UNIVERSITY of VIRGINIA
ENVIRONMENTAL HEALTH and SAFETY
Special Materials Handling Facility

June 28, 2007

Penny Lanzisera
Health Physicist
U. S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

03003296

Dear Ms. Lanzisera,

Enclosed are a number of documents that provide additional information which you requested in the Exit Interview on June 15, 2007 for License 45-00034-26.

To restrict the movement of a radioactive material package in the transportation vehicle being used to deliver packages from the Special Materials Handling Facility (SMHF) to the Authorized User at the University, heavy duty plastic containers have been attached to the floor in the rear of the delivery vehicles. A description of the procedures for "Blocking and Bracing" radioactive material during transport is described (Appendix 1) and includes pictures of the containers. A review of the records and interviews indicate that we have not had contamination on the outside of packages received at the SMHF. The printout of the counting data for contamination surveys will be attached to the receiving form as well as being entered into the computer database. All radiation safety technologists who receive and deliver RAM packages have been retrained individually and as a group on the new procedures.

You asked about a skin dose assessment for the researcher who spilled 32-P last month. The skin contamination was low and a result of checking her arm with her contaminated gloves still on. Appendix 2 gives a brief description and a worst case calculated skin dose. Response and clean up were prompt so any potential exposure was low.

You also asked about the inventory sheet for a vial labeled as 3-H (Appendix 3) GABA observed in Room 5227, Jordan Hall. The inventory sheet was in an older inventory notebook as the material had been received in 1994. The last time it was used was July 1994 and since your inspection the vial has been picked up as waste.

In response to the observations that a researcher had left RAM unsecured in a laboratory at the North Fork Research Park, we have retrained this research group on lab security. They have also agreed to secure stock materials in a locked cabinet when RAM is not being used. An email has been sent to all Principal Investigators reminding them of security requirements and encouraging them to keep all stock RAM in locked cabinets as an additional security measure.

The issue of two patients (sisters) being treated for cancer with 131-I on June 6, 2007 has been investigated. Statements from the two Nuclear Medical physicians who communicated with the patients, the nurse who met with the patients, and the assistant radiation safety officer are attached

515 Edgemont Road • P.O. Box 400322 • Charlottesville, VA 22904-4322
Phone: 434-982-4911 • http://keats.admin.virginia.edu

(Appendix 4). From my interviews with those involved I conclude that no one at the University of Virginia recommended that the sisters stay in a hotel when they were released from the hospital following their treatment. In fact the physician indicated that this was unnecessary. The patients met the release criteria and it was concluded that there were no NRC restrictions on patients sharing a room. The patients answered questions about their ability to restrict others from radiation exposure and indicated a low occupancy factor. Using the occupancy factor of 0.125 the maximum total likely exposure was calculated for each of the patients based upon measured exposure rates at one meter following therapy. While the decision to release the patients was based upon the forms (Patient Questionnaire as a Basis for Authorizing Release for 131-I Doses greater than 30mCi) the calculation in Appendix 5 were made to confirm a patient specific value for the maximum total likely dose. They were given written instructions (Appendix 6). The information transmitted to the nurse suggests that the sisters had access to information that lead them to go to a hotel and take steps to reduce exposures to the public (e.g. notifying the hotel to remove linens so they could bring their own which the patients would remove, asking the hotel to not clean the rooms, having food brought in by one of the husbands etc). We do not know the source of this information but if they followed all the procedures which were indicated to the nurse then exposures to hotel staff or other guests would be far less than the 500mR used in the release criteria.

Further information on the release criteria and about the patients treated with over 200 mCi of 131-I over the last two years is attached. The form used in the Department of Nuclear Medicine (Appendix 5) includes the questions given in US Nuclear Regulatory Guide 8.39 and NUREG 1556 Volume 9 Appendix U to determine the probable occupancy factor for a patient who may be released post 131-I therapy. Based upon the occupancy factor the physician can calculate the activity that can be used to keep the exposure from an average patient to below 500 mR. The table gives an activity level that was calculated (Appendix 7) indicated that up to 230 mCi could be used if the potential for internal exposure to others was included. If this internal exposure is not included the calculation indicates that up to 300 mCi could be used. Comments from the NRC to the Asst. RSO when this form was being developed (after our last NRC inspector suggested more documentation of the release criteria), indicated that "no one included the internal dose". A copy of the page from NUREG-1559, Vol. 9 Appendix U with the notes made while in discussion with the NRC (in 205 are included as Appendix 8). This exposure form was developed and has been in use in Nuclear Medicine since June 2005. For the last year the actual exposure level at a meter from each patient has also been documented. All of the patient files for patients receiving 131-I thyroid cancer therapies over the last 2 years have been reviewed. The decisions to release an individual patient was made on the basis of the form (Appendix 5) that indicated that a patient would have an occupancy factor of 0.125 (and this factor as found in the patients charts is indicated in the attached table (Appendix 9). Of the 127 patients, there were 28 that had cancer therapy involving over 200 mCi of 131-I. For this small group of patients a series of calculations have been made (Appendix 9) using various assumptions to indicate an estimated maximum exposure to the public from the released patient.

Sincerely,

Ralph Allen

Ralph O. Allen
Asst. Vice President for Research
Chairman, Radiation Safety Committee

Enclosure:
Appendix 1, 2, 3, 4, 5, 6, 7, 8, 9

Blocking and Bracing Radioactive Material during Transport

In accordance with DOT and NRC regulations concerning the loading of radioactive material for transportation, effective immediately, EHS will secure each package containing radioactive material being transported such that It is loaded so that it cannot fall or slide and is safeguarded in such a manner that other freight cannot fall onto or slide into it under normal operating conditions during transportation.

All radioactive material packages checked-in at EHS will be distributed to the users via two specially equipped vans. Each delivery van has two containers bolted to the vehicle. The containers have latching lids. Typically, these boxes will be used to contain the radioactive material during transport. Occasionally, a radioactive material order will arrive in a package that is too large for the transport containers. These over-sized packages will be secured to the wall of the van using cargo straps.

The van cargo areas will be cleared of all items not related to the package delivery. Acceptable items such as hand trucks will be secured to the walls of the van using bungee cords.

The van cargo areas will be locked before the packages are transported.

Radioactive waste containers will be secured as follows:

- ⇒ DAW will be strapped to the wall of the transport truck using cargo straps
- ⇒ Bulk Liquid carboys will be placed in secondary containment bins inside a secured carrier
- ⇒ Small volume liquid containers and stock vials (that are not packaged in the DAW) will be packaged in 1.0 cu ft waste boxes and strapped with the DAW waste or placed in the same carriers as the bulk liquid waste and held in place using bungee cords.
- ⇒ Large animal waste boxes will be strapped to the wall of the transport truck using cargo straps

The waste vehicle cargo area will be locked before the waste is transported.

The EHS technicians have been instructed to never transport radioactive material without employing these package /container securing systems. Any unusual transportation of radioactive material issues will be reported to EHS supervisors and a specific plan developed before the radioactive material will be transported.

Radioactive Material Security

UVA considers radioactive material security as a top priority. UVA has an established security program for radioactive material. EHS inspects for radioactive material security during laboratory audits, waste pick-up, and

whenever a staff member is in a radioactive material area. Security is addressed as part of the annual re-training.

Historically we have seen very few security violations, and correct observed security lapses immediately via re-training and increased surveillance. The Herr Lab violation was the result of one individual not thinking when he left his lab unsecured for approximately 5 minutes. He received immediate security re-training. EHS visited the other Herr labs and discussed security regulations with the rest of the laboratory personnel. Dr. Herr was informed of the security violation. He was concerned and will continue to emphasize the importance of radioactive material security to his staff.

Review of previous Herr Lab audits indicated that there have not been any other observed security violations. EHS will monitor the Herr Lab for security violations until further notice.

An E-Mail will be sent to UVA's Radioactive Material Users reminding them of the importance of maintaining security in radioactive material areas.

EHS Radioactive Package Receipt

UVA radioactive material package receipt has typically been operated using two technicians. Occasionally, this task is performed by only one tech. Each technician is given initial training and is observed by a Supervisor during the year (when staffing requires that a Supervisor assist with package check-in). The staff has been directed to report all unusual events during package receipt to a Supervisor. Unusual events can include high background readings, incorrect labeling, missing paperwork, and greater than twice background package swipe results.

After evaluating our radioactive material package receipt program training process, it was determined that although we feel that the technicians are performing this job safely and legally, the system can be improved. Our principle package check-in tech (Jean Varner) was deficient in her ability to evaluate the LSC out-put, but her partner (Jon Hall) who performed the actual physical contamination survey, swipe counting and survey analysis was proficient. During the rare times where there is no technician available to assist Ms. Varner with package check-in, she understands that any problems with package receipt including LSC values greater than twice background need to be immediately reported to a Supervisor.

