UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

March 5, 2010

EA-10-023
NMED NO. 090748

Mr. Gary Williams, M.S., Interim Director
National Health Physics Program (115 HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 030-34325/2009-002(DNMS), VETERANS AFFAIRS SAN DIEGO HEALTHCARE SYSTEM, SAN DIEGO, CALIFORNIA

Dear Mr. Williams:

On November 2 and 3, 2009, the U.S. Nuclear Regulatory Commission (NRC) inspectors conducted a reactive inspection at the Department of Veterans Affairs (DVA), Master Materials License (MML), Veterans Affairs San Diego Healthcare System (VASDHS, permittee). The purpose of the inspection was to review the circumstances surrounding a reported medical event involving a therapeutic dose of sodium iodide iodine-131 (I-131) that was administered to a patient through a gastrostomy feeding tube (g-tube) that occurred between September 21 and 25, 2009. The medical event was the direct result of the administration of the majority of the I-131 dosage into the wrong port of the gastrostomy feeding tube which resulted in an underdose to the patient's thyroid and an unintended dose to the patient's stomach. Our inspection included in-office review through February 3, 2010, to review the dose assessment for the patient's stomach. The enclosed report presents the results of this inspection. The NRC also contracted a medical consultant, Ronald E. Goans, M.D., Ph.D., MPH, to review the medical significance of the medical event. Dr. Goans' report is enclosed.

This inspection examined activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions in your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, three apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforcement-pol.html. The apparent violations involve the failure to: (1) develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive as required by Title 10 Code of Federal Regulations (CFR) 35.41(a)(2); (2) instruct supervised individuals on procedures for administering byproduct material through a gastrostomy feeding tube in order to ensure that byproduct material was administered in accordance with the written directive as required by 10 CFR 35.27 (a)(1); and (3) report a medical event to the NRC by the next calendar day after

discovery as required by 10 CFR 35.3045 (c). The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with members of your staff at the on site exit meeting on November 3, 2009, and during the final telephone exit meeting on February 3, 2010. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision.

In addition to the apparent violations, the NRC identified two concerns which were associated with the medical event. Specifically, the manner in which the permittee staff handled and transferred the I-131 dosage within the patient's room, prior to the administration, could have resulted in a spill and in the contamination of personnel. In addition, the permittee's As Low As Reasonably Achievable (ALARA) assessment regarding the I-131 dosage transfer did not exhibit conservative decision-making.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violations and concerns addressed in this inspection report within 30 days of the date of this letter; or (2) request a predecisional enforcement conference. If a conference is held, it will be open for public observation. The NRC will also issue a press release to announce the conference. Please contact Patricia J. Pelke at 630-829-9868 within seven days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in Inspection Report No(s). (030-34325/2009-002); EA-10-023" and should include for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation(s). The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

Sincerely,

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

Docket No. 030-34325
License No. 03-23853-01VA

Enclosure(s):
1. Inspection Report No. 030-34325/2009-002(DNMS)
2. Medical Consultant's Report
3. G-Tube Diagram

cc w/ encls: Stan Johnson, Medical Center Director, VASDHS
Rene Michel, M.S., Radiation Safety Officer, VASDHS

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-34325
License No.:	03-23853-01VA
Report No.:	030-34325/2009-002(DNMS)
EA No.:	EA-10-23
Licensee:	Department of Veterans Affairs (DVA)
Location:	Veterans Affairs San Diego Healthcare System [permittee under the DVA's Master Materials License]
Address:	3350 La Jolla Village Drive San Diego, California
Dates:	November 2 and 3, 2009, (On-site exit meeting November 3, 2009) with continued in-office review through February 3, 2010
Final Exit Meeting:	February 3, 2010 (Telephone)
Inspectors:	Peter J. Lee, Ph.D. CHP, Health Physicist Deborah A. Piskura, Health Physicist
Approved By:	Patricia J. Pelke, Chief Materials Licensing Branch Division of Nuclear Materials Safety

Enclosure 1

EXECUTIVE SUMMARY

Veterans Affairs San Diego Healthcare System (VASDHS)
NRC Inspection Report No. 030-34325/09-002(DNMS)

The U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection on November 2 and 3, 2009. The purpose of the inspection was to review the circumstances surrounding a medical event involving a therapeutic dose of sodium iodide iodine-131 (I-131) that was administered to a patient through a gastrostomy feeding tube (g-tube) that occurred between September 21 and 25, 2009. The medical event was the direct result of the administration of the majority of the I-131 dosage into the wrong port of the gastrostomy feeding tube which resulted in an underdose to the patient's thyroid and an unintended dose to the patient's stomach.

Based on the results of this inspection, three apparent violations were identified involving the licensee's failure to: (1) develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive; (2) instruct supervised individuals on procedures for administering byproduct material through a g-tube in order to ensure that byproduct material was administered in accordance with the authorized user's written directive; and (3) report a medical event to the NRC by the next calendar day after discovery.

In addition to the apparent violations, the NRC identified two concerns which were associated with the medical event. Specifically, the manner in which permittee staff handled and transferred the I-131 dosage within the patient's room, prior to the administration, could have resulted in a spill and in the contamination of personnel. In addition, the permittee's As Low As Reasonably Achievable (ALARA) assessment regarding this event did not exhibit conservative decision-making.

The root causes of the medical event were: (1) a lack of written procedures for administrations through a g-tube; (2) a lack of training and experience among the staff participating in g-tube administrations; (3) a lack of awareness among the staff involved regarding: (a) the condition of the patient (required treatment via a g-tube) and (b) the type of g-tube involved and how it functioned; (4) a lack of communication between key personnel such as the authorized user, the chief nuclear medicine technologist, and the Radiation Safety Officer (RSO) who were intermittently either off-site or otherwise unavailable for consult by staff during the course of the patient treatment; and (5) a lack of a questioning attitude. The root causes of the apparent violations were: (1) a lack of recognition of the importance of providing clear guidance and direction for infrequently performed administrations of I-131 dosages through g-tubes with inexperienced staff; and (2) the staff's "wait and see" approach for assessing the I-131 treatment.

The NRC contracted a medical consultant to review the medical event and determine if any adverse health consequences to the patient were expected. The medical consultant concurred with the inspector's and the licensee's dose estimates to the patient's stomach wall which was approximately 17 to 19 Gray (Gy) (1,700 to 1,900 radiation absorbed dose (rads)). The medical consultant did not report any adverse health effects to the patient as a result of the unintended dose to the patient's stomach, which was confirmed with the patient's physician.

The permittee immediately halted any g-tube administrations until the direct cause of the medical event could be identified. The permittee also suspended one individual's participation in administrations requiring a written directive. The RSO provided informal training to the nuclear medicine technologists. The permittee established a root cause analysis team to review this medical event. The permittee is continuing to develop and implement long-term correction action to prevent recurrence of the violations.

Report Details

1 Program Scope and Inspection History

The Department of Veterans Affairs (DVA) holds a master materials license (MML), which authorizes the DVA to issue permits for the possession and use of licensed material, and ties the licensee to a framework of oversight consistent with NRC regulations and inspection and enforcement policies, procedures, and guidance. The DVA National Radiation Safety Committee (NRSC) has the responsibility for providing oversight of the DVA's implementation of its MML and associated permittee activities. The NRSC has delegated the authority to manage the DVA radiation safety program to its National Health Physics Program (NHPP). The licensee is the Department of Veterans Affairs (DVA). The Veterans Affairs San Diego Healthcare System (VASDHS) is a permittee under the DVA's MML.

The VASDHS is a medical broad scope permittee authorized to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments included sodium iodide iodine-131 (I-131) for the treatment of thyroid diseases, including thyroid cancer. The permittee's Radiation Safety Committee (RSC) approved two authorized physician users to administer approximately 10-12 thyroid carcinoma treatments annually. Seven nuclear medicine technologists worked under the supervision of the authorized physician users. Typically, the permittee administered I-131 treatments to patients orally, using capsules. All patients administered dosages greater than 33 millicuries (mCi) were hospitalized at the VASDHS in accordance with the requirements in Title 10 Code of Federal Regulations (CFR) Part 35.75. On June 10, 2009, the permittee administered I-131 in liquid form through a single lumen gastronomy tube (g-tube) for the treatment of thyroid carcinoma. This procedure was completed successfully.

The NRC last inspected the VASDSH on March 10, 2005, with no violations identified. The NHPP inspected the VASDHS on February 21-22, 2007, and March 17-18, 2009, with no violations identified. In response to the medical event reported on September 26, 2009, regarding a patient undergoing treatment for metastatic thyroid carcinoma on September 21, 2009, who received a dose (administered through a feeding tube) that was less than 80 percent of the prescribed dose, the NHPP conducted a reactive inspection at the VASDHS on September 30, 2009 with continued review through December 23, 2009. They identified four violations, which included the VASDHS's failure to: (1) have adequate written procedures to provide high confidence that each administration was in accordance with the written directive; (2) have adequate written procedures to address verification that the administration was in accordance with the written directive; (3) perform adequate surveys for contamination; and (4) provide adequate radiation safety training.

2 Sequence of Events

2.1 Inspection Scope

The inspection included a review of the sequence of events that resulted in an unintentional dose to the patient's stomach. The inspection included interviews of selected licensee staff, reviews of selected records, and observations of equipment and facilities.

2.2 Observations and Findings

On Monday, September 21, 2009, the VASDHS admitted a 63 year-old male patient for treatment of metastatic thyroid cancer. The patient had previous surgery for removal of tumors and required a gastronomy tube (g-tube) for feeding. The authorized physician user (AU) prepared a written directive prescribing the treatment with a dosage of 200 mCi of I-131. Prior to the administration of the dosage, the chief nuclear medicine technologist (CNMT) and the AU interviewed the patient and provided instructions on radiation safety precautions. During these discussions, the patient informed the staff that he had a g-tube (see diagram, Enclosure 3). The g-tube consisted of two lumens with three ports of entry: a balloon port which is used to inflate a balloon that holds the g-tube in place, a medication port which is used for administering medications, and a feeding port which is used for administering nutritional supplements, water, etc. The balloon port was connected to one lumen with a closed end. The medication and the feeding ports were connected to the second separate lumen which had an open end that allowed nutritional supplements, water, medications, etc. to pass into the patient.

The nuclear medicine staff placed the order for the I-131 in liquid form with the intent of administering the material through the patient's g-tube. Once the package arrived from the radiopharmacy, the CNMT drew the I-131 into a syringe. At approximately 3:30 pm, the CNMT, a senior nuclear medicine technologist (SNMT), and the AU brought the dosage to the patient's room for the administration. The team deferred the administration to the SNMT because he had prior experience administering agents (excluding nuclear materials) through g-tubes. However, no instruction was provided to either of the nuclear medicine technologists present on radiation protection procedures or written directive procedures involving g-tube administrations.

Title 10 CFR Part 35.27(a)(1) requires in part that the licensee instruct supervised individuals on the licensee's written radiation protection procedures and written directive procedures with respect to the use of byproduct material. The licensee's failure to instruct two nuclear medicine technologists, working under the direct supervision of an AU, on the administration of licensed material through a g-tube is an apparent violation of 10 CFR Part 35.27(a)(1). The root cause was a lack of recognition of the importance of providing clear guidance and direction for infrequently performed administrations of I-131 dosages through g-tubes with inexperienced staff. Typically, therapeutic administrations were performed only by the CNMT with over 30 years of experience. However, for this event, the procedure was a training case in the administration of nuclear materials via a g-tube for the SNMT.

The SNMT intended to administer the I-131 dose through the "medication" port of the g-tube. However, the orientation of the patient's g-tube made it difficult to view the markings on the ports. Further, the medication port stopper was closed and the balloon port was open, leading the SNMT to believe that the balloon port was the medication port. As the SNMT attempted to inject the dosage in what he thought was the "medication" port he noted back pressure on the syringe and aborted the process. The SNMT did not believe any material was administered at this time. The team agreed to administer the dosage through the feeding port. However, the syringe did not fit the coupling of the feeding port. Therefore, the team agreed to administer the dosage using an irrigation syringe which fit the coupling of the feeding port.

The SNMT transferred the contents of the syringe into an irrigation syringe by aligning the two syringe couplings and injecting the contents from the syringe into the irrigation syringe. This transfer of I-131 occurred in the patient's room with the AU and the CNMT present. No additional engineering controls were in place such as the use of a portable mini-hood (equipped with a charcoal filter). No written radiation protection procedures were in place at the time of this transfer for staff to reference. No practice run was performed for this procedure and the potential for contamination was eminent if the SNMT failed to complete the transfer. The manner in which the staff transferred the dose of I-131 within the patient's room could have resulted in a spill with a high likelihood of contamination of not only the permittee's staff, but also the patient, which could have resulted in overexposures. The staff also could have transported the dose to the nuclear medicine hot lab and transferred the contents into the irrigation syringe within the fume hood. The staff expressed concern that they did not have a syringe shield that would fit the irrigation syringe, so for the sake of time and patient care, they elected to transfer the dose of I-131 in what they considered to be the most efficient manner. The staff also stated to the inspectors "it was not ALARA to handle and transport the dose of I-131 to the hot lab, through the hospital, and then re-attempt to administer the dosage." The manner in which permittee staff handled and transferred the I-131 dosage within the patient's room, prior to the administration and their ALARA assessment of this activity have been identified as areas of concern.

The SNMT transferred the dose of I-131 into the irrigation syringe and added sterile water to bring the total volume to approximately 20 to 30 cubic centimeters. He administered the contents of the irrigation syringe through the feeding port of the patient's g-tube and followed with additional water flushes. Based on the activity administered, the AU anticipated that the patient would be released from the hospital on Wednesday, September 23, 2009.

