you go to the toilet. Keep the toilet very clean. Also, flush the toilet two or three times after each use. Men are advised to urinate sitting down to avoid splashing urine outside the toilet bowl or in its borders. Rinse the bathroom sink and tub thoroughly after using them to reduce the chance of exposing others to the radioiodine in your saliva and sweat. Separate a towel for your exclusive use. Wash your underwear and bed linens separate from the rest and rinse it several times. Use separate (or disposable) eating utensils for the first few days and wash them separately to reduce the chance of contaminating other family members with radioiodine in your saliva. Do not prepare or handle food with your bare hands (such as making dough) to avoid contamination food with small amounts of hand perspiration.

Other guidelines to consider:

- If you are pregnant, or think you are, tell your doctor because radioiodine should not be given during pregnancy. If you are planning to become pregnant, ask your doctor how long you should wait after the treatment.
- If you have been breastfeeding your baby, you must stop because radioiodine is secreted in breast milk. Talk to your doctor to find out when you can resume breastfeeding.

Practical Advice:

Ask your doctor to give you all the necessary recommendations in detail to avoid unnecessary radiation to people who are close to you and other individuals. Clarify all your doubts and do not be afraid to ask.

University Health Network
Toronto General Hospital | Toronto Western Hospital | Princess Margaret Hospital

Patient Treatment Instructions for I-131 Outpatient Administration Therapy Dose 75 mCi to 150 mCi

NOTE: Patient treatment instructions have been calculated based on the patient I-131 therapy dose administered. Calculations were performed using spreadsheet on patient releasability from medical confinement NCRP No. 155 – Management of Radionuclide Patients and the uptake fractions and effective half lives for the extrathyroidal and thyroidal component for I-131 treatments as described in UHN procedure Outpatient Iodine-131 Therapy Greater than 1100MBq(30mCi).

Nuclear Medicine staff to verify that patient can follow instructions provided and review emergency contact information. Any deviations from the instructions below must be pre-approved by the Radiation Safety Officer/ Manager and referring physician.

When traveling home after treatment, preferably travel alone; if not, maintain as large a distance as possible between yourself and the driver. If you are feeling well enough, you should drive yourself.
If you feel nauseated after the treatment take 50 mg Gravol orally, up to every 6 hours (if needed), for up to two days. If you vomit, call the Emergency Contact numbers provided to you.
If no bowel movement occurs within the first 24 hours post-treatment, take a mild laxative, such as milk of magnesia.
You may spend up to a maximum of 3 hours per day at 1 metre (3.5 feet) from other people, up to a maximum of 12 hours per day at 2 metres (7 feet) from other people. Spend as much time as you like 3 metres (13 feet) from other people. This precaution lasts **3 days** (72 hours) from the time you receive the therapy.
Stay at your home for a minimum of **3 days**.
Drink plenty of liquids starting 90 minutes after you take the dose of Iodine-131 for **3 days**.
Suck on sour candies for the first **2 days** to reduce uptake to your salivary glands.
Avoid alcoholic beverages for **3 days**.
Reserve a bathroom for your personal use for **3 days.** You should be the only person to use this bathroom during this time. Keep the toilet clean by flushing 3 times after each use. Men should sit when urinating to avoid splashing.
Use good hygiene habits. Wash your hands thoroughly after each toilet use.
Take at least 1 shower or bath per day; wash hands frequently for **3 days**.
On the **4th day**, thoroughly clean your entire bathroom. **Discard all personal toiletry items**. This MUST be done prior to allowing anyone else to use your bathroom.
Launder your clothes, bedclothes, towels, etc. separate from the clothes of anyone else for **7 days**.
Wash dishes and cutlery separately or use disposal dishes and cutlery for the first **7 days**
Do not return to work for **3 days**.
Do not travel on public transit for **3 days**.
Sleep alone for **10 days**.
Try to minimize time spent with pregnant women for **7 days.**
Try to minimize time spent with young children. Children **< 12 years** old must be **away from the residence you are staying in** for the **first 2 days**. Maintain a 1 meter distance and minimize time spent holding children < 12 years, up to 1 hour per day for the next **7 days**.
Do not become pregnant or father a child after the therapy for **6 months** for women and **2 months** for men. You may wish to discuss contraceptive methods with your physician.
IF YOU HAVE QUESTIONS OR CONCERNS call your physician or the Radiation Safety Officer.

University Health Network
Toronto General Hospital | Toronto Western Hospital | Princess Margaret Hospital

Patient Treatment Instructions for I-131 Outpatient Administration Therapy Dose 75 mCi to 150 mCi

Emergency Contact Information

Should an emergency arise during the first 72 hours post administration of the I-131 therapy, the Radiation Safety Officer and the Nuclear Medicine Physician should be informed and will help direct a response.
In no case should life saving measures be delayed.

Contacts:

Working hours:	416 340-4801	Radiation Safety Officer / Radiation Safety Manger
	416 596-4200 ext 4446	Nuclear Medicine Department – Dr. Aaron Hendler or Dr. Marc Freeman
After hours:	416 340-3155	Radiation Safety Officer Nuclear Medicine Physician (via hospital communications dept.)

Fire: In the case of a fire at the patient's residence, the fact that the patient is radioactive should not effect response. The patient should exit the residence as quickly as possible. When safely away from the fire and after the fire department has been called, the patient should attempt to inform the RSO of the situation.

Patient Information:

Clearly Imprint Patient Identification

I-131 therapy dose information:

Date Given (YYYY-MM-DD):	Time Given (24h clock):
Amount of Radioactivity:	Measured Dose Rate at 1 metre:

I have read and understand the above information. I recognize that I have primary responsibility to follow the recommendations of this procedure. I have informed and reviewed these instructions with my family and friend caregivers to ensure that their exposure to radiation is As Low As Reasonably Achievable.

I agree to abide by the above precautions:

Patient's signature _____ Date _____

Witness' signature _____ Date _____

☐ **The Radiation Safety Officer has reviewed the patient treatment instructions for this patient who has children < 12 years of age residing with them.**

Radiation Safety Officer signature _____ Date _____