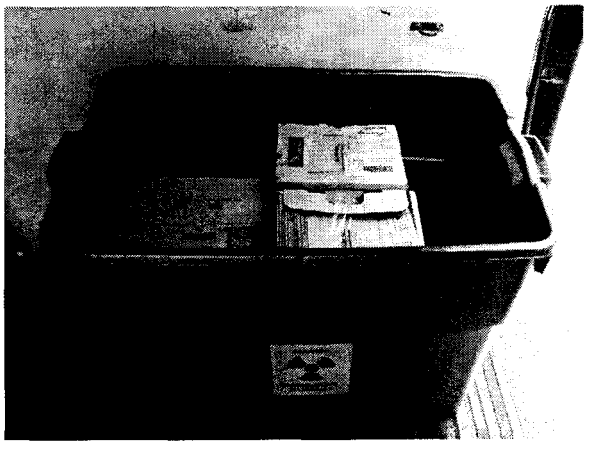
The EHS staff has been retrained on how to receive a radioactive package at UVA. Re-training included:

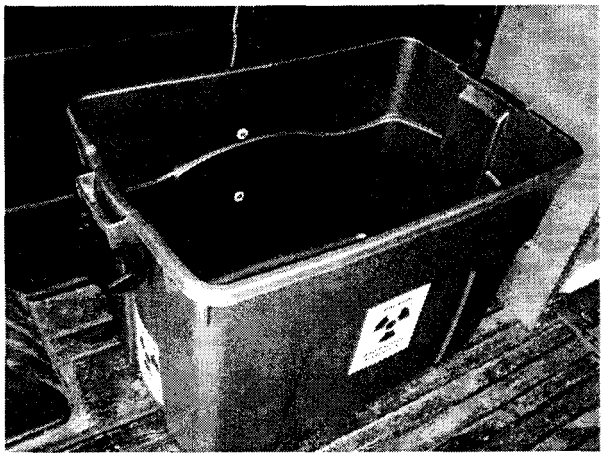
- ⇒ All staff reviewed the EHS Radioactive Package Check-In Procedure
- ⇒ All staff was given basic training on the proper use and interpretation of radiation detection equipment

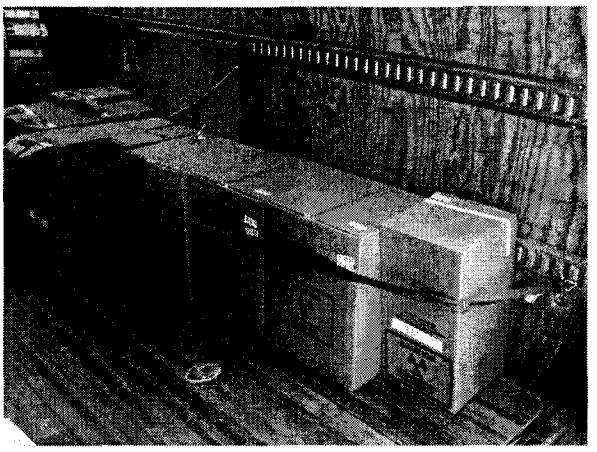
⇒ A supplemental procedure has been developed for the staff concerning the recording of contamination swipes in the on-line package check-in program. Effective immediately:
  - All LSC output will be identified with the package receipt date, individuals performing the surveys, number of packages received, the radio-isotopes being surveyed, this paperwork will be filed for regulatory review
  - Supervisor will be notified if any package swipes are greater than twice background
  - Package swipe information will be entered into the software program, using the default "zero" DPM is not acceptable

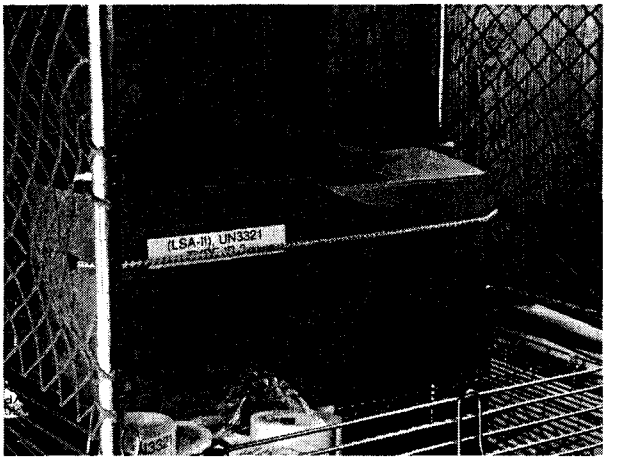
⇒ Staff will be given a test to determine their knowledge base and re-trained accordingly if required at least annually

⇒ Packages will be placed on bench paper until confirmed free of external removable surface contamination









Inventory Problem (H-3 GABO in the Lynch Lab)
Dr. Lynch was interviewed concerning the H-3 GABO stock vial found in his cold room that was not in his inventory records. After looking in older archived records, he found the missing inventory sheet. It is on file at EHS and available for regulatory review. Dr. Lynch and his staff were given an in-service about inventory and proper storage of stock vials.

An E-Mail will be sent to UVA's Radioactive Material Users reminding them of the importance of maintaining accurate up-to-date inventories of radioactive material.

H-3 and C-14 Incinerator Ash
UVA has operated its incineration program under the guidance and authority of the NRC since its inception. UVA's H-3 and C-14 disposal plan has been reviewed and accepted during numerous NRC Inspections and Broad By-Product License renewals,. We believe that our program has been conducted in a safe, legal, and responsible manner. In light of this inspection, we have been asked to revisit our assumptions that no C-14 or H-3 remains in the ash after incineration.

Because of the liability and the reinterpretation of the disposal of H-3 and C-14 incineration ash, effective immediately, the UVA Radioactive Material Incineration Program is terminated.

All H-3 and C-14 waste will be shipped for off-site disposal.

The ash from 2004 to the present residing in a secured dumpster will be removed, sampled for radioisotope contamination by a commercial laboratory, and packaged for shipment.

All areas, items and equipment associated with the storage, clean-out and ash sampling will be surveyed, decontaminated if necessary, and released for unrestricted use.

Beta Irradiation of the Skin -- Results

Dose to hand from contaminated gloves following spill:

The radiation dose rate to the skin from a spill of 0.50 cc of a solution containing 20.0 microcuries of Phosphorus-32 per cc is about **3.5 rads per hour**, assuming the following PPE between the skin and the spill: Exam Glove, Medium (10 mil)

For an exposure time of 0.50 hours, the total dose would be about **1.7 rads .**

Dose to skin of arm from contamination transferred from glove during disrobing:

The radiation dose rate to the skin from a spill of 0.50 cc of a solution containing 20.0 microcuries of Phosphorus-32 per cc is about **5.2 rads per hour**, assuming the following PPE between the skin and the spill: NONE (Directly on Skin)

For an exposure time of 0.05 hours, the total dose would be about **261 millirads .**

.The two doses are additive so the total beta skin dose to skin is about 1.961 rads. The annual occupational dose limit to the skin is 50 rads. Therefore, the dose from this spill is about 4.0 percent of the annual occupational limit This represents a worst-case scenario with significant P-32 solution on the worker's lab gloves for 30 minutes during spill cleanup. The P-32 solution in contact with the worker's bare skin was accidentally applied when the worker pushed up lab coat sleeves during the cleanup and decontamination procedure. Decontamination of worker was successful..

Reference:

Varskin_Mod_2 software written by Dr. James Durham

EHS response to P-32 spill

0:00 EHS receives phone call from lab with spill

0:05 EHS is en route to Chemistry department with spill kit

0:10 EHS arrives at lab and assesses situation

0:12 EHS begins contamination survey of floor and individual in the lab

0:15 EHS determines areas of contamination in both the room and on the individual

0:16/17 EHS sets up clean staging area in order to initiate the decon of both individual and lab space

0:18-0:22 EHS isolates contamination on lab member PPE and clothing

0:23-0:30 Lab member's contaminated PPE and clothing is removed in the contaminated lab and decontamination of lab member's forearm is performed in the restroom.

0:30 – 0:35 Hot area isolated on the floor and marked off.

0:35 – 1hr:00min. Floor is decontaminated. Fixed hot spots remain.

1hr:00 – 1hr:15min. Benchtop contamination is isolated to a few pieces of equipment and are set aside. Determined most of spill occurred on the floor.

1hr:16min. EHS staff arrive with plexiglass sheets to secure on top of contaminated areas of flooring. Survey performed to ensure no exposure is seen from the floor.

1hr:20 min. EHS discusses safe lab practices with lab member and instructs her on cleaning contaminated lab equipment and spill procedures.