Typically, for patients administered therapeutic doses of I-131 orally, with normal renal function, 90 to 95 percent of the administered dosage of I-131, which had not been adsorbed by the residual and metastatic thyroid tissues, is rapidly metabolized and excreted in the urine. For such patients, there is a rapid reduction in the external radiation profile commensurate with the biological elimination of unbound I-131. Following this initial rapid decline in external radiation levels, the measurements would normally diminish according to an effective half-life of about three days (due to a combination of physical radiological decay and biological decay).

During each day the patient was hospitalized, a health physicist measured radiation levels at the patient's bedside and at one meter from the patient. Since the I-131 was injected into the balloon port of the feeding tube and not into the feeding port, the majority of the I-131 was not metabolized by the patient, but remained in the balloon. The result was little biological elimination of the I-131 and no initial rapid reduction in radiation levels. Radiation levels measured on September 21, post-administration of the dosage were 33 milliRoentgen per hour (mR/hr) at one meter from the patient. Radiation levels measured on September 22 and 23; were 34 and 27 mR/hr at one meter from the patient, respectively.

On September 23, the patient was transported to the nuclear medicine department for imaging. The staff noted I-131 uptake in the patient's head and neck regions and a significant region of interest in the abdominal area. The AU suspected that some I-131 might have been lodged within the g-tube and requested the tube be flushed with water. The AU informed the patient that he would not be released from the hospital at this time. On September 24, radiation measurements were 25 mR/hr at one meter from the patient, which confirmed that the radiation levels were diminishing according to the physical decay of I-131. The AU instructed the nuclear medicine staff that if the radiation levels were still high the next day, then they were to transport the patient to the interventional radiology department for removal and exchange of the g-tube.

On Friday morning, September 25, the radiation measurements were 22 mR/hr at one meter from the patient. The nuclear medicine staff concluded the readings were high, and scheduled the removal of the g-tube. Nuclear medicine staff coordinated the removal of the g-tube and transported the patient to the interventional radiology suite. The SNMT informed members of the interventional radiology staff present that this was a "hot" patient and to place all waste from this patient procedure in a biohazard waste bag ("red bag"). However, no instruction on radiation safety precautions such as contamination control and waste control was provided to the interventional radiology members who provided care to the patient. Title 10 CFR Part 35.27(a)(1) requires, in part, that the licensee instruct supervised individuals on the licensee's written radiation protection procedures with respect to the use of byproduct material. The licensee's failure to provide radiation safety instruction to the interventional radiology staff is another example of an apparent violation of 10 CFR Part 35.27(a)(1). The root cause was a lack of recognition of the importance of providing clear guidance and direction for infrequently performed administrations of I-131 dosages through g-tubes with inexperienced staff.

The interventional radiology staff prepped the patient and proceeded to exchange the potentially contaminated g-tube with a new tube. In order to remove the g-tube, the interventional radiologist withdrew the fluid to deflate the balloon. The interventional radiologist put the g-tube into the waste container by tossing it into the container, which created a splatter of contamination on the floor of the interventional procedure room in the interventional radiology suite. This act demonstrated that if proper radiation safety instruction had been provided, proper precautions for handling potentially contaminated articles would have been taken. All draping, gloves, the g-tube, and the syringe were placed in a biohazard waste bag ("red bag"). The SNMT transported the patient to his hospital room and called the Radiation Safety Officer (RSO) requesting that he survey the patient. The "red bag" waste and a sharps container were transported to the nuclear

medicine waste storage room. When the RSO arrived at the patient's room, he reviewed the survey readings posted on the patient's door and noted that the radiation levels from the patient were higher than usual for the duration of the patient's stay. The RSO surveyed the patient and measured 1.5 mR/hr at one meter from the patient.

The biohazard waste bag was transferred to the waste storage room within the Nuclear Medicine Department. Labeling, postings, and material controls were adequate as required by 10 CFR Part 20. The RSO requested a health physicist to survey the biohazard waste bag. The "red bag" measured a maximum of 800 mR/hr on direct contact and 14-15 mR/hr at 1 meter; and the sharps container measured 2.6 mR/hr at one meter. These readings confirmed that a significant amount of the I-131 dosage remained in the contents of the waste bag. The permittee's initial assumption was that the dose of I-131 remained within the g-tube. Based on the survey measurements of the waste bag and sharps container, corrected for decay, the permittee estimated that approximately 113 mCi of I-131 remained in the g-tube. Therefore, based on these preliminary assessments, the patient would have received a dosage of approximately 74 mCi of I-131, less than 40 percent of the prescribed dosage of 200 mCi. The RSO notified the NHPP office of the medical event on September 25, 2009.

Title 10 CFR Part 35.41(a)(2) requires in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The licensee's failure to develop, implement and maintain written procedures for administering I-131 via a g-tube, which resulted in a medical event, is an apparent violation of 10 CFR 35.41(a)(2). The violation addresses all aspects of the administration including the manner in which the dosage was handled within the patient's room. The root cause was a lack of recognition of the importance of providing clear guidance and direction for infrequently performed administrations of I-131 dosages through g-tubes with inexperienced staff.

2.3 Conclusions

The inspectors determined that on September 21, 2009, the VASDHS administered a therapeutic dosage of I-131 to a patient for the treatment of metastatic thyroid carcinoma which resulted in an unintended dose to the patient's stomach. The event was the result of a lack of training and experience among the staff involved in the treatment; a lack of written procedures for administering licensed material through a g-tube; a lack of awareness among the staff involved regarding: (a) the condition of the patient (required treatment via a g-tube), and (b) the type of g-tube involved and how it functioned; and a lack of communication between key personnel such as the authorized user, the chief nuclear medicine technologist, and the Radiation Safety Officer (RSO) who were intermittently either off-site or otherwise unavailable for consult by staff during the course of the patient treatment. Two apparent violations of regulatory requirements were identified including the VASDHS's failure to: (1) instruct supervised individuals on the administration of licensed material through a g-tube and in radiation protection procedures (10 CFR 35.27(a)(1)); and (2) develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive (10 CFR 35.41(a)(2)). In addition to the apparent violations, the inspectors identified two concerns. Specifically, the manner in which the permittee staff

handled and transferred the I-131 dosage within the patient's room prior to administration, could have resulted in a spill and most likely personnel contamination. In addition, the permittee's ALARA assessment regarding the I-131 dosage transfer in the patient's room did not exhibit conservative decision-making.

3. Licensee Investigation

3.1 Inspection Scope

The inspectors evaluated the licensee's investigation of the event which included a root cause assessment. The inspectors interviewed the AU, the RSO, and other selected licensee staff to independently assess the causes of the event.

3.2 Observations and Findings

The RSO became aware of the higher then expected radiation levels from the patient on either September 23 or 24, 2009, through conversations with the AU. The RSO was not aware that the patient had a g-tube until Thursday, September 24, and he was unaware of the specific type of g-tube. During the week that the patient was treated, the RSO was either attending a professional conference or attending various meetings within the hospital. The AU and the CNMT were also intermittently available for consult during the week of the medical event. Consequently, the limited availability of principal staff involved with the administration resulted in delays in communicating and reacting to the information available, which delayed decision-making regarding the patient's treatment. Once the RSO became more fully aware of the events surrounding the administration and the potential medical event, he initiated an investigation on Friday, September 25, 2009. The RSO reviewed patient records including the written directive and interviewed the AU and the nuclear medicine technologists involved (CNMT and SNMT). The RSO obtained written statements on the event from the AU, the CNMT and SNMT, and members of the interventional radiology staff.

Following the removal of the patient's g-tube, the RSO directed members of the radiation safety office and the nuclear medicine department to perform surveys of the interventional radiology suite on September 25 and 26, 2009. These surveys identified contamination in several areas with the highest levels around the waste receptacle. All contamination was isolated within the interventional procedure room where the g-tube was removed. The staff attempted to decontaminate these areas. The contamination was determined to be fixed and the areas were covered and allowed to decay. On September 28, 2009, the radiation safety office collected and sent the personnel dosimeters for all the individuals involved with the administration to the dosimetry vendor for emergency processing. All of the results were less than ten percent of the annual occupational dose limits in 10 CFR Part 20. The RSO performed dose assessments for the interventional radiology staff that were not monitored with extremity dosimeters. The results of these dose assessments were below ten percent of the monitoring requirements in 10 CFR Part 20. The radiation safety office also performed thyroid bioassays on nine individuals involved with the I-131 administration, including the interventional radiology staff members present during the procedure to exchange the g-tube. All bioassay measurements were below the permittee's action level of 40 nanocuries. On September 29, 2009, the RSO surveyed the shoes of several

individuals including interventional radiology staff members present in the interventional radiology suite during the g-tube removal. Some individual's shoes showed detectable amounts of contamination, but these levels were less than the VASDHS's established trigger level of three times background.

On September 28, 2009, the VASDHS's RSO and the AU contacted a VA expert and an external expert at the Radiation Emergency Assistance Center/Training Site (REAC/TS) in Oak Ridge, Tennessee for a preliminary dose assessment of the patient's stomach. Based on the preliminary information available at that time, REAC/TS estimated a potential dose of approximately 14.2 Gy (1,420 rad) (equivalent to 14.2 Sievert (Sv) or 1,400 radiation equivalent man (rem)) to the patient's stomach. In order to monitor for adverse health effects, photographs of the patient's abdomen were taken semi-weekly for evidence of skin erythema. If the patient exhibited erythema, then the VA expert opined that further imaging and tests should be considered for evaluation of the patient. If no localized skin changes were noted within three to four weeks following the medical event, then the VA expert believed no complications would be expected. According to the AU, the patient had no complaints and no skin changes or other symptoms were noted.

On September 30 through December 23, 2009, the NHPP conducted a reactive inspection of the event. The permittee initially believed that the root cause of the medical event was due to unexpected adherence of the I-131 within the lumen of the g-tube or a kink within the tube which prevented the I-131 from being absorbed by the patient.

The permittee elected to retrieve the g-tube from the waste bag in order to determine the root cause of the event and to more accurately estimate the dosage actually administered to the patient. The NRC inspectors expressed concern regarding the decision to open a sealed bag of biohazardous waste for this investigation and potentially exposing staff to biohazardous materials, sharps, and radioactive wastes. Further, no radiographs of the waste bag were performed to aid in locating the syringe within the bag. The permittee staff indicated that they had prior experience performing work with biohazardous materials. On October 26, 2009, the VASDHS RSC reviewed and approved procedures to permit the radiation safety office to open the biohazard waste bag containing the g-tube.

On October 26, 2009, a member of the radiation safety staff opened the bag and retrieved the g-tube. Utilizing imaging and survey data, the staff determined that approximately 10 mCi of I-131 was in the g-tube at that time. The permittee expected a larger amount of material within the g-tube based on its initial understanding of the event. A re-enactment of the administration revealed that the majority of the I-131 dosage must have been injected into the balloon port of the g-tube rather then the intended medication port. When the interventional radiologist removed the g-tube, he deflated the balloon which held the tube in place by withdrawing the fluid into a syringe. The staff determined that since the SNMT injected the I-131 into the balloon port, the interventional radiologist would have removed this I-131 from the balloon during the process to deflate the balloon and remove the tube from the patient. The staff imaged the bag and found a hot spot indicating that the syringe remained in the bag and contained a significant amount of activity. Based on the additional surveys and revised calculations performed by the permittee, they estimated that approximately 112-160 mCi of I-131 was injected into the

balloon and approximately 10 mCi of I-131 remained in the g-tube. The patient received a dosage of approximately 20 mCi rather then the intended 200 mCi as prescribed on the written directive.

3.3 Conclusions

The inspectors concluded that permittee staff investigated the circumstances associated with the medical event. The root causes of the medical event were: (1) a lack of written procedures for administrations through a g-tube; (2) a lack of training and experience among the staff participating in g-tube administrations; (3) a lack of awareness among the staff involved regarding: (a) the condition of the patient (required treatment via a g-tube) and (b) the type of g-tube involved and how it functioned; (4) a lack of communication between key personnel such as the authorized user, the chief nuclear medicine technologist, and the Radiation Safety Officer (RSO) who were intermittently either off-site or otherwise unavailable for consult by staff during the course of the patient treatment; and (5) a lack of a questioning attitude. The inspectors attributed the limited and intermittent availability of principal staff involved with the administration, which resulted in delays in communicating and reacting to the information available, as contributing factors to the medical event.

4 Patient Dose Assessment

4.1 Inspection Scope

The inspection included a review of the licensee's dose assessment to the patient's stomach resulting from the September 21, 2009, administration. The inspectors interviewed selected permittee staff and reviewed the dose assessment submitted in letter dated November 6, 2009. The inspectors also conducted an independent assessment of the dose to the patient's stomach wall.

4.2 Observations and Findings

Based on a comparison of patient and waste radiation exposure-rate data, the inspectors estimated that approximately 160 mCi of I-131 was retained in the balloon of the g-tube at the time of administration. In order to assess the dose to the patient's stomach wall from the I-131 in the balloon of the g-tube, the inspectors assumed 160 mCi of I-131 was uniformly distributed in the stomach content and only the gamma radiation would reach the patient's stomach wall. The guidance from the Medical Internal Radiation Dose (MIRD) Committee was used to calculate the stomach wall dose for reference man. Specifically, the inspectors referred to gamma energy absorbed fractions from Table 10, MIRD Pamphlet No. 3. The dose to the stomach content was approximately 38 Gy, equivalent to 38 Sv (3,800 rem). The MIRD method assumes the dose to the stomach wall was about 50 percent of the dose to the stomach content. Therefore, the inspectors calculated the dose to the stomach wall was approximately 19 Gy, equivalent to 19 Sv (1,900 rem).

The permittee contracted with an independent health physics consultant with expertise in radiation dose calculations in nuclear medicine to independently assess the dose to the patient's stomach. The health physics consultant used a customized model for the dose

assessment. Assuming an activity of 160 mCi of I-131 residing in the balloon of the g-tube for approximately 92 hours, the estimated dose to the patient's stomach was 16.7 Gy, equivalent to 16.7 Sv (1,670 rem).

4.3 Conclusions

Based on the information obtained during the inspection, the inspectors calculated the dose to the patient's stomach wall to be approximately 19 Gy, equivalent to 19 Sv (1,900 rem). According to the assessment performed by the licensee's consultant, a dose of approximately 16.7 Gy, equivalent to 16.7 Sv (1,670 rem) was assigned to the patient's stomach. Both dose assessments were in general agreement.

5 Licensee Corrective Actions

5.1 Inspection Scope

The inspectors reviewed the permittee's proposed corrective actions for the medical event involving the unintended dose to the patient's stomach. The review included interviews of selected permittee personnel.

5.2 Observations and Findings

Following the medical event the permittee halted all g-tube administrations. To date, no g-tube administrations have occurred since the medical event. The permittee also suspended one individual's participation in therapeutic administrations. The permittee established a root cause analysis team to review this medical event. The team comprised of the AU, the RSO, an interventional radiologist, and a risk management specialist. The root cause analysis team recommended the following actions: (1) develop step-by-step written procedures for g-tube administrations; (2) provide training in the revised written procedures; (3) improve communication between the radiation safety and nuclear medicine departments; and (4) institute a "time-out" process when encountering new or unfamiliar apparatus.

The permittee developed step-by-step written procedures for administering I-131 through a g-tube. The permittee also revised its policies and procedures for administering radiopharmaceuticals requiring a written directive to include instructions to the staff to take a "time out" when encountering any unusual patient apparatus. The permittee submitted these procedures to its RSC for review and approval on January 21, 2010. The RSO discussed the medical event with the nuclear medicine staff with the intent to provide formal training to both the nuclear medicine and the interventional radiology staff.

5.3 Conclusions

The inspectors determined that the licensee's initiated immediate corrective actions appeared to adequately address the medical event. The licensee's long term corrective actions for the apparent violations had not been completed.

6 Notifications and Reporting

6.1 Inspection Scope

The inspectors reviewed the information that was available to the AU, the RSO, and the nuclear medicine staff. The inspectors also reviewed the September 26, 2009, event notification to the NRC Operations Center and reviewed the licensee's 15-day report dated October 7, 2009. The inspectors interviewed the RSO to determine what event notifications had been made.

6.2 Observations and Findings

The NRC inspectors reviewed the information that was available to the licensee to make a determination that a medical event occurred. The inspectors identified that sufficient information was available to the licensee on Wednesday, September 23, and by Thursday, September 24, 2009, at the latest, to make a determination that a medical event occurred. Specifically, based on the radiation surveys of the patient, the data was available to ascertain that the dosage of I-131 was not being metabolized and eliminated by the patient. This was evident because the radiation levels from the patient did not decrease as expected. On September 25, 2009, permittee staff removed the g-tube based on continued higher then expected radiation measurements from the patient. Survey readings of the waste bag confirmed that the g-tube and contents contained higher quantities of I-131 then expected. The elevated radiation levels from the patient indicated that the patient was not absorbing and eliminating the I-131. As of Wednesday, September 23, or by Thursday, September 24, 2009, at the latest, the permittee had sufficient information to determine a medical event occurred. The medical event was not reported to the NRC until Saturday, September 26, 2009, two days after sufficient information was available to make the medical event determination.

This event was initially reported because the licensee estimated that the patient received less then half of the intended dosage. Further investigation determined that this event also involved a dose to an organ or tissue (the stomach) other than the treatment site, that exceeded 50 rem to an organ or tissue and 50 percent or more of a dose expected from the administration as defined in the written directive. According to the licensee's procedures, the expected dose to the stomach wall would be 255 rads (equivalent to 255 rem) per 150 mCi dosage of I-131. Based on the inspector's calculations, for a 200 mCi dosage as originally prescribed, the expected dose to the stomach wall would be approximately 340 rads (equivalent to 340 rem). In this case, the patient received an unintended dose to the stomach of approximately 1,670 to 1,900 rem which exceeds the 50 rem dose to an organ and 50 percent or more of a dose expected from the administration as defined in the written directive.

Title 10 CFR Part 35.3045(a)(1)(ii) and (3) respectively, requires a licensee to report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in a dose that differs from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin and the total dosage delivered differs from the prescribed dosage by 20 percent or more; and a dose to the skin or an organ or tissue other than the

treatment site that exceeds by 0.50 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive. Title 10 CFR Part 35.3045(c) requires the licensee to notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of the medical event. The licensee's failure to notify the NRC of a medical event by the next calendar day after discovery of the medical event constitutes an apparent violation of 10 CFR Part 35.3045(c). The root cause of the licensee's failure to timely notify the NRC of the medical event was the staff's "wait and see" approach for the patient treatment. Although the staff had sufficient information, based on the patient survey data, to indicate that the administration was apparently not as expected, the staff failed to use the information they had and act accordingly by notifying the NHPP as well as the NRC prior to September 26, 2009.

The licensee submitted a written report on the medical event in its letter dated October 7, 2009. The written report included a description of the event, why the event occurred, the possible effects on the patient, immediate corrective actions, and when the patient and the referring physician were notified. The licensee provided an addendum by e-mail on January 21, 2010, to its initial written report describing additional information it obtained during its October 2009 investigation of the event.

6.3 Conclusions

The inspectors identified an apparent violation of NRC requirements associated with the license's failure to provide telephonic notification of the medical event to the NRC by the next calendar day after discovery of the medical event as required by 10 CFR Part 35.3045(c). The medical event was reported to the NRC by telephone on Saturday, September 26, 2009, two days after sufficient information was available to make the determination that a medical event occurred. The written report and the addendum included all the required information.

7 NRC Medical Consultant's Review

7.1 Inspection Scope

The medical consultant reviewed the written directive, patient survey data, and other documentation associated with the administration of the dosage. The medical consultant summarized his findings in his report dated January 21, 2010 (Enclosure 2). The inspectors reviewed the medical consultant's written report to determine if any health consequences occurred as a result of the medical event

7.2 Observations and Findings

The NRC contracted a medical consultant, Ronald E. Goans, M.D., Ph.D, MPH, to review the medical event and determine if any adverse health consequences to the patient were expected. Dr. Goans concurred that the dose to the patient's stomach wall was approximately 17 to 19 Gy (1,700 to 1,900 rads), equivalent to 17-19 Sv (1,700 to 1,900 rem). The medical consultant did not report any adverse health effects to the patient as a result of the unintended dose to the patient's stomach, which was confirmed with the patient's physician.

7.3 Conclusions

The medical consultant agreed with the permittee's dose estimates to the patient. The medical consultant did not report any adverse effects to the patient as a result of the unintended dose to the patient's stomach.

8 Other Areas Inspected

8.1 Inspection Scope

The inspector reviewed other aspects of the licensee's radiation protection program which included personnel monitoring, approval of authorized users by the permittee's RSC, and another patient g-tube administration. The inspector interviewed selected individuals, toured the licensee's facilities, and examined selected records.

8.2 Observations and Findings

The technologist primarily responsible for handling and administering therapeutic doses of I-131 was monitored for extremity exposures using a wrist dosimeter exchanged on a monthly basis. The inspectors explained that there can be a large differential between radiation exposure to the fingers and radiation measured at the wrist. Therefore, a wrist dosimeter may not be the most accurate monitoring device for this technologist. The RSO provided dose assessments for the technologist's extremities to account for the extremity exposures resulting from the preparation of the g-tube I-131 therapy in June 2009, as well as the I-131 dose involved in this medical event. All exposures were within 10 CFR Part 20 extremity exposure limits. The RSO agreed that using a finger-type dosimeter to measure the technologist's extremity exposure would provide a more accurate estimation of the extremity exposure and initiated use of a finger badge in November 2009 for this individual.

The permittee established an RSC to review uses and users of licensed material. The RSC approved two physicians as authorized users for therapeutic administrations within the nuclear medicine department. The RSC meeting minutes specified the approvals and materials (diagnostic or therapeutic uses) for the physicians.

On June 10, 2009, the permittee administered a 150 mCi I-131 therapy dosage to a patient through a g-tube. As previously mentioned in this report, the g-tube in this case was a different model with only one lumen and two ports (a feeding port and a medication port). The authorized user prepared a written directive which specified the route of administration through a g-tube. According to the patient records and survey data, the administration had no complications and the radiation levels decreased as expected. The patient was released from the hospital two days following the administration when the radiation measurements were below regulatory limits.

8.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspector determined that no violations of NRC requirements were identified.

9 Exit Meeting

The inspectors discussed the conclusions described in this report with the licensee during preliminary exit meetings conducted at the licensee's facility on November 3, 2009, and a subsequent final telephone exit meeting on February 3, 2010. The licensee did not identify any information reviewed during this inspection as proprietary in nature.

ATTACHMENT: SUPPLEMENTAL INFORMATION

Medical Consultant Report
(To be completed by medical consultant)

Medical Consultant Name: Ronald E. Goans, PhD, MD, MPH
Report Date: Final analysis 1/21/2010

Signature Ronald E Goans, MD

Licensee Name	Veterans Affairs Healthcare System, San Diego 3350 La Jolla Village Drive San Diego, CA 92161
License No.	03-23853-01VA
Docket No.	030-34325
Event No.	45383
Facility Name:	Nuclear Medicine Department Veterans Affairs Healthcare System, San Diego
Incident Dates:	9/21-9/25, 2009
Date of Notification:	Initial notification 9/26/2009

Individual's / Patient Physician Name and Address:

Ernest Belezzouli, MD
Director, Nuclear Medicine
Veteran Affairs Healthcare System, San Diego
3350 La Jolla Village Drive
San Diego, CA 92161

Individuals Contacted During Investigation:

Ernest Belezzouli, MD
Director, Nuclear Medicine
Veteran Affairs Healthcare System, San Diego
3350 La Jolla Village Drive
San Diego, CA 92161
(858) 552 7511

Rene Michel, MS, RSO
Veteran Affairs Healthcare System, San Diego
3350 La Jolla Village Drive
San Diego, CA 92161
(858) 642 1059

Enclosure 2

Records Reviewed: (General Description)

1. NRC Enclosure - Description of the Medical Event
2. NRC Preliminary Notification of Event (Event # 45383)
3. NRC Medical Event Reporting and supporting literature
4. NRC Notes on the event
5. Department of Veterans Affairs Medical Center correspondence to the NRC
6. Internal Dose Calculations of Michael Stabin, PhD, CHP
7. REAC/TS working notes on internal dose calculations

Estimated Dose to Individual or Target Organ:

17-19 Gy to the gastric wall. See notes below.

Probable Error Associated with Estimation: <20 %, primarily due to uncertainty in source geometry. Monte Carlo Method with full beta spectrum and all photons from I-131.

Prescribed Dose (Medical Misadministration Only): 200 mCi I-131 for metastatic thyroid cancer.

Method Used to Calculate Dose: Clinical dose profile by Monte Carlo and physical dosimetry using the point kernel technique.

Description of Incident:

The NRC was notified, pursuant to 10 CFR 35.3045, of a medical event that occurred at the VA San Diego Healthcare System in San Diego, California. Nominal prescribed activity 200 mCi I-131 NaI.

An activity of 187 millicuries of I-131 sodium iodide was administered to a 63 year old patient with metastatic thyroid carcinoma through a feeding tube (Kimberly-Clark MIC Gastrostromy feeding tube; g-tube) on September 21, 2009. The patient was kept in a shielded room at the facility. Daily measurements of the exposure rate at one meter from the patient showed only a small decrease, consistent with radioactive decay, but not the expected biological elimination. The feeding tube was replaced on September 25, 2009. The activity in the feeding tube after removal from the patient was estimated as over 80 millicuries. At this time, it is estimated that the patient received less than half of the administered dose. Most of the activity (~160 mCi) I-131 had been injected into the balloon port rather than into the medication port as intended.

The basis for the medical event derives from the fact that the total dosage delivered differs from the prescribed dosage by more than 20 percent. The facility has notified the patient of the medical event and has notified the referring physician. The facility has also assessed any adverse medical effects on the patient. The NHPP is performing a reactive inspection regarding the medical event. A 15-day written report for the medical event has been submitted to NRC Region III.

Clinical Course

An activity of 187 mCi (6920 MBq) of Na I-131, was administered to a patient through a silicon G-tube on September 21, 2009. It is estimated that 112-160 mCi (4100-5900 MBq) of this activity was inadvertently injected into the balloon compartment, which contained 7-10 cc of distilled water. The patient was ambulatory and received nutrition through the feeding tube. The

G-tube was surgically removed from the patient on September 25, 2009. At the time of the incident the RSO called for assistance from the Radiation Emergency Assistance Center/Training Site (REAC/TS). This reviewer is a radiation medicine consultant to REAC/TS and participated in initial dose calculations for this case. With the little information initially available, a preliminary dose of 14-15 Gy to the stomach wall was estimated.

The Veteran Affairs Healthcare System, San Diego subsequently contacted Mike Stabin, PhD, CHP at Vanderbilt University of provide more extensive dose estimation. Dr. Stain's complete report is attached in Appendix I.

There are no available model dose factors that can estimate the dose from the balloon to the stomach wall or other tissues of the patient. Thus, Dr. Stabin was created a mathematical model in the MCNP Monte Carlo code (Briesmeister 1997). From this analysis, doses were estimated to several tissues of interest in the problem. The thickness of the skin was set to 0.2 cm, as suggested by Cristy and Eckerman. The stomach was modeled as suggested by Cristy and Eckerman, namely as two concentric ellipsoids, the inner representing the stomach contents (250 ml) and the space between the two ellipsoids representing the stomach wall (152 ml). The source was then modeled as a simple sphere of 10 ml in contact with the stomach wall.