UNIVERSITY OF VIRGINIA
ENVIRONMENTAL HEALTH AND SAFETY
RADIATION SAFETY OFFICE

RADIOISOTOPE INVENTORY LOG SHEET

Isotope ^{3}H Location of Isotope 4°C Fridge

Compound GABA Room(s) used in Jordan 5-34

INVENTORY *				WASTE DISPOSAL *			
DATE	Amt. Received on hand	Amount Removed for Expt.	Amount Remaining	vials	Solid Waste	Liquid Waste	Animal Carcasses
2/10/94	~~250uCi~~ ~~10mCi~~	5 uCi	245uCi	<1uCi	<1uCi	4uCi	
2/14/94	245	10 uCi	235uCi	<1uCi	<1uCi	9uCi	
2/18/94	235	10 uCi	225uCi	<1uCi	<1uCi	9uCi	
2/21/94	225	10uCi	215uCi	<1uCi	<1uCi	9uCi	
2/22/94	215uCi	10uCi	205uCi	<1uCi	<1uCi	9uCi	
3/21/94	solid waste pick-up			<0.001mCi	.0025mCi		
5-9-94	vial pick up						
7-5-94	liquid waste pick up					+49uCi	
						~~0~~	
6-15-07	201	201	0		201		
					0		

* please note act. in mCi or uCi amounts only

Total each waste column and indicate the date of disposal next to each disposal. These figures should correspond with the activity written on waste tag.

Appendix 4

Subject: Release of Patient Sisters following 131-I Therapy
From: "Rehm, Patrice K *HS" <PKR3B@hscmail.mcc.virginia.edu>
Date: Thu, 21 Jun 2007 10:34:55 -0400
To: "Allen, Ralph O" <roa2s@Virginia.EDU>
CC: "Amato, James *HS" <JA5G@hscmail.mcc.virginia.edu>, "Perham " <IMCEAMAILTO-csp2t+40virginia+2Eedu@hscmail.mcc.virginia.edu>, "Williamson, Brian R J *HS" <BRW9NB@hscmail.mcc.virginia.edu>

The purpose of this email is to recount events, to the best of my knowledge and recollection and to the extent of my involvement, relating to the treatment and release of two patients, who happened to be sisters, receiving 131-I radioiodine therapy for thyroid cancer, after disclosing voluntarily their intent to share a hotel room following treatment. The names of the patients are being withheld in compliance with HIPAA, hospital policy and general patient privacy considerations.

During the week of May 28, 2007, Dr. Chabra, an outside endocrinologist who regularly refers patients to the UVA Nuclear Medicine thyroid clinic, contacted me by phone regarding a patient. Dr. Chabra advised me that she was referring to UVA two patients, sisters of one another, who were scheduled for treatment the week of June 4. Prior to our phone conversation, Dr. Chabra had documented that Patient-Sister A had an abnormal, high thyroid stimulating hormone (TSH) factor, and was thus hypothyroid and medically ready for 131-I therapy, but had been given an appointment for the next week. To maximize the effectiveness of 131-I therapy, the medical standard of care calls for the suspension of thyroid replacement therapy, with induction of hypothyroidism, before 131-I therapy. Patient-Sister B did not yet have a high TSH factor, was not yet hypothyroid and therefore was not ready for 131-I therapy.

Dr. Chabra asked whether I could intervene to schedule Patient-Sister A at an earlier date to shorten her period of hypothyroidism. The symptoms of hypothyroidism broadly are mental and physical sluggishness, including the possibility of weakness, fatigue, depression, joint and muscle pain and in extreme cases coma. By accelerating the date of therapy, we could accelerate the date upon which Patient-Sister A could resume her thyroid replacement therapy and be relieved of hypothyroid symptoms. I told Dr. Chabra that I would contact Patient-Sister A directly to offer to advance the date of treatment. Dr. Chabra gave me Patient-Sister A's name and telephone number.

On or about the same day as my conversation with Dr. Chabra, I contacted Patient-Sister A by telephone. I introduced myself and explained that I had spoken with Dr. Chabra and was calling to offer to accelerate Patient-Sister A's appointment for 131-I therapy, since she was hypothyroid and ready for treatment. Patient-Sister A told me that her sister, Patient-Sister B, was scheduled for treatment on the same day as her originally scheduled appointment. Patient-Sister A asked whether her appointment could remain on the same day as her sister's appointment.

For medical (not radiation safety) reasons, I strongly encouraged Patient-Sister A to come in for treatment as soon as possible at two points in the conversation, once in the middle and another time at the end of the conversation. I was concerned that Patient-Sister A might suffer from hypothyroid symptoms for longer than necessary given that she was medically-ready for treatment, and that she might experience an adverse event during a period of unnecessarily prolonged hypothyroid conditions. In response, Patient-Sister A told me that she did not feel that bad and wanted to wait to undergo treatment at the same time as her sister. (As I recall, Patient-Sister A told me that she and her sister had "always done everything together.")

In the course of that telephone conversation, Patient-Sister A volunteered that she and her sister had planned to receive treatment on the same day and then share a hotel room following treatment. I did not ask or otherwise solicit information from Patient-Sister A about her plans following treatment. In response to this volunteered information, I advised Patient-Sister A that "we don't recommend that you go to a hotel" after receiving 131-I treatment. I advised her further that seclusion in a hotel room was not necessary for radiation safety reasons. Patient-Sister A explained that there were "small children involved," and they were concerned that they could not keep the children "off our laps" per radiation safety instructions (they had learned of on their own) if they returned home immediately following treatment. [It was not clear to me in the telephone conversation which sister had small children. I was later informed by Nurse Katherine Willard that both of the patient-sisters had small children and shared similar concerns about limiting contact with the children.] Patient-Sister A did not specify to me which hotel they intended to stay at or how long they intended to remain in a hotel.

Patient-Sister A gave no definitive answer in our telephone conversation. At the end of the telephone conversation, Patient-Sister A indicated that she wanted to discuss my offer to advance her appointment date with her sister, Patient-Sister B. As noted, I encouraged her a second time to accelerate her appointment for medical reasons. At this point, we concluded our telephone conversation. I have had no further contact with either Patient-Sister A or Patient-Sister B since that telephone conversation.

On the day following my telephone conversation with Patient-Sister A, still during the week of May 28, I had a second telephone conversation with Dr. Chabra to follow up on the possible change in appointment. To the best of my recollection, I initiated the call. Dr. Chabra informed me that in a separate conversation with her, Patient-Sister A had discussed the question with her sister and decided to keep her original appointment on the same day as her sister. Dr. Chabra also confirmed Patient-Sister A's statements to me that Patient-Sister A "did not sound too uncomfortable" in her hypothyroid condition.

I am familiar with NRC regulations and guidelines for release of patients following 131-I therapy. I was not aware of any NRC prohibition, instruction or guideline that required providers to instruct patients not to go to hotels/motels following treatment. But I was not certain whether two patients sharing a room – whether in a hospital, at home, in a hotel or anywhere else – would trigger NRC prohibitions against release.

Upon learning from Dr. Chabra that Patient-Sister A planned to keep her original appointment on the same day as her sister, I recalled her volunteered comment that the two sisters intended to share a hotel room following treatment. Prior to speaking to Dr. Chabra, the radiation safety question of two patients sharing a room was moot since the sisters would have received treatments on different days in different weeks had Patient-Sister A accelerated her appointment as recommended. Once I learned that the patient-sisters had determined to continue as originally planned, however, I suspected that they might also continue with their original plan to share a hotel room following treatment (as volunteered to me by Patient-Sister A in our telephone conversation) in spite of my recommendation against it, and thought it best to check on the radiation safety requirements that might apply.

I therefore contacted Catherine Perham in the UVA Radiation Safety Office by phone on the same day as and shortly after my conversation with Dr. Chabra, still during the week of May 28. Ms. Perham confirmed me that the NRC had no prohibition against release to hotels. Ms. Perham further explained that NRC guidelines specifically permitted two radioiodine therapy patients to reside in the same hospital room following 131-I therapy. She could recall no concern expressed by the NRC about radiation exposure to each other when patients shared a room. Ms. Perham accordingly advised me that she could think of no radiation safety basis for objecting to the patient-sisters sharing a hotel room, so long as they otherwise following our radiation safety instructions.

That ended my involvement in the treatment of these patients. UVA records indicate that the patient-sisters were treated and released on June 6, 2007, during the week following the events described above. I was not on clinic and was out of the hospital during the week of June 4, 2007. UVA records indicate that the patient-sisters were seen in standard 7-day follow up consultation on June 13, 2007. I was not assigned to clinic duty on Wednesday, June 13. Whatever additional information I have learned about the treatment and release of these patients I learned after the fact from other staff members, including Dr. Brian Williamson, Nurse Willard and Ms. Perham, or in connection with the NRC site inspection visit.