The full beta spectrum of I-131, as provided by the RADAR dose information group (Stabin and da Luz 2002), was used in the transport calculations, as well as the energies of all discrete electrons and photons. Sufficient particle histories (200,000) were run to reduce uncertainties in most reported values below 1%. The number of disintegrations estimated for 160 mCi (5900 MBq) residing in this balloon for 91.7 hours, accounting for the radioactive decay of the I-131, was 1.65x1015. The estimated doses to the various modeled structures are shown in Tables 1 and 2.

When one averages all energy absorbed throughout the entire stomach wall, the dose is estimated to be about 17 Gy; this is remarkably close to the REAC/TS result, derived using the point kernel method. In addition, a small region in the stomach wall right adjacent to the source received an estimated dose of 135 Gy. Similarly for the skin, an average over the entire region is estimated to be 0.28 Gy, but the small region modeled in the skin near the source has an estimated dose of 11 Gy.

I have been assured by Dr. Ernest Belezzouli that there have been no adverse effects to the patient. Specifically, I asked about ulceration in the stomach or erythema to the anterior abdominal wall. Dr. Belezzouli has kindly provided sequential pictures of the patient's anterior abdominal wall and there is no clinically significant erythema. Furthermore, there appears to have been no gastric bleeding to date. Both of these are positive indicators for the patient.

References

Briesmeister, J. MCNP - A general Monte Carlo n-particle transport code, version 4B. Los Alamos National Laboratory, report LA-12625-M, 1997.

Cristy, M. and Eckerman, K. (1987): Specific absorbed fractions of energy at various ages from internal photons sources. ORNL/TM-8381 V1. Oak Ridge National Laboratory, Oak Ridge, TN.

Fajardo L-G, LF, Berthrong, M, and Anderson, RE. *Radiation Pathology*. Oxford Press. 2001.

Fletcher GH. Textbook of Radiotherapy. 3rd edition. Lippincott, Williams& Wilkins, 1980.

Goans RE. Clinical Care of the Radiation Accident Patient: Patient Presentation, Assessment, and Initial Diagnosis. In The *Medical Basis for Radiation-Accident Preparedness. The Clinical Care of Victims.* Eds. Robert C. Ricks, Mary Ellen Berger, and Frederick M. O'Hara, Jr. Proceedings of the Fourth International REAC/TS Conference on the Medical Basis for Radiation-Accident Preparedness, March 2001, Orlando, FL. The Parthenon Publishing Group, 2002.

Stabin MG, da Luz CQPL. New Decay Data for Internal and External Dose Assessment, Health Phys. 83(4):471-475, 2002.

Stabin MG, Sparks RB, and Crowe E. OLINDA/EXM: The Second-Generation Personal Computer Software for Internal Dose Assessment in Nuclear Medicine. J Nucl Med 2005;46 1023-1027.

Was individual or individual's physician informed of DOE Long-term Medical Study Program?

No patient contact resulted from this consult.

If yes, would the individual like to be included in the program? N/A

COMPLETE FOR MEDICAL MISADMINISTRATION
(To be completed by Medical Consultant)

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to the NRC pursuant to 10 CFR 35.33 in the following areas:

a. Why the event occurred – Yes. Circumstances of this event were largely documented in the Department of Veteran Affairs National Health Physics Program memorandum.

b. Effect on the patient – Patient records were examined and my independent dose estimates generally agree with those provided by the hospital. The patient is said to be in satisfactory condition.

c. Licensee's immediate actions upon discovery – There was immediate reporting of the event to the NRC, once the index case was noted..

d. Improvements needed to prevent recurrence - Yes. This is a multiple human factors issue, correctable by education and improved procedures. I don't expect a recurrence.

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 35.33, provide the basis for your opinion: N/A

3.

Did the licensee notify the referring physician of the misadministration? Yes

Did the licensee notify the patient's or the patient's responsible relative or guardian? Yes

If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification consistent with 10 CFR 35.33?
N/A

Explain rationale for response.

4. Provide an opinion of the licensee's plan for patient follow-up. If available.

The patient in question will be followed clinically by the San Diego VA medical center. After discussion with all of the principal participants, I feel that the VA system will institute an effective program to prevent a recurrence of these events.

Appendix 1

RADIATION DOSE ESTIMATES FOR AN 131I SOURCE IN A BALLOON SOURCE IN THE STOMACH OF A PATIENT AT THE VA HOSPITAL IN SAN DIEGO, CALIFORNIA
C O N F I D E N T I A L R E P O R T

Michael G. Stabin, PhD, CHP
Department of Radiology and Radiological Sciences Vanderbilt University 1161 21st Avenue South Nashville, TN 37232-2675
November 6, 2009

INTRODUCTION

An activity of 187 mCi (6920 MBq) of Na I-131, was administered to a patient through a silicon G-tube on September 21, 2009. It is estimated that 112-160 mCi (4100-5900 MBq) of this activity was inadvertently injected into the balloon compartment, which contained 7-10 cc of distilled water. The patient was ambulatory and received nutrition through the feeding tube. The G-tube was surgically removed from the patient on September 25, 2009. This report summarizes efforts to estimate the radiation dose to tissues of the patient.

METHODS

Figure 1 shows the geometry of the problem, as provided by representatives of the VA Hospital in San Diego, CA.

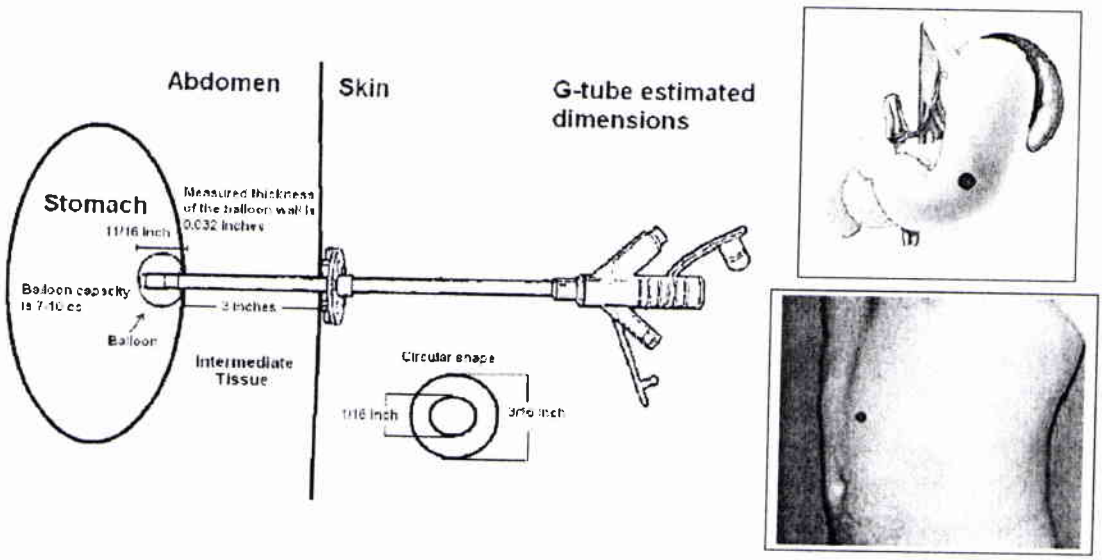


Figure 1. Geometry of the G-tube in the patient

There are no available model dose factors that can estimate the dose from the balloon to the stomach wall or other tissues of the patient. Thus, a new model was created in the MCNP Monte Carlo code (Briesmeister 1997) and doses were estimated to several tissues of interest in the problem. Figure 2 shows a representation of the cross section from the model developed. The whole body was designed as a cylinder with the dimensions of the trunk used in the model of the adult male suggested by Cristy and Eckerman (1987).

Other specific elements of their whole body phantom, like legs and head, were not modeled, rather the body was represented as a simple cylinder whose height (111 cm) was chosen to provide the approximate correct mass for the whole body (70 kg). A second cylinder was placed within the outer cylinder, with the space between them representing the skin. The thickness of the skin was set to 0.2 cm, as suggested by Cristy and Eckerman also. The stomach was modeled as suggested by Cristy and Eckerman, namely as two concentric ellipsoids, the inner representing the stomach contents (250 ml) and the space between the two ellipsoids representing the stomach

wall (152 ml). The source was then modeled as a simple sphere of 10 ml in contact with the stomach wall.

Table 2. Doses to the modeled structures, Gy.

	Doses (Gy)		
Target Region	Photons	Electrons	Total
Rest of body	4.12E-01	0.00E+00	4.12E-01
Skin	2.76E-01	0.00E+00	2.76E-01
Stomach contents	2.98E+01	3.95E+00	3.37E−01
Stomach wall	1.67E−01	5.81E-02	1.67E−01
Source	3.36E−02	4.79E+03	5.12E−03
Small stomach wall region	1.24E+02	1.08E+01	1.35E+02
Small skin region	1.10E−01	0.00E+00	1.10E+01

The full beta spectrum of I-131, as provided by the RADAR dose information group (Stabin and da Luz 2002), was used in the transport calculations, as well as the energies of all discrete electrons and photons. Sufficient particle histories (200,000) were run to reduce uncertainties in most reported values below 1%. Dose to the entire stomach wall was estimated in the simulations, but the localized dose to the stomach wall was also estimated by placing a small sphere of the diameter of the stomach wall inside of the stomach wall near the source (not shown in Figure 2). A small sphere was also placed in the skin region, with the diameter of the skin thickness, to estimate the highest dose to the skin expected (also not shown in Figure 2).

The number of disintegrations occurring in the source region was calculated assuming that the entire 166 mCi was present in the balloon for the time span noted in the Introduction (i.e. 91.7 hours). Doses to other organs were estimated by assuming that the source was uniform within the stomach contents and employing the dose factors from the OLINDA/EXM software program (Stabin et al. 2005), using the adult male model.

RESULTS

The number of disintegrations estimated for 160 mCi (5900 MBq) residing in this balloon for 91.7 hours, accounting for the radioactive decay of the I-131, was 1.65x1015. The estimated doses to the various modeled structures are shown in Tables 1 and 2.

Table 1. Doses to the modeled structures, Gy/disintegration in the source region. Doses (Gy) per disintegration in the source region		
Target Region	Photons	Electrons
Rest of body	2.49E-16	0.00E+00
Skin	1.66E-16	0.00E+00
Stomach contents	1.80E-14	2.39E-15
Stomach wall	1.02E-14	3.51E-17
Source	2.03E-13	2.89E-12
Small stomach wall region	7.50E-14	6.55E-15
Small skin region	6.68E-15	0.00E+00