4b

Subject: Treatment of two sisters with radioactive iodine and sharing a hotel room post therapy
From: "Deane, Sherry S *HS" <SSD7N@hscmail.mcc.virginia.edu>
Date: Fri, 22 Jun 2007 09:27:46 -0400
To: "Allen, Ralph O" <roa2s@Virginia.EDU>
CC: "Dake, Michael D *HS" <MDD2N@hscmail.mcc.virginia.edu>, "Rehm, Patrice K *HS" <PKR3B@hscmail.mcc.virginia.edu>, "Amato, James *HS" <JA5G@hscmail.mcc.virginia.edu>, "Perham, Catherine S" <csp2t@virginia.edu>, "Steva, Deborah P" <dps3c@Virginia.EDU>, "Agarwal, Anup *HS" <AKA6E@hscmail.mcc.virginia.edu>, "Christopher, Gina S *HS" <GDS7X@hscmail.mcc.virginia.edu>, "Williamson, Brian R J *HS" <BRW9NB@hscmail.mcc.virginia.edu>

My knowledge of the treatment of the two sisters with radioactive iodine and sharing a hotel room post therapy.

In the week prior to therapy, I heard a communication of Dr. Rehm with Ms. Perham, RSO in respect of the two sisters sharing a single hotel room post therapy. It was decided that the two patients could share the same hotel room and no stricture against that behavior was passed to me.

The two sisters came for therapy on 6/6/07. They both, individually, received evaluation and education in a standard fashion. They both were able to adhere to our standard protocol restrictions – blank forms attached.

Following consent, both patients were treated, one with 102.2 mCi orally and one with 158.5 mCi orally (both in capsule form). The dose difference reflects different staging. The patients were monitored and subsequently discharged in a routine fashion. They returned one week later for a routine post therapy scan – both scans satisfactory.

Brian R. J. Williamson, M.D., F.A.C.R.
Professor Radiology & Nuclear Medicine
Department of Radiology
University of Virginia Health System

NRC directives.rtf	**Content-Description:**	NRC directives.rtf
	Content-Type:	application/rtf
	Content-Encoding:	base64

survey form.rtf	**Content-Description:**	survey form.rtf
	Content-Type:	application/rtf
	Content-Encoding:	base64

Note to File:
June 11, 2007
Katherine Willard, MSN, RN
Nuclear Medicine

J.H. is a 33 year old who lives an 1 bathroom home in Ruckersville with her husband and infant son. Her sister, C.S., lives with 2 small children and a husband in a home in town. Both sisters had thryroidectomies for thyroid cancer within one week of each other. They then made their appointments for the Iodine 131 TX on the same day so they could be isolated together in a hotel without having to worry about being around their small children. Dr. Rehm called the OEHS to make sure this was appropriate and was told that this was OK. Though not actively involved in the conversation, Dr. Williams was present for this conversation. I also was present and in the room for this phone call.

The sisters chose a hotel outside the city and made reservations for 2 nights. This hotel was chosen because it had an outside walking trail that offered the sisters some exercise without being in a gym On the day of their treatment, they checked into the hotel before coming to the hospital. They requested that all linens (including sheets, pillows, and towels) be removed from the room. They brought from home all sheets, towels, and pillows. The sisters took a cooler with water, soda, and snacks. Their families brought them their meals. The sisters bagged all linen to take home to wash, and removed all trash from the room when they left. In talking with one sister, when she returned for her scan, she stated that they did very little for the 2 days they were at the hotel besides sleep, read, and watch movies on TV.

Appendix 4d

Justification for Release of I-131 Patients JH and CS under Section 35.75

20 June 2007

In accordance with 10 CFR 35.75 Release of iindividuals containing unsealed byproduct material or implants containing byproduct material, (a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). In section (b) of the same the licensee shall provide the released individual with instructions, including written instructions,on actions recommended to maintain doses to other individuals as low as reasonably achievable if the TEDE to any other individual is likely to exceed 1 mSv (0.1 rem). In section (c) of 35.75 A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with 35.2075 (b).

All of the conditions stated in 10 CFR 35.75 have been met and records maintained. Therefore the University of Virginia released the individuals in question "from its control." Once out of the licensee's control, actions belong to the individual treated with unsealed byproduct material.

For clarification here is the story as reconstructed for this document: Two sisters by coincidence developed thyroid cancers at the same time and each underwent a thyroidectomy. The two patients, being sisters and very close, requested that they receive their post-thyroidectomy I-131 treatments together. One sister indicated by phone conversation with a Nuclear Medicine physician and Authorized User PR that the sisters would like to be treated together and go to a hotel for the days immediately succeeding the administration. UVa Medical Center does not recommend this and does not know where the patient first got the idea of going to a hotel, however it appears that this advice may be available on the internet at patient-oriented websites. The Nuclear Medicine physician told the patient that this was not necessary and that she preferred that the patient go home following treatment. Patient was also told that she needed immediate treatment because of her low-thyroid state and should not wait for her sister. The Assistant Radiation Safety Officer was made aware of this request at the time and had advised that it was permissible for the sisters to be dosed together and to stay in the same room. After reflection ARSO sent an email to physician with a third option of hospitalization as inpatients.

The two patients decided to go ahead and schedule I-131 therapy treatments for the same day [06/06/07]. They indicated to a nurse that they intended to go to a hotel. Each sister was expected to receive I-131 therapies allowing their release with instructions under Part 35.75. Both attended separately a Nuclear Medicine

consult with a physician, and were asked a series of questions that would determine if in fact they were candidates for immediate release. Each sister indicated on the patient questionnaire that she could follow the necessary restrictions and signed the questionnaire. There was no medical or regulatory indication to hospitalize either sister. Each sister received instructions as per Part 35.75. Both promised to sleep alone, to use a separate bathroom, to not take public transportation and etc. in order to minimize the risk of exposure to another individual. Each patient received instructions in ways to further minimize the potential for exposure to a member of the public or family member including but not limited to using disposable eating utensils and dishware, showering frequently, flushing 2-3 times, drinking copious amounts of water and voiding frequently. Nuclear Medicine physician and Authorized User BW, saw the patients that day. The sisters each were given a preliminary thyroid uptake scan prior to radioiodine treatment on a Phillips ADAC model Forte Nuclear Medicine scanner and the results of each scan showed an uptake "too low to calculate." For that reason the default uptake values given in NUREG 1556 Volume 9 Appendix K representing the maximum possible uptake after cancer surgery and the most conservative estimate of a dose to a member of the public were used to calculate maximum potential dose to a member of the public. The maximum potential dose {TEDE including internal] to a member of the public was 2.23 mSv from patient KS and 3.08 mSv from patient JH at time of dosing according to equation B.5 of NUREG Guide 1556 volume 9.. Both patients were held until first void and in fact patient JH was held at the medical center for more than 4 hours as she was waiting for her sister. This 4-hour wait and post-treatment void lowered the I-131 body load in the sister receiving the higher dose. The potential dose to a member of the public could further be portioned into pre- and post-hotel stay, but as both dose potentials are below 5 mSv, this was deemed not necessary. Hotel staff members were exposed to no external dose as they were not present in the room with or the vicinity of the patients, and family members were not exposed to internal dose as this risk is confined to the first two days post-administration of I-131 for thyroid cancer. In addition, hotel guests who might have been in the adjoining room could not have been internally exposed, and were not exposed for more than 16 hours to external gamma assuming a worst-case scenario of the same hotel guest in the adjoining room for both nights. Again this potential dose would be below 5 mSv.

While none of the UVa Medical Center staff approved of the patients going to a hotel [nor did we recommend it], with the realization that the sisters intended to do so, the staff gave additional instructions to protect hotel guests and employees. The following account is hearsay and based on conversations with a nurse but are included for clarification: *On their own the patients decided to check into the hotel prior to coming to the hospital and had the management strip the room of all linens and bedding, as they brought their own including sheets, towels, washcloths and pillows. They requested an outside room with a separate entrance. In addition they instructed the hotel staff not to enter the room at any time during their stay. Patient's husbands were to drop off meals and the sisters*

would not leave the room. The patients reportedly bagged and removed all bedding and trash At the request of one patient, the ARSO demonstrated the use of a GM meter already present in the Nuclear Medicine suite, should they decide to survey the hotel room [one sister said that a husband or friend of a husband had a Geiger counter.]. We do not know where they received the instructions but they seemed very well-informed and extremely conscientious. There seems to be information on this available on the internet and in fact the ICRP suggests a hotel as a "rarely discussed alternative" to home and hospital in a 2003 document as both have drawbacks. Additional instructions were given at the medical center regarding cleaning of potentially contaminated surfaces.

This justification is based on the premise that the two patients did indeed go to a hotel. According to the outreach nurse, the patients stayed two days post-administration in the hotel room. In addition, I feel that I can assume that they obeyed the Radiation Safety instructions provided by the medical center and followed their own plans, taking the extreme care that they said they would take as far as the additional precautions stated in italics above. Patient-specific dosimetry that takes into account internal dose potential and accounts for no patient attenuation or shielding is attached.