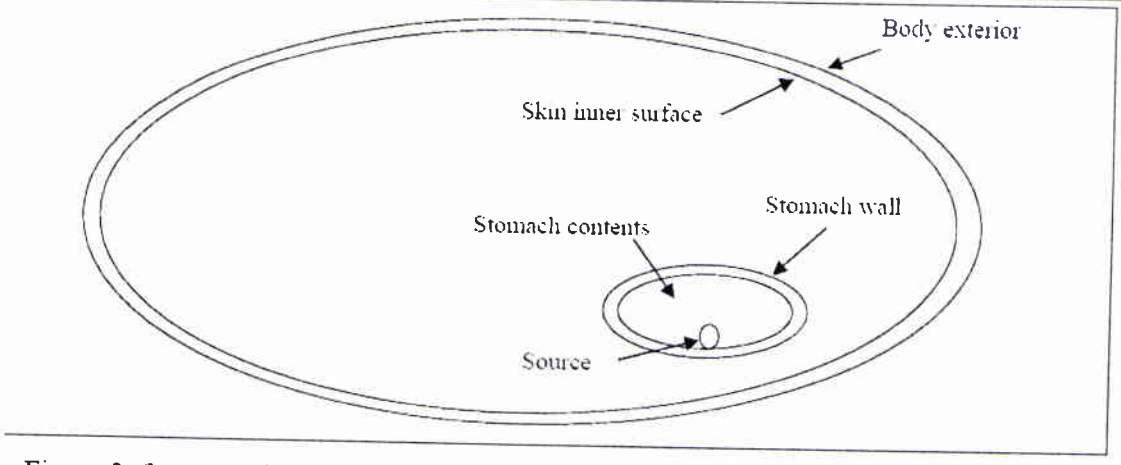
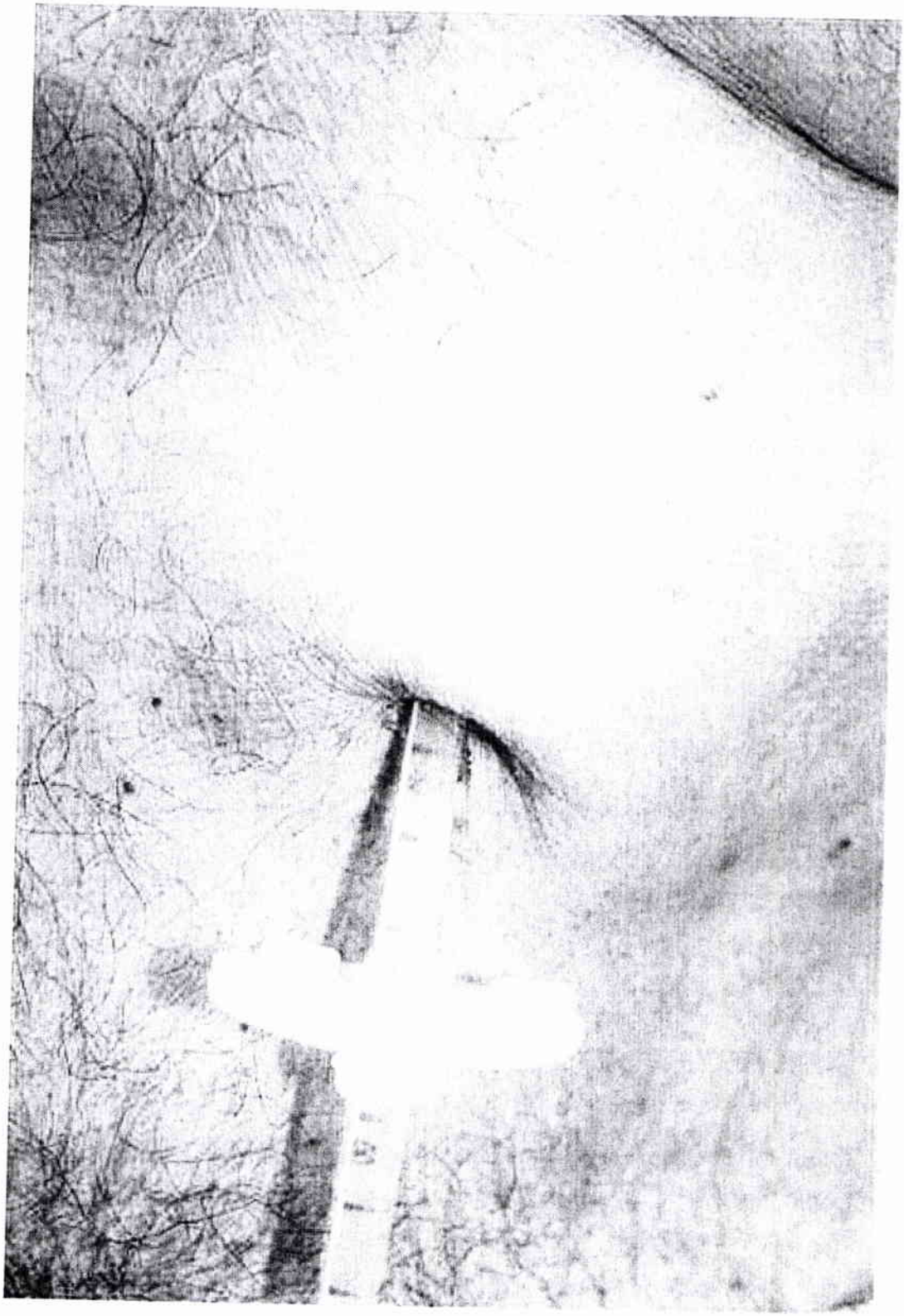
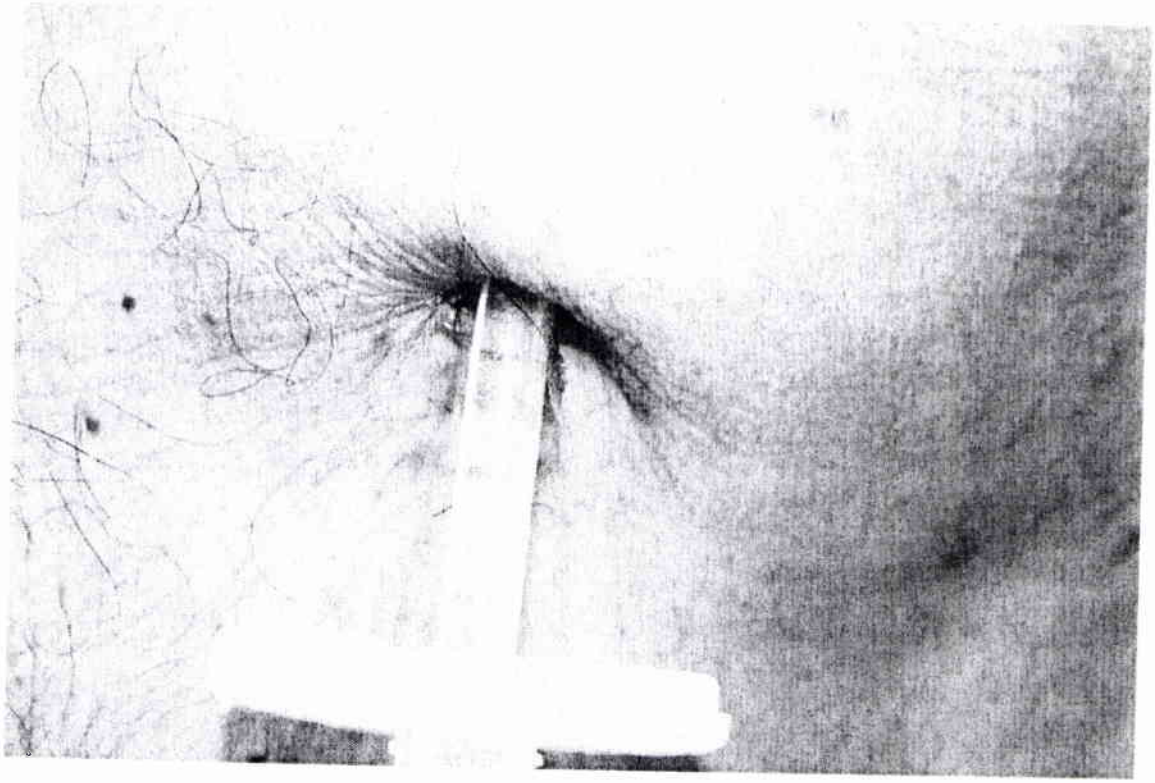
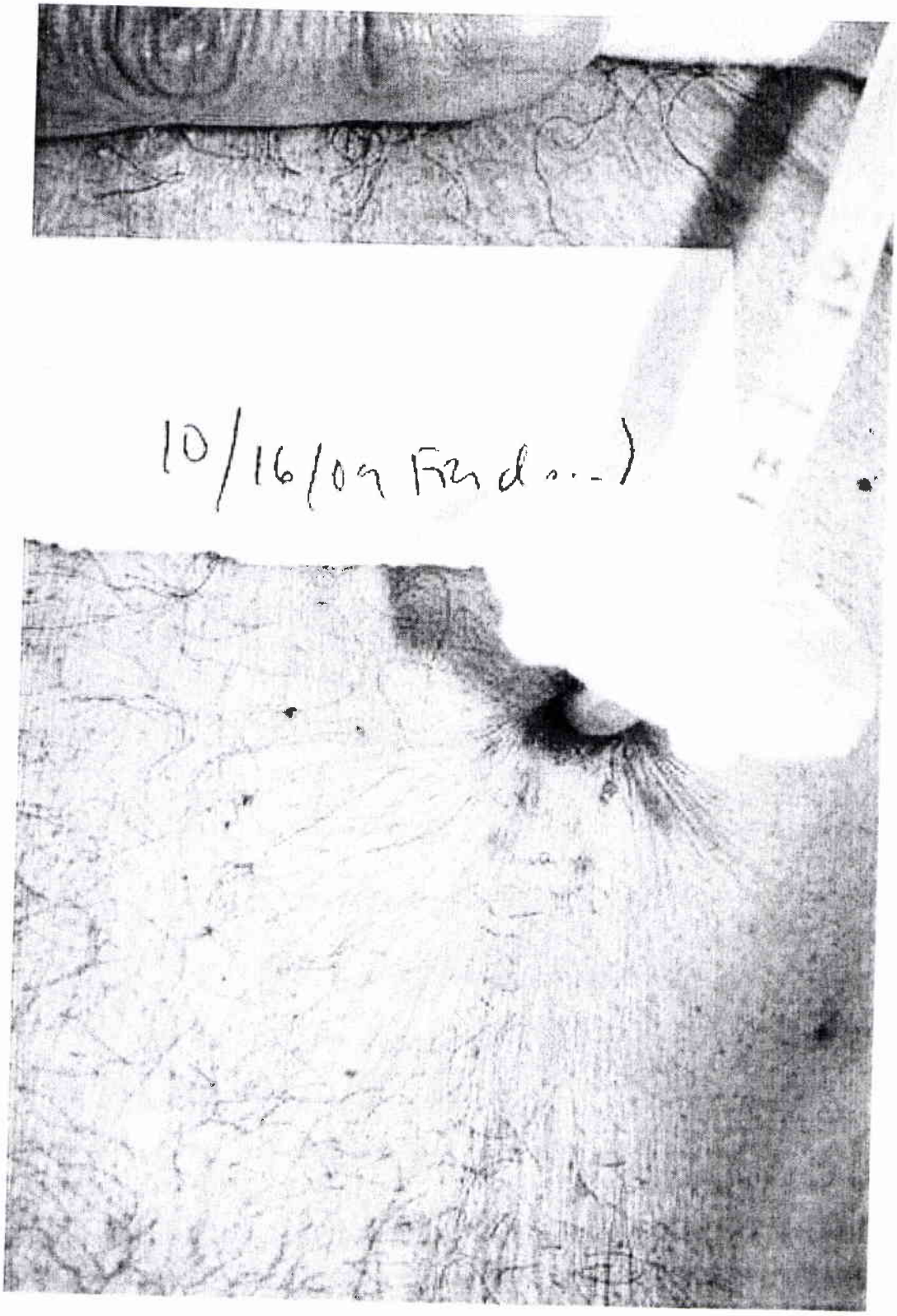


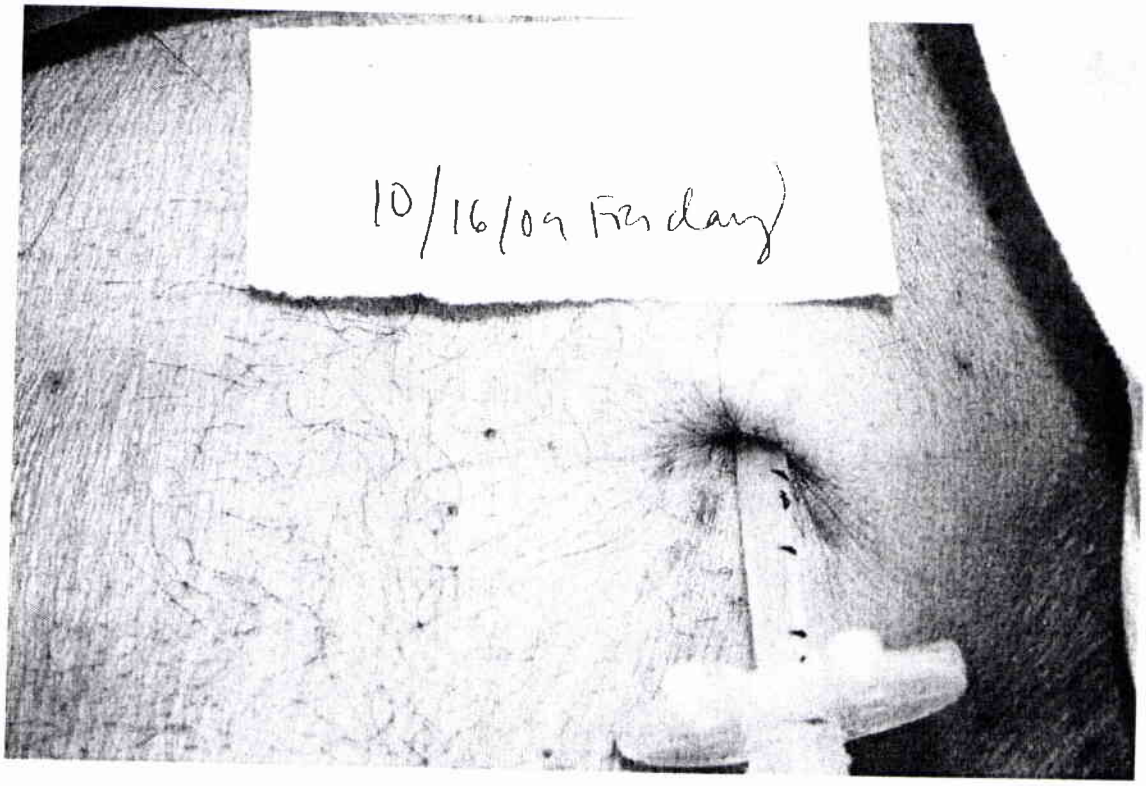
Figure 2. Cross section showing approximate problem geometry modeled in MCNP.

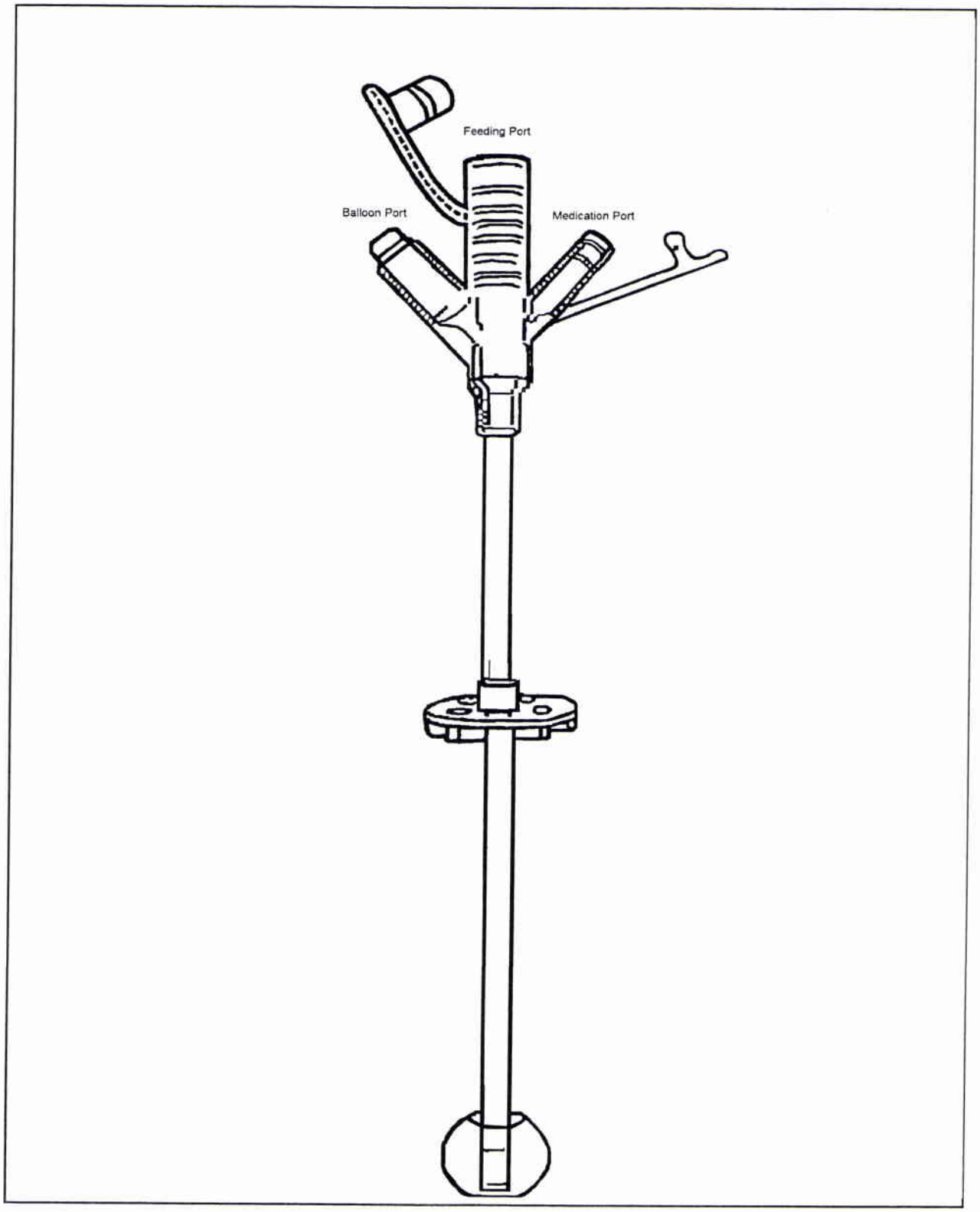
Appendix 2 Anterior Abdominal Wall Pictures






10/16/09 Fnd...)


10/16/09 Friday



G-Tube Diagram

Enclosure 3

SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Veterans Affairs San Diego Healthcare System

Ernest V. Belezzuoli, M.D., Chief, Nuclear Medicine Service
Cindy Butler, Public Affairs Officer
Russell J. Cain, CNMT, Chief Technologist/Administrative Officer
Alan Ekberg, RT(R), Radiological Technologist
Edwin M. Leidholdt, Jr., Ph.D. Program Manager, NHPP
Stan Johnson, Medical Center Director
Rene Michel, M.S., Radiation Safety Officer
John Naheey, M.D., Senior Resident, Interventional Radiologist
David Suarez, CNMT, Senior Technologist
Robert Smith, M.D., Acting Chief of Staff
Michael J. Zorn, NRRPT, Health Physicist

National Health Physics Program

Edwin M. Leidholdt, Jr. Ph.D.

Kimberley-Clark

Marie Day, Quality Analyst II

LIST OF ACRONYMS USED

AU	Authorized Physician User
ALARA	As Low As Reasonably Achievable
CFR	Code of Federal Regulations
CNMT	Chief Nuclear Medicine Technologist
DVA	Department of Veterans Affairs
Gray	Gray
mCi	millicurie
MIRD	Medical Internal Radiation Dose (Committee)
MML	Master Materials License
mR/hr	milliroentgen per hour
NHPP	National Health Physics Program
NRSC	National Radiation Safety Committee
NRC	Nuclear Regulatory Commission
rad	radiation absorbed dose
REAC/TS	Radiation Emergency Assistance Center/Training Site
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
rem	radiation equivalent man
SNMT	Senior Nuclear Medicine Technologist
Sv	Sievert
VASDHS	Veterans Affairs San Diego Healthcare System

Attachment

VA SAN DIEGO HEALTHCARE SYSTEM

A Division of VA Desert Pacific Healthcare Network

Manual of Radiation Safety Policies and Procedures

January 2010

INTRODUCTION

This revision of the Manual of Radiation Safety Policies and Procedures, approved by the Radiation Safety Committee (RSC) supersedes all other revisions. It also supersedes and takes precedence over any memoranda, notices or condensed versions issued prior to the date of issuance of this manual.

In this manual are the policies and standards for work with radioactive material at VA San Diego Healthcare System (VASDHS).

These radiation safety policies meet or exceed regulatory requirements of the Nuclear Regulatory Commission (NRC).

The requirements of this document apply to all personnel working with radioactive material at VASDHS facilities located at 3350 La Jolla Village Drive, San Diego, California.

Revised January 2010 – NOTICE

This manual contains definitions and concepts taken from the Code of Federal Regulations (CFR), specifically, Title 10 CFR Parts 19, 20, 30-33, 35, and 71 as well as Title 49 CFR Parts 100 to 177. The above referenced regulations, as well as other regulations applicable to the use of radioactive material, are available at the Radiation Safety Office and through the NRC. Changes to these regulations may require corresponding changes to this manual.

Table of Contents

SECTION 1: ADMINISTRATION AND OVERSIGHT OF THE RADIATION SAFETY PROGRAM

The VA San Diego Healthcare System (VASDHS) executive management has established a Radiation Safety Committee (RSC) and a Radioactive Drug Research Committee (RDRC) to oversee, with the assistance of the Radiation Safety Officer (RSO), the use of all sources of ionizing radiation for all uses. The RSC is to give proper and continuing recognition to problems relating to all potential radiation hazards resulting from activities performed at VASDHS. The RSC is further charged with establishing and maintaining appropriate procedures for the use, care and control of all sources of ionizing radiation within all VASDHS facilities. This is to ensure compliance with existing requirements and is to afford a maximum degree of protection to VASDHS personnel, patients, visitors, and the general public from radiation hazards arising out of the use of radioactive materials and radiation generating devices, such as x-ray machines.

Policies developed by the RSC regarding the use of radioactive material are documented in this Radiation Safety Manual. Any work performed with radiation generating devices must be performed in accordance to all applicable federal regulations and VA and VASDHS policies.

The responsibility for ensuring that approved procedures are carried out, including the rules and regulations regarding radiation safety, is assigned to the RSO. The RSO is responsible for identifying radiation safety problems; initiating, recommending, or providing corrective actions; and verifying implementation of corrective actions. Other duties of the RSO are enumerated in Section 3 of this manual.

ADMINISTRATIVE ORGANIZATION FOR RADIATION SAFETY

Director
Associate Director
Chief, Environment, Health and Safety
Radiation Safety Officer
Radiation Safety Staff

RADIATION SAFETY COMMITTEE

The RSC consists of approximately nine members (including a chairperson) appointed by the Director, who has ultimate authority for the safe use of sources of ionizing radiation. The Committee membership includes individuals who have broad research and/or clinical experience in the use of sources of ionizing radiation, the RSO, a physician identified as an authorized user, a representative from executive management and a representative of the Nursing Service. The Director may appoint alternate members to take the place of those members unavailable to attend a meeting with the exception of the RSO. Both, the RSC Chair and the RSO have stop-work authority and direct access to the Director.

RADIOACTIVE DRUG RESEARCH COMMITTEE

The RDRC meets quarterly to review, comment on, and approve all research protocols involving the administration of radioactive drugs to human subjects.

The Director also appoints the RDRC chairperson and members. These appointments must be in accordance with 21 CFR 361.1.

Applications must be made to the RDRC for non-routine human uses of unsealed radioactive material or radiation. After initial review by the RSO, applications are evaluated by the RDRC.

Radioactive drug research applications must also be submitted to the appropriate UCSD Institutional Review Board (IRB) for approval if required by the FDA and VASDHS Research and Development (R&D) Committee.

The UCSD Human Research Protections Program (HRPP) exists to promote high quality, ethical research. HRPP does this by serving as the advocate for the rights and welfare of persons who participate in research programs conducted by UCSD and VASDHS researchers. The HRPP office assists researchers in complying with all applicable policies regarding experimentation involving human subjects, and oversees the review and conduct of research conducted by federally registered IRBs.

The R&D Committee is responsible for maintaining high standards throughout the R&D program. These standards include those assuring the scientific quality of research projects, protection of human subjects in research, safety of personnel engaged in research, and animal welfare. No research may be undertaken without R&D Committee approval.

All approved applications are subject to periodic review by an IRB, RDRC and R&D Committee.

RSC SUBCOMMITEE ON HUMAN EXPOSURES

A Radiation Safety Subcommittee on Human Exposures (RSSHE), consisting of at least three members of the RSC, has been established by this committee to review and approve the administration of radiation (x-rays and radioactive drugs not covered by the RDRC) to human subjects in support of research. This subcommittee delegates authority to the RSO to perform expedited reviews and approve protocols that are simple and/or involve low radiation doses to human subjects.

SECTION 2: RESPONSIBILITIES AND DUTIES OF THE RSC

The RSC meets at least semiannually to review the performance of the Radiation Safety Program and discuss issues relating to the safe and compliant use of sources of ionizing radiation at VASDHS. A quorum consists of not less than one half the RSC members and must include the RSO and a representative from executive management. Issues discussed may include, but are not limited to, activities of the Radiation Safety Program, Permit Holders with an excessive number of deficiencies, and proposed changes in policy. Other items are discussed as necessary. The responsibilities and duties of the RSC are listed below.

Responsibilities

The RSC must:

1. Ensure procedures for the use, and care of sources of ionizing radiation within the facility are established and maintained and that these procedures are in accordance with all applicable regulations and policies.
2. Ensure that the RSO effectively administers the Radiation Safety Program to ensure that all use of sources of ionizing radiation is accomplished safely and in accordance with all applicable regulations.

Duties

The RSC must:

1. Be familiar with all pertinent NRC and other regulations, the terms and conditions of the institution's broadscope VHA radioactive materials permit (VHA RAM Permit), and the information submitted in support of the request for the permit and its amendments.
2. Ensure the training, experience, and qualifications of all prospective radioactive material Permit Holders is appropriate to enable them to perform their duties safely and responsibly.
3. Monitor the facility's ALARA program to ensure individual and collective doses are maintained as low as is reasonably achievable.
4. Establish a table of investigation levels for occupational radiation exposures which when exceeded will initiate an investigation and consideration of corrective action by the RSO.
5. Ensure that individuals whose duties may require them to work in the vicinity of radioactive material (i.e., Security, and Housekeeping personnel) are instructed at least biennially.
6. Ensure that the Radiation Safety Program is reviewed at least annually to determine that activities are being conducted safely and in accordance with applicable regulations as well as terms and conditions established in the VHA RAM Permit.

7. Review diagnostic and therapeutic radioactive material quality assurance information on a quarterly basis to ensure that administrations are conducted in accordance with NRC regulations as well as terms and conditions of the VHA RAM Permit.
8. Review and determine the adequacy of remedial actions taken to correct any deficiencies identified in the Radiation Safety Program.
9. Review and determine the adequacy of corrective or disciplinary actions imposed upon Permit Holders with an excessive number of deficiencies noted during laboratory audits.
10. Maintain written records of all committee meetings (including members present), documenting actions, recommendations, and decisions.
11. Ensure that the VHA RAM Permit is amended, when required, prior to any changes in facilities, equipment, policies, procedures, radioactive material, possession limits and personnel, as specified in the radioactive materials permit.
12. Ensure that any work performed with radiation generating devices is performed in accordance to all applicable VA policies and federal regulations.
13. Receive concurrence in writing from executive management and the RSO for all committee actions.

Responsibilities

The RSO must:

1. Implement measures to ensure that safe radiological working conditions are established and maintained for all VASDHS personnel, patients, visitors, and the general public.
2. Implement measures to ensure compliance with all pertinent regulations and policies.
3. Fulfill the duties of the RSO as described in all sections of this manual.

Duties

The specific duties of the RSO include the following:

1. The RSO is a member of the RSC and must present to that Committee applications of individuals wishing to use radioactive material. The RSO must also make recommendations concerning the applications. In making these recommendations, the RSO must consider: analysis of qualifications and training of the applicant, the appropriateness of the radioactive material and quantities, analysis of the laboratory equipment and procedures, the expected controls that will be needed, the possible need for written procedures and hazard analysis, the need for record keeping of use, surveys, disposal, inventories, and other essential information.
2. The RSO has the authority to temporarily grant or cancel any individual's permit to use radioactive material. The RSO will refer such actions to the RSC for final decision.
3. The RSO has the authority to "clear the area" in the event of a radioactive material spill of whatever nature and to further restrict reentry until such time as the hazard is removed or reduced to a safe level.
4. The RSO has the authority to require the use of personnel monitoring equipment (e.g., thermoluminescent dosimeters) in those cases that he deems necessary and require the use of protective apparel.
5. The RSO or his designee must function as a controlling agent for all radioactive material used throughout the facility. His function in this regard is to ensure radioactive material shipments are checked for contamination, leakage, breakage, etc.; prevent persons working within the facility from obtaining radioactive material without proper authorization; and ensure proper record keeping as required by applicable regulations.
6. The RSO is designated the official representative of VASDHS to the various governmental bodies and agencies at all levels with regard to radioactive material use.
7. The RSO or his designee acts for VASDHS to arrange for shipment of radioactive waste, as needed, to a suitable receiving agent.

8. The RSO will implement measures to ensure that radioactive material use and storage areas are properly supervised.
9. The RSO will provide consulting service concerning radiation hazards and safe working procedures to all employees whose duties necessitate the handling of radioactive material and/or working near radioactive material use areas.
10. The RSO regularly briefs executive management on the kinds of radioactive material being used, employee involvement and exposure to radiation, regulatory requirements, potential radiation safety problems, and the ALARA program.