Thank you.

Catherine S. Perham
Assistant Radiation Safety Officer
University of Virginia

References:

1. U.S. Nuclear Regulatory Commission, 10 CFR Part 35.75 and 35.2075

2. U.S. Nuclear Regulatory Commission, NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Use Licenses", Appendix U – Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials, October 2002.

3. U.S. Nuclear Regulatory Commission, Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials", April 1997.

Patient Release Calculation
I-131 for Thyroid Cancer

Patient Name	KS		
Activity (millicuries)	102.2		
Occupancy Factor	0.125		
Occupancy Factor (1st 8 hours)	0.75		
Physical Half-Life	8.04	Released considering patient attenuation? (yes or no)	no
R/mCi-h @ 1 cm	2.2	Exposure rate at 1 meter (mrem/hr):	28
Extrathyroidal Uptake Fraction	0.95	Revised gamma ray constant:	2.73972603
Extrathyroidal Eff. Half-Life	0.32		
Thyroidal Uptake Fraction	0.05		
Thyroidal Eff. Half-Life	7.3		
Distance (cm)	100		
Maximum likely external dose	168 millirems		
Maximum likely internal dose	54 millirems		
(can be ignored if < 10% external dose)			
MAXIMUM TOTAL LIKELY DOSE	**223 millirems**		

Radiation Safety Representative

Patient Release Calculation
I-131 for Thyroid Cancer

Patient Name	JH		
Activity (millicuries)	158.5		
Occupancy Factor	0.125		
Occupancy Factor (1st 8 hours)	0.75		
Physical Half-Life	8.04	Released considering patient attenuation? (yes or no)	yes
R/mCi-h @ 1 cm	1.89	Exposure rate at 1 meter (mrem/hr):	30
Extrathyroidal Uptake Fraction	0.95	Revised gamma ray constant:	1.89274448
Extrathyroidal Eff. Half-Life	0.32		
Thyroidal Uptake Fraction	0.05		
Thyroidal Eff. Half-Life	7.3		
Distance (cm)	100		
Maximum likely external dose	224 millirems		
Maximum likely internal dose	84 millirems		
(can be ignored if < 10% external dose)			
MAXIMUM TOTAL LIKELY DOSE	**308 millirems**		

Radiation Safety Representative

UNIVERSITY OF VIRGINIA HEALTH SYSTEM

PLACE LABEL HERE.

IF LABEL NOT AVAILABLE, WRITE IN PT NAME & MR#

0700001

Nuclear Medicine
NRC WRITTEN DIRECTIVE AND BASIS FOR AUTHORIZING RELEASE FOR I-131 DOSES GREATER THAN 30 mCi

Note: Seek guidance from NM MD or chief tech if directives or procedures are not understood. Oral directives are not acceptable.

Patient Name: _____ **Hospital #:** _____ **Date:** _____

Radiopharmaceutical and Dose Prescribed

- ☐ I-131 for Hyperthyroidism
- ☐ I-131 for Thyroid Cancer
- ☐ I-131 for Thyroid Cancer Met
- ☐ I-131 Bexxar (After dosimetry)
- ☐ Other _____

- ☐ **Draw Bloods?** TSH Thyroglobulin B-Hcg
- ☐ **Pregnancy excluded by** _____
- ☐ **Patient Requires Dialysis?** (If yes, notify RSO)
- ☐ **Patient Breastfeeding?** (If yes, notify RSO)
- ☐ **Anyone in the household pregnant?** (Give extra instructions)

Prescription (to order but not to administer): Radiopharmaceutical, Dose, Form Route

_____

_____

Authorized User Signature: _____ **Date:** _____

Basis for Authorizing Release from Patient Questionnaire (pg 2) verified by Authorized User according to:

☐ Internal Dose INCLUDED ☐ Internal Dose EXCLUDED ☐ Patient Measurements attached

☐ **Maximum dose to a member of the general public from exposure to the patient will be less than 500 mRem**

Order to Administer - Authorized User Signature: _____ **Date:** _____

☐ **Two Patient ID Confirmations prior to Administration:**

☐ Full Name ☐ Date of Birth ☐ ID Band ☐ Home Address ☐ Drivers License

☐ **Patient provided with written instructions**

Doses Preparation & Administration: Lot # _____ Callibration Date/Time _____

Measured Activity _____ *minus* Residual Activity _____ *equals*

Activity Administered _____

Signature-Tech administering dose: _____ Signature-Dose Calibrator Checked: _____

Patient Questionnaire as a Basis for Authorizing Release for I-131 Doses Greater Than 30 mCi

Patient Name: _____ **Hospital #:** _____ **Date:** _____

Patient Release Criteria Determination

YES	NO	
☐	☐	1. Can maintain a distance of at least 3 feet from others for at least 2 days
☐	☐	2. Can sleep alone in a room for at least the first night
☐	☐	3. Will avoid travel by plane or mass transportation during the first 2 days after therapy
☐	☐	4. Will avoid travel on a prolonged automobile trip with others for at lease the first 2 days after therapy
☐	☐	5. Will be able to use a bathroom without sharing with others for the first 2 days after therapy.
☐	☐	6. Will be able to drink a cup of fluid every 4 hours for the first 2 days after therapy.
☐	☐	7. Will be able to live alone (or in a separate part of the house) for at least the first 2 days
☐	☐	8. Will have few visits by friends and family for at least the first 2 days

Patient Signature: _____ **Date:** _____

For NM Staff Use Only

Additional description of circumstances: _____

A. ☐ Answers to **1- 8** are all yes, occupancy factor is **0.125 and go to B**

☐ Answers to 1-6 are all yes but either **7** or **8 is no**, occupancy factor is **0.25** and go to B.

☐ Answer to any of patient questions **1- 6 is no, or additional circumstances are atypical**, then **STOP** as additional calculations and/or exposure rate measurements will be necessary prior to proceeding. Use Patient-Specific Calculation Record Form to document basis for alternate calculation and consult with authorized user and Radiation Safety office (982-4911).

Questionnaire administered by (sign & print): _____

B. ☐ **Includes internal dose contribution** Maximum dose to a member of the general public from exposure to the patient will be less than 500 mRem if the administered activity does not exceed that shown in the table below.

Purpose of Administration	Occupancy Factor	Admin. Activity (mCi)
Post-Thyroidectomy for Thyroid Cancer+	0.250	178 mCi or less
	0.125	230 mCi or less
Hyperthyroidism	0.250	53 mCi or less
	0.125	89 mCi or less

[Calculations use equations and referenced tables of Volume 9 of NUREG-1556 (which supercedes Reg. Guide 8.39) on file at OEHS and Nuclear Medicine.]

If the desired dose exceeds the above table, before going to **C**; please ENSURE the patient can adhere to **all** of the other precautions to reduce the spread of radioactive iodine on the instructions to patients.

C. ☐ **Excludes internal dose contribution** Maximum dose to a member of the general public from exposure to the patient will be less than 500 mRem if the administered activity does not exceed that shown in the table below.

Purpose of Administration	Occupancy Factor	Admin. Activity (mCi)
Post-Thyroidectomy for Thyroid Cancer+	0.250	220 mCi or less
	0.125	300 mCi or less
Hyperthyroidism	0.250	56 mCi or less
	0.125	98 mCi or less

If the desired dose exceeds the above table, **STOP** as additional calculations and/or exposure rate measurements will be necessary prior to proceeding. Use Patient-Specific Calculation Record Form to document basis for alternate calculation and consult with authorized user and Radiation Safety office (982-4911).

UNIVERSITY OF VIRGINIA HEALTH SYSTEM

PLACE LABEL HERE.

IF LABEL NOT AVAILABLE, WRITE IN PT NAME & MR#

0100000

CONSENT FOR ADMINISTRATION OF RADIOACTIVE IODINE-131 THERAPY FOR THYROID CANCER

A. CONSENT FOR PROCEDURE

I have received information about my condition, the proposed treatment, alternatives, and related risks. This form contains a brief summary of this information. I have received an explanation of any unfamiliar terms and have been offered the opportunity to ask questions. I understand I may refuse consent and I GIVE MY INFORMED AND VOLUNTARY CONSENT to the proposed procedures and the other matters shown below. I also consent to the performance of any additional procedures determined in the course of a procedure to be in my best interests and where delay might impair my health.

If an exploratory operation is proposed, I have been informed of possible conditions that may be discovered and I consent to performance of procedure(s) as determined by my physician to be in my best interests.

1. I authorize Dr. Patrice Rehm, Nuclear Medicine Attending and such physicians in training and assistants as s(he) may select, to treat my condition, including performing further diagnosis and the procedures described below, and taking any needed photographs. **I UNDERSTAND THAT PHYSICIANS IN TRAINING MAY PERFORM PORTIONS OF THE PROCEDURES DESCRIBED BELOW UNDER THEPARTICIPATORY SUPERVISION OF MY ATTENDING PHYSICIAN.**

2. I understand my condition to be: **Thyroid Cancer**

3. I understand the proposed procedure(s) to be: **Treatment of Thyroid Cancer with Radioactive Iodine orally and destruction of any remaining thyroid tissue.**

4. I understand the risks associated with the proposed procedure(s) to be:
I will need to take medication to replace thyroid hormone, this is no longer made by my body for the rest of my life. There is some whole body radiation, which could theoretically injure portions of the body. Of most concern is the possibility of increased risk of leukemia, but this is not a proven risk. There is a risk of temporary or permanent injury to the salivary glands, resulting in change in taste and the amount of saliva; temporary or rarely permanent radiation damage to the parathryoid glands; decrease in sperm production with associated decreased fertility in men.

5. I also understand that there may be other RISKS OR COMPLICATIONS, SERIOUS INJURY OR EVEN DEATH from both known and unknown causes. I am aware that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantees have been made to me concerning the risks of the procedure.

6. I understand the alternatives to the proposed procedures and the related risks to be: **a) Surgery with possible injury to structures in the neck; and risks related to general anesthesia; b) Radiation therapy by external sources with possible radiation injury to the neck and nearby structures; c) No treatment except thyroid hormone, which may not adequately control the cancer; or d) I may do nothing.**

☐ I consent to the above as a series of the same procedure over a time period from ___/___/___ to ___/___/___.

8. Vendor Presence: (Check box if applicable)
☐ I understand that, at the request of my physician, a vendor or medical equipment representative may be present during the performance of my procedure. Presence shall be limited to providing information for coordination of treatments, such as advice or education on medical device specifications and selection for proper sizing during the procedure, and providing technical expertise on the implant, use and operation of the vendor's equipment, by operating programmers, analyzers and other support equipment under the supervision of my physician.

B. CONSENT FOR ANESTHESIA OR SEDATION ☐ Not required

1. When local anesthesia and/or sedation is used by the physician on page one, Section A1:

☐ I consent to the administration of such ***local anesthetics*** as may be considered necessary by the physician in charge of my care. I understand that the risks of local anesthesia include: local discomfort, swelling, bruising, allergic reactions to medications, and seizures.

☐ I consent to the administration of ***sedative medications*** by or under the direction of the physician named in Item A1 or the physician in charge of my sedation care. I acknowledge that I have been informed of the nature of the planned sedation and that I understand the risks of sedation to include: allergic reactions to medications, changes in breathing, changes in blood pressure and heart function, nausea and vomiting, aspiration of stomach contents and/or excitement. I understand that recall of the procedure is possible.

---

2. When regional anesthesia, general anesthesia, or monitored anesthesia care is provided by the personnel in the **Department of Anesthesiology**:

☐ I consent to care provided by the physicians of the Department of Anesthesiology. I acknowledge that the anesthesia may actually be administered by a physician in training (resident) or nurse anesthetist under the direction of the anesthesiologist who is assigned to care for me. The anesthetic technique may be a general anesthetic ("being put to sleep") and/or a nerve block. I understand that the risks of anesthesia include: sore throat and hoarseness, nausea and vomiting, aspiration of stomach contents, muscle soreness, injury to the eyes, injury to the gums or lips, damage to the teeth or dental work, allergic reactions to medications, recall of procedure, changes in breathing, changes in blood pressure and heart function, nerve injury, cardiac arrest, brain damage, paralysis, or death.

Additional information regarding the various forms of anesthesia and pain control, risks, and options is available from the anesthesiologist directing your care.

C. PATIENT OR PARENT/LEGAL REPRESENTATIVE CERTIFICATION:

By signing below I state that I am 18 years of age or older, or otherwise authorized to consent. I have read or have had explained to me the contents of this form. I understand the information on this form and give my consent to what is described above and to what has been explained to me.

SIGNATURE OF PATIENT _____ DATE _____

If patient is a minor, incompetent or unable to give consent:

SIGNATURE OF RESPONSIBLE PARTY _____ DATE _____

RELATIONSHIP TO PATIENT OR LEGAL AUTHORIZATION _____

D. PHYSICIAN ATTESTATION

I have explained the procedure(s), alternative(s) and risks to the person or persons whose signature is affixed above. The patient and/or their legal representative has verbally communicated to me that they understand the contents of this form.

SIGNATURE OF PHYSICIAN OR DESIGNEE OBTAINING CONSENT _____ DATE _____

E. INTERPRETER ATTESTATION (when applicable)

I have provided translation to the person(s) whose signature(s) is affixed above.

SIGNATURE OF INTERPRETER _____ DATE _____

UNIVERSITY OF VIRGINIA HEALTH SYSTEM

1600000

PLACE LABEL HERE.

IF LABEL NOT AVAILABLE, WRITE IN PT NAME & MR#

INSTRUCTIONS TO PATIENTS RELEASED FROM UVA HOSPITAL CONTAINING GREATER THAN 6.9 mCi OF $Na^{131}I$

Patient Name: _____ **Hospital #:** _____ **Date:** _____

Patient and Family Instructions (write additional instructions on the back as needed)

- **Medications** - Resume previous thyroid medications as follows: _____
  _____
  _____
  _____
- Do not eat for 2 hours after swallowing the radioiodine. You may, however, drink clear liquids (water, coffee, tea, fruit juices and /or soft drinks).
- In the rare case you should vomit within two hours of receiving therapy, use paper towels to soak up the material and flush it down the toilet. Try not to spread the material around, as it will be radioactive. Wash your hands. Inform the nuclear medicine doctor as soon as possible.
- Drink as much fluid as tolerable for the first 2 days (48 hours)
- Chew gum, or suck on hard or sour candy, frequently, for 2 – 7 days to encourage the flow of saliva.
- Empty your bladder frequently (every 2 hours if possible) Men should sit down to urinate during this time to minimize contamination of toilet surfaces.
- Sit while urinating and flush the toilet 2 – 3 times after each time you urinate for the first 2 days and be sure to wash your hands well after each use.
- Maintain a prudent distance from others (approximately 6 feet or more). Avoid close contact with other people for the first 2 days, especially infants, children and pregnant women. Radioactive contamination may be spread to others through you perspiration, saliva, urine and feces. If a small child is in the home, limit close contact to that required for the child's care.
- Sleep alone in a bed for a least the first 2 nights.
- Avoid becoming pregnant for 6 months.
- Do not travel by airplane or mass transportation for at least the first 2 days
- Do not travel on a prolonged automobile trip with others for a least the first 2 days.
- Minimize time in public places (example: grocery stores, shopping centers, theaters, restaurants, sorting events).
- If you develop significant soreness or swelling in the salivary glands, contact the Nuclear Medicine doctor.
- If you have not had a bowel movement within 2 days after your radioactive iodine therapy, take a laxative.

Other precautions to reduce the spread of radioactive iodine.

- Do not let others use your bathroom, if possible, for the first 2 days.
- Menstruating women should use tampons that can be flushed down the toilet.
- Shower daily and use separate towels for the first 2 days
- Use separate washcloths and toothbrush from rest of household.
- Wear clothing that can be laundered (not dry cleaned) for the first 2 days.
- After 5 days, wash your clothing, towels and bedding separately (put through wash/rinse cycles twice).
- Use disposable cups, plates and silverware for the first few days and wash them separately.

Important Telephone Numbers

During normal business hours (8:00 am–5:00 pm call Nuclear Medicine at 434-924-9358
After hours urgent calls can be made to 434-924-0000 and ask to speak to the Nuclear Medicine doctor on call.
If you have an Emergency, call 911.

Additional Instructions: _____

_____

_____

_____

_____

_____

_____

I have reviewed the release instructions with the patient and /or family or caregiver. The patient or caregiver was able to verbalize understanding of the instructions. A copy of these written instructions was given to the patient or caregiver.