SECTION 4: RESPONSIBILITY OF RADIOACTIVE MATERIAL PERMIT HOLDERS

A radioactive materials use permit holder (Permit Holder) is defined as any Principal Investigator authorized to use radioactive material in a research program. Principal investigators must obtain approval from the RSC prior to performing any research with radioactive material. The use of radioactive material at VASDHS is restricted to Permit Holders and their approved staff. This authorization is indicated by the issuance of a permit specifying the name of the Permit Holder, the room(s) in which radioactive material may be used, the radioisotope(s) to be used, and the maximum quantity of each isotope permitted to be held by that Permit Holder at any given time.

Permit Holders are responsible for the safe use of all radioactive material obtained under their permit or used in the laboratory space assigned under their permit. Permit Holders are also responsible for ensuring that all applicable regulations and VASDHS policies are followed at all times.

Permits are issued by the RSO on behalf of the RSC. Prospective Permit Holders must complete and submit an application package to the RSO, who will review the materials and submit them to the RSC for consideration. An application package includes,

- A copy of the Principal Investigator's curriculum vitae;
- Completed In Vitro and/or Animal Use form (VARSO 1000 or 1010, respectively)

Applicants must have at least 40 hours of training and experience (T&E) in safe handling of radioactive materials. At least 8 hours must be from formal VASDHS instruction. This instruction should cover the following subjects:

- Principles and practices of radiation protection,
- Radioactivity measurements, monitoring techniques and instrumentation,
- Mathematics and calculations basic to the use and measurement of radioactivity, and
- Biological effects of radiation.

Personnel not meeting the 40-hour T&E requirement must work under an approved Permit Holder to gain experience prior to receiving their own permit. Permit Holders who are physicians using radioactive material for patient treatment must meet other requirements that are described in greater detail in Section 20 of this manual.

If a Permit Holder will be absent from his/her laboratory for a prolonged period of time (in excess of four consecutive weeks) he/she must designate an alternate person to assume responsibility for their permit during their absence. The alternate must be a person approved by the RSC as a Permit Holder. In the absence of a designated alternate, the permit must be inactivated, all radioactive material collected for storage or disposal, and the laboratory space closed out radiologically (surveyed and all radiological signs removed). Other specific responsibilities of Permit Holders are noted below.

It is the responsibility of all Permit Holders to:

1. To amend their permits for any changes in laboratory space, radionuclide(s) to be used, maximum on hand or single order activities, or chemical form of radioactive material to be used prior to commencing a new experimental protocol.
2. Notify Radiation Safety of the completion of an experiment or plans to terminate the use of radioactive material at VASDHS. Such notification must be made at least four weeks before leaving the facility. The RSO has authority to terminate Permits for laboratories that remain inactive (do not perform any work with radioactive material) for more than 2 years.
3. Ensure that surveys for radioactive material contamination are performed and documented as required when radioactive material is in use and that these surveys are performed with the appropriate instrumentation. Research laboratories are required to document weekly or monthly surveys. The frequency of survey documentation is based on the toxicity classification and the levels of radioactive material handled at any one time as shown in the table below:

Toxicity Classification	**Sample Radionuclides**	**Monthly Survey**	**Weekly Survey**
High	^{45}Ca, ^{125}I, and ^{131}I	$\leq$ 100 μCi (3.7 MBq)	> 100 μCi (3.7 MBq)
Moderate	^{14}C, ^{18}F, ^{32}P, ^{33}P, ^{35}S, ^{51}Cr, and Co^{57}	$\leq$ 1000 μCi (37 MBq)	> 1000 μCi (3.7 MBq)
Low	^{3}H and ^{99m}Tc	$\leq$ 10,000 μCi (370 MBq)	> 10,000 μCi (370 MBq)

   Most research laboratories at VASDHS are required to document surveys on a monthly basis. These surveys should be performed on or just after the last day of use, and before the end of the month. If a laboratory does not use radioactive material in a given month, no survey is required for that month, but a NO USE entry should be documented in the laboratory's survey records.
4. Inform all employees of potential health hazards as well as the safeguards being used to prevent adverse exposures.
5. Ensure that all employees who have been provided a radiation dosimeter:
   - Wear their dosimeter when working with radioactive material;
   - Return their dosimeter in a timely fashion when requested;
   - Wear their dosimeter only when being exposed to ionizing radiation at VASDHS.
6. Ensure that personnel using greater than 1,000 μCi (37 MBq) of radioiodine or 80,000 μCi (2.96 GBq) of H-3 are available for bioassay when required by the Radiation Safety Office.
7. Ensure compliance with possession limits by properly inventorying radioactive material and disposing of radioactive waste and contaminated items. In addition, ensure that updated inventories are submitted to Radiation Safety when requested.
8. Ensure that all radioactive waste is delivered to Radiation Safety for disposal. All waste must be in suitable sealed containers and labeled with a completed waste tag.

Radioactive waste is NEVER to be left unattended in hallways. Liquid radioactive waste may NOT be disposed of via laboratory sinks unless specifically authorized in writing by the RSO.

9. Ensure that radioactive material is secured from unauthorized access or removal via physical security (e.g., locked cabinet, drawers, refrigerators doors, etc.) and/or via visual security (e.g. approved radioactive material users monitor use and storage areas).
10. Notify Radiation Safety of the acquisition of any equipment containing radioactive sealed sources. Examples of such equipment are analytical balances, liquid scintillation counters, and gas chromatographs.
11. Develop and review procedures to ensure that all radiological work is conducted safely.
12. Notify Radiation Safety of any prolonged absences (in excess of four consecutive weeks) and designate an alternate Permit Holder for this period.
13. Notify Radiation Safety immediately in the event of any radiological emergencies such as spills of radioactive material, contamination of laboratory personnel, or the loss of radioactive material.
14. Ensure all radioactive material users have received radiation safety training prior to commencing work with radioactive material and that they complete refresher training.
15. Administer and enforce radiation safety rules and regulations in all areas within the scope of their authority.
16. Ensure that each researcher properly controls any contamination in his/her work area and that appropriate surveys are performed when work has been completed. If contamination above established limits is detected routinely, the researcher must inform the Principal Investigator and the RSO and decontaminate the area.

Permit Holders who fail to carryout their assigned responsibilities and duties jeopardize VASDHS's ability to utilize radioactive material. Such failure will not be tolerated. Non-compliant Permit Holders may be subject to temporary or permanent revocation of their authorization to use radioactive material. Specific policies relating to this subject are documented in Section 5 of this manual.

SECTION 5: POLICY FOR IDENTIFYING AND ADDRESSING DEFICIENCIES

Radiation Safety performs periodic laboratory audits to ensure compliance with applicable regulations and the policies set forth in this manual. Deficiencies of requirements will be addressed by the policies of this manual. Radiation Safety recognizes that specific circumstances and severity of deficiencies call for different corrective or, if necessary, disciplinary actions.

This policy applies to all personnel using radioactive material at VASDHS.

Policy

1. Deficiencies may be noted at any time. Reporting of deficiencies is not limited to formal audits.
2. Deficiencies may be corrected on the spot by the person noting them if appropriate. Although no notice of such deficiencies may be issued in these circumstances, the Permit Holder must be notified.
3. Deficiencies will be counted against the specific room in which they were noted and will be charged against the permit under which that room is listed. Deficiencies that take place in unauthorized laboratory spaces will be charged against the Permit Holder responsible for the research being performed. Deficiencies noted in common areas (e.g., corridors, equipment rooms, etc.), unauthorized areas, or in laboratory space that does not belong to a radioactive material user will be charged against the permit under which the radiation worker is listed or under which the radioactive material was ordered, as appropriate.
4. All memoranda of deficiency must be approved by the RSO prior to issuance to Permit Holders.
5. Upon receipt of a deficiency memorandum, the Permit Holder must provide a written response to the RSO within 10 working days. This written response must provide a brief description of the circumstances that lead to the deficiency and identify the actions that will be taken to prevent recurrence. If the Permit Holder feels the deficiency cited was issued in error or that there were mitigating factors, the deficiency may be contested to the RSO, who will decide whether or not to withdraw it. All communications with the Permit Holder will be retained in the Permit Holder's file, where they will be available for review by the RSC upon request. Permit Holders who do not provide a written response within 10 working days will be referred to the RSC chair for further action.
6. Any Permit Holder receiving more than two memoranda of deficiency in any 12-month period will be subject to further review and possible disciplinary action. In these instances, the RSO will notify the Permit Holder, conduct a review to determine root causes for deficiencies, and require the Permit Holder to respond in writing, detailing corrective actions. The RSO will then refer the matter, along with his recommendations, to the RSC chair for him to review. If the RSC chair deems that the actual or proposed corrective actions are adequate, no further action will be

taken and the RSC will be informed of the case at its next regularly scheduled meeting. If, however, the RSC chair deems that disciplinary action may be warranted, he/she will refer the matter to the entire RSC. If warranted, the Permit Holder may be required to appear before the RSC. Disciplinary actions will be intended to discipline the Permit Holder or the responsible party for repeated deficiencies or for particularly flagrant or egregious violations of regulations or radiation safety practices. A list of possible corrective and disciplinary actions is included below.

7. In the case of particularly willful, flagrant, or egregious violations of regulatory requirements, radiological safety requirements, or health and safety practices, the RSO may immediately suspend a radioactive material permit and all work under it. Such suspensions will be immediately referred to the RSC chair for concurrence. If the RSC chair agrees with the suspension, the RSC will determine subsequent actions to be taken. If the RSC chair does not concur with the suspension, the Permit will be reinstated immediately. Upon completion of all corrective or disciplinary actions, the RSO will perform a follow-up audit of all spaces listed under the Permit in question to verify compliance with all required actions, regulations, and standards. Following this inspection, the RSO will recommend restoration of the Permit and resumption of radiological work.
8. Following Permit restoration, audits will be performed monthly for a three-month probationary period, after which the normal audit periodicity will resume.
9. Further deficiencies noted during this probationary period will result in a recommendation for additional corrective or disciplinary actions.

Examples of Laboratory Deficiencies

1. Loss of security or control of radioactive material
2. Eating, drinking, or food storage in radiologically posted laboratory space
3. Use of radioactive material by unauthorized personnel
4. Use of radioactive material in an unauthorized laboratory or room
5. Removable radioactive contamination in excess of 2000 dpm/100 cm^2 in any area (200 dpm/100 cm^2 for radioiodines)
6. Unauthorized receipt, transfer, or shipment of radioactive material
7. Loss of radioactive material
8. Evidence of internal exposure to radioactive material resulting from abnormal incidents
9. Failure to wear required radiation dosimetry
10. Radioactive material in non-radioactive waste containers
11. Evidence of the disposal of liquid radioactive waste into laboratory sinks
12. Persons using radioactive material while his/her laboratory is under suspension
13. Unlabeled contaminated laboratory equipment

14. Failure to wear proper personal protective equipment (e.g., lab coat, gloves, etc.)
15. Failure to participate in required bioassay programs (if appropriate)
16. Failure to perform and document weekly or monthly radioactive contamination surveys during months in which radioactive material was used
17. Pipetting by mouth
18. Survey meter out of calibration or use of inoperable survey meter
19. Incorrect documentation of radioactive material inventory
20. Improper waste segregation
21. Failure to use proper radiological survey techniques
22. Poor radiological housekeeping
23. Improper use of a fume hood, absorbent pads, or bench covers not used in radiological work or storage areas
24. Failure to remove or obliterate radiological symbols from empty containers
25. Failure to report a radiological incident (e.g., spill, skin contamination, loss of radioactive material, etc.) to Radiation Safety within 2 hours of its occurrence
26. Failure to take appropriate immediate actions in the event of radiological emergencies such as spills or skin contamination incidents
27. Any other activities that violate NRC regulations or the provisions of the referenced documents.

Examples of Possible Recommended Corrective or Disciplinary Actions

1. Temporary suspension of an individual's authorization to use radioactive material
2. Permanent suspension of a specific individual's authorization to use radioactive material
3. Mandatory refresher training for personnel listed under a specific permit
4. Suspension of authorization to order radioactive material under a specific permit for various periods of time up to two months
5. Suspension of radioactive material use permit for periods of time up to one year
6. Complete revocation of radioactive material use permit and the ability of specific individuals to use radioactive material under any other permit at VASDHS

SECTION 6: RADIATION DOSE LIMITS

The NRC specifies dose limits for radiation workers (occupational) and the general public (non-occupational). These dose limits do not apply to patients or human subjects exposed to ionizing radiation during x-ray examinations, radiation therapy or from the administration of radioactive materials for research purposes.

6.1 Occupational Dose Limits for Adults

1. The annual limit is the more limiting of
   - the total effective dose equivalent being equal to 5 rem (50 mSv); or
   - the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) being equal to 50 rem (500 mSv).
2. The annual limits to the lens of the eye, to the skin, and to the extremities are
   - an eye dose equivalent of 15 rem (150 mSv), and
   - a shallow dose equivalent of 50 rem (500 mSv) to the skin or to any extremity.

The determination of deep, shallow, and internal dose is estimated by procedures presented in 10 CFR Part 20.

These limits must be reduced by the amount of the occupational dose that an employee may have received at a previous place of employment.

6.2 Radiation Exposure During Pregnancy

With regard to the radiation worker who declares (defined under 10 CFR 20.1003 as a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception) her pregnancy, VASDHS is committed to ensuring that the exposure of the embryo/fetus to ionizing radiation is kept as low as reasonably achievable (ALARA) and less than the following exposure limits set by VASDHS and the USNRC

Exposure Limits for Embryo/Fetus and Declared Pregnant Worker

VASDHS……≤ 40 mrem (0.4 mSv) per month and 400 mrem (4 mSv) over the entire pregnancy
USNRC……..500 mrem (5 mSv) over the entire pregnancy, fairly uniformly distributed

Please refer to the attachments for more information regarding the radiation worker pregnancy declaration policy and procedure.