Name: _____ Date: _____ Time: _____

Release instructions have been explained to me and/or my family or caregiver. I have received a copy of the instructions and I understand them

Name: _____ Date: _____

Circle one: Patient/Family/Caregiver Signature

NRC Regulatory Guide 8.39
Calculating Doses Based on Patient-Specific Factors

Calculation

$$D(t) = \frac{34.6\ \Gamma\ Q_o\ T\ E\ (1 - e^{-0.693\ t\ /\ Tp})}{r^2}$$

Q_o = Administered activity (mCi)
T = Half Life
Γ = 2.2 R/mCi x hr @ 1 m
r = 100 cm (1 meter)

Resulting Dose D(t)	Administered Activity (Q_o)	Calculation Assumptions	Record of Calc. Required? Basis
500 mrem	30 mCi	Dose to total decay t = ∞ so $(1 - e^{-0.693\ t/Tp})$ is set = 1 Use physical half-life T = 8.04 d Occupancy Factor (E) = 0.25, nuclide has T_p > 1 day	No
500 mrem	60 mCi	Use physical half-life E = 0.125	Yes 35.75 c E < 0.25 at 1 meter used

Calculation

$$D(\infty) = \frac{34.6\ \Gamma\ Q_o}{(100\ cm)^2}\left[E_1\ T_p\ (0.8)\ (1 - e^{-0.693(0.33)/Tp}) + e^{-0.693\ (0.33)\ /\ Tp}\ E_2\ F_1\ T_{1eff} + e^{-0.693\ (0.33)/Tp}\ E_2\ F_2\ T_{2eff}\right]$$

first component | 2nd component | 3rd component

453 mrem 501 mrem (internal dose added)	200 mCi 179 mCi	Patient administered dose for treatment of **Postthyroidectomy for Thyroid Cancer** First component E_1 = 0.75 T_p = 8.04 day Table B-1 Values for Second component E_2 = 0.25 and Third component E_2 = 0.25, based on occupancy factor questionnaire Extrathyroidal Component F_1 = 0.95 T_{1eff} = 0.32 day Thyroidal Component F_2 = 0.05 T_{2eff} = 7.3 day $D_{0.25}$ = 2.27 Q_o	Yes Use of retained activity Use of effective half-life
334 mrem 500 mrem 500 mrem (internal incl.)	200 mCi 300 mCi 230 mCi	Same as above except 2nd and 3rd component occupancy factors E = 0.125 (not include internal) $D_{0.125}$ = 1.67 Q_o	Yes 35.75c Use of retained activity effective half-life E < 0.25 at 1 meter

Calculation

$$D(\infty) = 34.6\,\Gamma\,Q_o - \frac{\left[E_1 T_p (0.8)(1 - e^{-0.693(0.33)/Tp}) + e^{-0.693(0.33)/Tp} E_2 F_1 T_{1eff} + e^{-0.693(0.33)/Tp} E_2 F_2 T_{2eff}\right]}{(100\text{ cm})^2}$$

first component 2nd component 3rd component

Resulting Dose D(t)	Administered Activity (Q_o)	Calculation Assumptions	Record of Calc. Required? Basis
486 mrem 500 mrem 500 mrem (internal incl.)	55 mCi 57 mCi 53 mCi	Patient administered dose for treatment of **Hyperthyroidism** First component $E_1 = 0.75$ $T_p = 8.04$ day Table B-1 Values for Second component $E_2 = 0.25$ and Third component $E_2 = 0.25$, based on occupancy factor questionnaire Extrathyroidal Component $F_1 = 0.20$ $T_{1eff} = 0.32$ day Thyroidal Component $F_2 = 0.80$ $T_{2eff} = 5.2$ day $D_{0.25} = 8.84\,Q_o$	Yes Use of retained activity Use of effective half-life
271 mrem 500 mrem 500 mrem (internal incl.	55 mCi 98 mCi 89 mCi	Same as above except 2nd and 3rd component occupancy factors E = 0.125 $D_{0.125} = 4.94\,Q_o$	Yes 35.75c Use of retained activity effective half-life E < 0.25 at 1 meter

10^{-5} = Assumed fractional intake; and

DCF = Dose conversion factor to convert an intake in millicurie to an internal committed effective dose equivalent (such as tabulated in Reference B-2).

Equation B-6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb was developed in reference B-3 for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility, but it does not specifically apply to cases of intake by an individual exposed to a patient. However, two studies (Refs. B-4 and B-5) regarding the intakes of individuals exposed to patients administered iodine-131, indicated that intakes were generally of the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of 10^{-5} has been assumed.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient to whom 1221 megabecquerels (33 millicuries) of iodine-131 has been administered. The ingestion pathway was selected because it is likely that most of the intake would be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

per Dwight no one includes

Solution: This is an example of the use of Equation B-6. The dose conversion factor DCF for the ingestion pathway is 53 rem/millicurie from Table 2.2 of Reference B-2.

Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (33\ \text{mCi})(10^{-5})(53\ \text{rem/mCi})$$

$$D_i = 0.17\ \text{mSv}\ (0.017\ \text{rem})$$

200 = 106 mrem
+ 453 for 200
559 mrem
10% of 453 = 45
106 > 45

Using Equation B-1 and assuming the patient has received instructions for reducing exposure as recommended for an occupancy factor of 0.25, the external dose is approximately 5 mSv (0.5 rem). Thus, the internal dose is about 3% of the external dose due to gamma rays. Internal doses may be ignored in calculations of total dose if they are likely to be less than 10% of the external dose because the internal dose due to this source is small in comparison to the magnitude of uncertainty in the external dose.

The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP. The NCRP addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients" (Ref. B-6). The NCRP concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely." For additional discussion on the subject, see Reference B-1.

Appendix 9

Attached please find a spreadsheet containing the 1-131 thyroid cancer therapies greater than 30 mCi for 2 years prior to your inspection of our facility [July 2005-June 2007]. Patient names have been reduced to initials to protect confidentiality. A chart explaining each column is below.

In all cases 1-131 was administered in capsule form and therefore there is no residual dose calculation. 1-131 dose amounts are as measured in the Capintec dose calibrator in millicuries and subsequently administered orally [not the prescribed dosage.] The practice since June of 2005 has been to determine occupancy factor for each potential patient according to the criteria outlined in **Patient Questionnaire as a Basis for Authorizing Release for 1-131 Doses Greater Than 30 mCi**. All 1-131 cancer therapies greater than 30 mCi must meet an occupancy factor of 0.25. In addition, those patients expected to receive an 1-131 dose of greater than 230 mCi must meet criteria for an occupancy factor of 0.125 for release. If those criteria are not met, the Authorized User and Radiation Safety Office must be consulted. Patients are then assigned a Patient Class and released based on the chart on said document.

1-131 theraputic doses greater than 200 mCi are highlighted and justification for release retrospectively generated with software using guidance from US NRC Regulatory Guide 8.39 and NUREG 1556 Volume 9 Appendix U equation B.5 and default values set therein are included. In addition I have provided justification for those patients with a higher occupancy factor [0.25] regardless of dosage. Whenever possible, a patient-specific calculation is offered as well using measured exposure rates. In the case of an exposure meter reading that is not justified by the dose, i.e. higher than expected for an unshielded source of the capsule strength, the default gamma ray constant for 1-131 has been used. The most likely reason for an aberrant meter reading is contribution from other radionuclides in use in the Nuclear Medicine suite at the time of measurement. In the some cases where no exposure rate was recorded, the patient-specific thyroid uptake values provided by a Nuclear Medicine physician were used. Prior to August of 2006, pertinent survey measurements of dose rate from the patient were not recorded by Nuclear Medicine staff. The 2006-2007 patient calculations support our release criteria.

When an 1-131 therapy patient cannot meet NRC release criteria because of occupancy factor concerns [there have been no doses over 300 mCi in the past two years] he or she is hospitalized in one of four lead-lined rooms in the Medical Center cancer wing 3-East, where nurses are dosimetry-badged and regularly care for patients with radioactivity restrictions. The data presented here support our current release policy.

Explanation of spreadsheet:
Column 1 Patient number
Column 2 Patient Initials
Column 3 Date of 1-131 therapy dose
Column 4 Calibrated 1-131 dose
Column 5 1 meter reading when recorded
Column 6 Occupancy as determined by Patient Questionnaire [copy attached]
Column 7 Physician determined patient-specific uptake when used for calculation
Column 8 Maximum dose to a member of the general public according to equation B.5, calibrated dose and patient-specific occupancy factor
Column 9 Maximum dose to a member of the general public generated using patient- specific exposure measurements as well as equation B.5 etc.
Column10 Notes

References:

1. U.S. Nuclear Regulatory Commission, 10 CFR Part 35.75 and 35.2075

2. U.S. Nuclear Regulatory Commission, NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Use Licenses", Appendix U – Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials, October 2002.

3. U.S. Nuclear Regulatory Commission, Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials", April 1997.

	Date	Patient Initials	Date	I-131 Dose	1mt reading mr/hr	Occupancy Factor	Patient Uptake	Dose Max to member general Public	Pt-specific dose Max incl internal	Notes:
1	6/21/2007	BS	6/21/2007	157.9	13.5	0.125				
2	6/14/2007	WM	6/14/2007	155.1	21	0.125				
3	6/13/2007	MC	6/13/2007	103.3	22	0.125				
4	6/13/2007	GM	6/13/2007	102.6	29	0.125				
5	6/6/2007	SK	6/6/2007	102.2	28	0.125				
6	6/6/2007	HJ	6/6/2007	158.5	30	0.125				
7	6/5/2007	WD	6/5/2007	208	24	0.125		342.9	290	
8	6/4/2007	BE	6/4/2007	103.2	25	0.125				
9	5/31/2007	BA	5/31/2007	161.1	11.6	0.125				
10	5/23/2007	MM	5/23/2007	150	32.1	0.125				
11	5/21/2007	TM	5/21/2007	234	10.5	0.125		387.5	203	
12	5/16/2007	SD	5/16/2007	226	21	0.125		372.6	277	
13	5/9/2007	BY	5/9/2007	150.2	17.5	0.125				
14	5/1/2007	MM	5/1/2007	103.4	13.5	0.125				
15	5/1/2007	SA	5/1/2007	30.8	6.3	0.125				
16	4/25/2007	PB	4/25/2007	110.5	12.1	0.125				
17	4/16/2007	MS	4/16/2007	157.2	13.2	0.125				
18	4/13/2007	ML	4/13/2007	159.6	52	0.125				
19	4/2/2007	ME	4/2/2007	158	6.7	0.125				
20	3/28/2007	GD	3/28/2007	100.8	10.5	0.25			161	
21	3/8/2007	WJ	3/8/2007	104.8	22	0.125				
22	3/6/2007	JJ	3/6/2007	244	21	0.125		402.2	287	
23	2/28/2007	CT	2/28/2007	107	39	0.125				
24	2/26/2007	WR	2/26/2007	212	43	0.125		349.5	433	
25	2/22/2007	LSG	2/22/2007	213	12.1	0.125		351.1	204	
26	2/5/2007	HAS	2/5/2007	211	60	0.125		347.8	460	Default gamma ray
27	1/29/2007	CK	1/29/2007	104.9	10	0.125				
28	1/25/2007	VM	1/25/2007	103.1	18	0.125				
29	1/19/2007	HH	1/19/2007	152	15.8	0.125				
30	1/15/2007	DW	1/15/2007	103.8	8	0.125				
31	1/12/2007	WE	1/12/2007	108.1	7	0.125				
32	1/11/2007	DR	1/11/2007	103.8	12	0.25			178	
33	12/28/2006	EMS	12/28/2006	203	9	0.125		334.6	175	

Date	Patient Initials	~~Date~~	I-131 Dos
7/12/2006	TJ	7/12/2006	208
7/11/2006	JDT	7/11/2006	109.
7/10/2006	CK	7/10/2006	102
7/7/2006	PR	7/7/2006	152.
6/27/2006	OL	6/27/2006	152
6/23/2006	RS	6/23/2006	157.
6/13/2006	DS	6/13/2006	287
6/13/2006	GK	6/13/2006	153.
5/30/2006	VJ	5/30/2006	163.
5/26/2006	HD	5/26/2006	101
5/9/2006	RR	5/9/2006	262
5/3/2006	AS	5/3/2006	205
5/2/2006	MS	5/2/2006	210
5/2/2006	CM	5/2/2006	153.
4/26/2006	FM	4/26/2006	101.
4/25/2006	AS	4/25/2006	202
4/20/2006	WP	4/20/2006	158.
4/19/2006	GL	4/19/2006	153
4/14/2006	BD	4/14/2006	200
4/10/2006	DK	4/10/2006	149.
4/3/2006	BT	4/3/2006	106.
3/27/2006	JF	3/27/2006	210
3/24/2006	TM	3/24/2006	101
3/22/2006	YS	3/22/2006	99.5
3/21/2006	HR	3/21/2006	154
3/20/2006	JF	3/20/2006	198.
3/14/2006	GJ	3/14/2006	157.
3/3/2006	FC	3/3/2006	150
2/23/2006	NM	2/23/2006	153
2/17/2006	PJ	2/17/2006	151.
2/16/2006	AL	2/16/2006	207
2/16/2006	DM	2/16/2006	152
2/1/2006	JJ	2/1/2006	213

	Date	Patient Initials	Date	I-131 Dose	1mt reading mr/hr	Occupancy Factor	Patient Uptake	Dose Max to member general Public	Pt-specific dose Max incl internal	Notes:
34	12/27/2006	WH	12/27/2006	178	7.7	0.125				
35	12/20/2006	PK	12/20/2006	50.7	2.7	0.125				
36	12/15/2006	TC	12/15/2006	147.6	6.1	0.125				
37	12/15/2006	DW	12/15/2006	104.6	13.3	0.125				
38	12/11/2006	CC	12/11/2006	148.2	7.2	0.125				
39	12/7/2006	HMM	12/7/2006	145.3	5	0.125				
40	12/4/2006	DD	12/4/2006	149.6	15	0.125				
41	11/9/2006	NK	11/9/2006	147.1	12.6	0.125				
42	11/3/2006	BJ	11/3/2006	100	0.54	0.125				
43	11/3/2006	HE	11/3/2006	99.7	9.3	0.125				
44	10/30/2006	LA	10/30/2006	103.8	11.4	0.125				
45	10/23/2006	YW	10/23/2006	147.3	27	0.125				
46	10/23/2006	WV	10/23/2006	98.3	10	0.125				
47	10/18/2006	ML	10/18/2006	98.6	7	0.25			124	
48	10/17/2006	RM	10/17/2006	99.4	10	0.25			156	
49	10/6/2006	RW	10/6/2006	142.3	21	0.125				
50	10/5/2006	CG	10/5/2006	145	24	0.125				
51	10/5/2006	SE	10/5/2006	103.1	16.7	0.125				
52	10/2/2006	SV	10/2/2006	152	18	0.125				
53	9/13/2006	JS	9/13/2006	261	60	0.125	>1%	430.2	498	Default gamma ray
54	9/13/2006	TY	9/13/2006	249	9	0.125		410.5	188	
55	9/12/2006	RM	9/12/2006	100.4	13.9	0.125				
56	8/30/2006	PN	8/30/2006	101.7		0.5				Hospitalized as inpatient
57	8/23/2006	CJ	8/23/2006	100.4	13.4	0.125				
58	8/18/2006	VC	8/18/2006	148.4	36	0.125				
59	8/15/2006	MC	8/15/2006	102.2	15.2	0.125				
60	8/8/2006	MW	8/8/2006	153.5		0.5				Hospitalized as inpatient
61	7/31/2006	DW	7/31/2006	51.9	9.5	0.125				
62	7/28/2006	WC	7/28/2006	167.5		0.125				
63	7/25/2006	LO	7/25/2006	114.3		0.125				
64	7/17/2006	JL	7/17/2006	160.4		0.125				
65	7/14/2006	PC	7/14/2006	156		0.125				
66	7/13/2006	CM	7/13/2006	105		0.125				

	Date	Patient Initials	~~Date~~	I-131 Dose	1mt reading mr/hr	Occupancy Factor	Patient Uptake	Dose Max to member general Public	Pt-s ecific Pt-specific dose Max incl internal	Notes:
100	2/1/2006	PO	2/1/2006	153.1		0.125				
101	1/30/2006	JB	1/30/2006	220		0.125		362.7		
102	1/30/2006	CA	1/3012006	157.7		0 125				
103	1/1612006	HA	1/16/2006	202		0.25		458		
104	I212812005	TE	12/28/2005	104.9		0.125				
105	12/19/2005	MK	12/19/2005	158		0.125				
106	12/14/2005	WC	12/14/2005	147.7		0.125				
107	12/13/2005	LB	12/13/2005	100.5		0.125				
108	12/9/2005	sl	12/9/2005	175		0.125				
109	12/1/2005	JL	12/1/2005	151.1		0.125				
110	11/21/2005	CJ	11/21/2005	156.3		0.125				
111	11/21/2005	WM	11/21/2005	155.4		0.125				
112	1011012005	DS	10/1012005	193.7		0.125				
113	10/4/2005	RS	10/4/2005	200.1		0.125		329.9		
114	9/23/2005	MW	9/23/2005	202		0.125		333		
115	8/29/2005	YT	8/29/2005	198		0.125				
116	8/25/2005	JS	8/25/2005	247		0 125		407.2		
117	8/25/2005	JE	8/25/2005	209		0.125		344.5		
118	8/15/2005	NK	8/15/2005	109.8		0.125				
119	8/15/2005	JP	8/15/2005	33.1		0.125				
120	8/12/2005	WT	8/12/2005	161.5		0.125				
121	8/9/2005	GC	8/9/2005	102.1		0.125				
122	8/8/2005	OF	8/8/2005	149		0.125				
123	8/4/2005	LA	8/4/2005	107.3		0.125				
124	8/3/2005	TM	8/3/2005	200		0.25	<1%	458	461	Patient specific uptake
125	7/29/2005	DJ	7/29/2005	202		0.125		333		
126	7/11/2005	ML	7/11/2005	148		0.25			414	
127	7/7/2005	VK	7/7/2005	98.9		0.125				