6.3 Occupational Dose Limits for Minors

The annual occupational dose limits for minors is 10% of the annual occupational dose limits specified for adult workers in Section 6.1.

6.4 Determination of Internal Doses

The Annual Limit on Intake (ALI) is the basis for estimating the dose of radiation from internally deposited radioactive material. Briefly, an estimate is made of the amount of a given radioactive material in the employee's body by testing urine, or directly monitoring a person with a radiation detector. This process is called bioassay. Based on the bioassay results, a dose is determined by Radiation Safety. All bioassay results must be reviewed by the RSO.

The Derived Air Concentration (DAC) is used to determine the committed effective dose equivalent in cases where people are exposed to contaminated atmospheres. In cases where procedures may result in the production of a radioactive atmosphere, provision may be made to apply respiratory protective measures. The RSO will consider these conditions on a case-by-case basis, using the appropriate measures discussed in 10 CFR 20.

When it is suspected that internal exposure (e.g., inhalation, ingestion, absorption, etc.) to radioactive material has occurred, the dose received will be calculated and compared to the ALI.

Those individuals using more than 1000 μCi (37 MBq) of radioiodine or 80,000 μCi (2.96 GBq) of tritium may require periodic bioassays.

6.5 Planned Special Exposures

VASDHS may authorize an adult worker to receive doses in addition to, and accounted for separately from, the doses received under the limits listed in 6.1 above, provided each of the following conditions are satisfied:

1. Only in an exceptional situation when alternatives that might avoid a higher exposure are unavailable or impractical.
2. The exposure must be authorized in writing by the RSO before the exposure occurs.
3. Each worker involved is informed of the planned operation, the estimated doses, and associated potential risks and radiation levels, and instructed in measures to keep doses ALARA.
4. The RSO must assess prior dose according to federal regulations.
5. The RSO must not authorize a planned special exposure in excess of 5 rem (50 mSv) in a single year. This dose is in addition to the allowable annual exposure of 5 rem (50 mSv) in a calendar year.
6. The RSO must document the best estimate of the dose from the planned special exposure and inform the exposed individual within 30 days of the exposure.

6.6 Radiation Dose Limits for Individual Members of the Public

The dose in any area outside of a controlled area must not exceed 2 millirem (0.02 mSv) in any one hour. The total dose to individual members of the general public must not exceed 100 millirem (1 mSv) with certain exceptions as approved by the

RSO, and in accordance with federal regulations. In addition to these specific radiation dose limits, VASDHS is committed to maintaining exposures as low as is reasonably achievable (ALARA). To this end, provided in the attachments is the VASDHS ALARA Program, which should be used by Permit Holders and approved users to minimize their occupational exposure to ionizing radiation.

SECTION 7: PERSONNEL MONITORING

7.1 Dosimeter Requirements

Dosimeters are required for adults working with radioactive material who are likely to receive greater than 10% of the dose limits of Sections 6.1 and 6.2. Monitoring is required for minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv). Monitoring is also required for declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv). Due to the relatively low activities used in research laboratories at VASDHS, most radiation workers are not required to wear a dosimeter. Additionally, dosimeters are not required for radioactive material that emits beta radiation of such low energy that it cannot be detected by a dosimeter (e.g., H-3, C-14, and S-35). In general, only individuals performing more than five procedures per month involving more than 1000 μCi (37 MBq) of high-energy beta or gamma emitters (e.g., P-32, Cr-51, Co-57, and I-125) are usually issued dosimeters.

VASDHS contracts with a vendor whose dosimetry service holds current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology. This vendor is approved in the aforementioned accreditation process for the type of radiation included in the NVLAP Program that most closely approximates the radiation for which VASDHS personnel may be monitored.

7.2 How to Obtain a Dosimeter

Personnel requesting dosimetry must first complete required training. For specific training guidelines, contact Radiation Safety. Next, personnel must complete and submit to Radiation Safety a radiation dosimeter application form. If deemed necessary, Radiation safety may require personnel to complete a Radiation Exposure Profile for Radiation Worker Form (VARSO 2015). Radiation Safety may request a dose history from previous employers for personnel who have worked with ionizing radiation in the past.

7.3 Wearing a Dosimeter

Dosimeters are to be clipped to an article of clothing between the waist and shoulder level at the front of the torso (unless otherwise instructed for the type of dosimeter issued (e.g., finger ring/extremity dosimeter)). This location should be the area where the body is expected to receive the greatest exposure. When wearing a lead apron, the dosimeter must be worn at the collar level outside the apron. Arrangements may be made for another dosimeter to be worn under the apron.

7.4 Proper Use of Dosimeters

Dosimeters are issued in accordance with federal regulations; therefore, dosimeters are a legal document, and as such, they must not be tampered with in any manner. Erroneous exposure readings caused by deliberate exposure may result in investigation by the NRC and remain part of a person's permanent exposure record.

Dosimeters issued are to be used to measure occupational exposure at VASDHS only. They may not be used at any other institution. They must not be worn while receiving medical or dental x-rays. Dosimeters are not to be worn at home. No person is permitted to wear somebody else's dosimeter at any time for any reason.

7.5 Periodic Exchange

Each group or series of dosimeters will have a designated person to handle their periodic exchange. Each exchange period, dosimeters are either hand delivered or mailed via intramural mail to the designated individual. This person will exchange the dosimeters and return the previous period's dosimeters by the return date. The dosimeters are to be exchanged on the date of the new dosimeters or as near as possible to that date. Return the dosimeters by intramural mail if they will arrive by the return date; otherwise, hand deliver to Radiation Safety.

7.6 Exposure Results

Exposure results are received from the dosimeter company approximately 3-4 weeks after the dosimeters are returned. Once this information is received, Radiation Safety reviews it to ensure that occupational doses are kept ALARA and within established limits.

7.7 Radiation Dosimetry Reports

At VASDHS, all personnel who are required to be monitored and receive at least 100 mrem during a calendar year are provided an annual occupational dose report. This report is given to monitored personnel individually. Monitoring reports are also given to workers upon request. Radiation Safety notifies an individual immediately whenever current monitoring results exceed what is reasonably expected, considering the nature of the work being done.

7.8 Misuse of Dosimeter

Personnel must not wear dosimeters which have not been assigned to them. The participant number is a lifetime assignment and is not transferable to another person. If a dosimeter is lost or misplaced, a temporary dosimeter will be issued upon request. Any abnormal exposure should be reported, and a new dosimeter should be issued if the old dosimeter is damaged or misused in any way. Dosimeters should be kept away from heat and radiation when not in use. Also, they should not be left on lab coats where they could be accidentally contaminated with radioactivity, or left in rooms where they could be exposed to radiation.

7.9 Notification and Investigation of Exposures

VASDHS has established the following Investigational Levels for individual occupational external radiation exposures, which, when exceeded, will initiate review or investigation by the RSO and/or the RSC. These levels apply to the exposure of individual workers for each monitoring period:

Exposed Organ or Tissue	Level I (Notification)	Level II (Investigation)
Total effective dose equivalent (For x-ray workers, effective dose equivalent is used)	125 millirem (1.25 mSv)	400 millirem (4 mSv)
Lens of the eye	375 millirem (3.75 mSv)	1200 millirem (12 mSv)
Skin and extremities	1250 millirem (12.5 mSv)	4000 millirem (40 mSv)

Except when deemed appropriate by the RSO, no action will be taken in those cases where an individual's dose is less than or equal to the values established for level I. For personnel receiving doses greater than level I, the RSO will review the dose of each individual exceeding this level and report the results of his/her reviews at the first RSC meeting following the quarter when the dose was recorded. If such dose does not exceed level II, no further action is required unless deemed appropriate by the RSO. The RSO will investigate, in a timely manner, the cause(s) of all personnel doses exceeding level II and, if warranted, take action. A report of the investigation and actions taken, if any, will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be recorded in the Committee minutes. In cases where a worker's or a group of workers' doses need to exceed Level II, a new, higher Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new level II will be documented.

7.10 Other Dosimetry Services

Other types of dosimeters are available for special needs (e.g., ring and wrist dosimeters). Routine analysis for internal exposure to radioactive material is available from Radiation Safety for users of H-3, I-125, and I-131. Other radionuclides may be monitored by special arrangement with Radiation Safety.

7.11 Visitors

The term “visitor” is used to designate all persons for whom personnel-monitoring equipment is not provided on a routine basis, including employees, students, and consultants, as well as visitors from outside.

If visitors, with the exception of building contractor personnel, expect to be in a radiation area from time to time for a period of four consecutive weeks or more, Radiation Safety should be notified by the Service concerned so that personnel-monitoring equipment can be issued, if required. Employees of building contractors are expected to use visitor badges when necessary, even though they

may be expected to work onsite for several months. Contractors may wear their own dosimetry with the concurrence of Radiation Safety.

7.12 Responsibility for Use of Dosimeters

It is the responsibility of all individuals and supervisors to wear personnel-monitoring equipment in accordance with the above policies and procedures. Supervisors must ensure compliance. It is the responsibility of all persons and supervisors to cooperate with Radiation Safety in an investigation of exposures when required. It is the responsibility of each individual to return his/her personnel-monitoring equipment to the appropriate place at the end of each workday. If a dosimeter is lost or damaged, Radiation Safety must be notified promptly.

If an investigator decides that dosimeters are no longer needed, it is his/her responsibility to notify Radiation Safety in writing. If Radiation Safety agrees, the dosimeters will be terminated promptly. If an employee terminates employment with VASDHS or transfers to a different department, the investigator should notify Radiation Safety so that the employee's dosimeter may be cancelled in a timely fashion.

SECTION 8: REQUIREMENTS FOR POSTING/LABELING LABS USING RADIOACTIVE MATERIAL

8.1 Radioactive Material Areas: Posting and Labeling

1. A sign or label with the words “Caution- Radioactive Material” and the radiation hazard symbol must be placed on each door, refrigerator, or storage locker where radioactive material is used or stored. The sign or label must also be affixed to storage and waste containers, contaminated waste cans, hoods, and work areas.
2. Laboratory equipment and containers, including beakers, flasks and test tubes, pipetters, centrifuges, and so forth, must be labeled as described above when they contain or are used in handling radioactive material.
3. Containers holding radioactive material must be labeled with the words “Caution, Radioactive Material,” the radiation hazard symbol, as well as the identities of the radioisotopes contained therein.
4. Exemptions to these labeling rules include
    - laboratory containers, such as beakers, flasks, and test tubes, used transiently in laboratory procedures (i.e., for a period of a few hours) in the presence of an authorized user; or
    - containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation (DOT).

8.2 Empty Containers

Empty containers that are free of contamination and are to be discarded must have all radioactive material labels, radiation symbols, and markings related to radiation or radioactive material removed or defaced prior to disposal. If this is not possible, Radiation Safety should be contacted for assistance.

8.3 Misuse of Caution Signs

Labels and signs required in this section must not be used for any purpose other than to warn against a radiation hazard.

SECTION 9: SURVEYS OF LABS USING RADIOACTIVE MATERIAL

Laboratory personnel are responsible for monitoring for and controlling radioactive contamination in their laboratories where radioactive material is used and/or stored. Meter and swipe surveys must be performed at the indicated frequencies so as to control radioactive contamination.

9.1 Meter Surveys

Using hand-held survey meters, personnel should monitor work areas before, during and after each use. For any work or storage area found to bear radioactive contamination at levels greater than three times background, decontamination and resurveying procedures must be performed immediately until levels are less than this action level. If it is reasonable to do so, laboratory personnel should attempt to decontaminate contaminated surfaces to acceptable levels (e.g., less than three times background). When decontamination efforts are not successful in reducing contamination levels, laboratory personnel must contact Radiation Safety for assistance. Radiation Safety does not require laboratory personnel to document meter survey results unless they are performed as part of the required weekly or monthly surveys (See Section 4). Laboratory personnel are advised that survey meters, for the most part, are unable to detect the radiation originating from low energy beta emitters such as Tritium (H-3). Therefore, meter surveys where only H-3 is used are not required.

9.2 Swipe Test Surveys

Swipe test surveys must be performed at frequencies commensurate with the radioactive material and quantity handled as stated in Section 4. Laboratory personnel are responsible for ensuring proper swipe test surveys are performed and documented at the specified frequency. The number of locations tested in a laboratory or storage area usually ranges from three to ten. Using an alcohol swab or filter paper, swipe test an area of approximately 100 cm^2 at each swipe test location. Count these samples in a suitable liquid scintillation or gamma counter. Results of such surveys should be recorded using a floor plan to indicate their exact locations. Small amounts of contamination may be unavoidable at times, but the degree of such contamination should be kept as low as possible. Work areas or pieces of equipment must be considered contaminated if 2000 (or 200 for I-123, I-125, I-129, or I-131) disintegrations per minute (dpm) are removable with a 100 cm^2 wipe test. Areas with contamination levels exceeding these amounts must be decontaminated immediately. When decontamination efforts are not successful in reducing contamination levels, laboratory personnel must contact Radiation Safety for assistance.

9.3 Surveys Conducted by Radiation Safety

As part of the laboratory audit program, Radiation Safety performs periodic surveys of laboratories where radioactive material is used or stored.

SECTION 10: GUIDELINES FOR SAFE USE OF RADIOACTIVE MATERIAL

Good radiological work practices can encompass a wide variety of methods that may vary from laboratory to laboratory. The following practices are general in nature and apply to most research and medical uses of radioactive material:

1. Prior to performing operations with quantities of radioactive material that may produce significant external or internal exposure, attention must be given by the user to precautionary measures. Such measures may include the use of remote handling devices, hoods, shielding, etc. Radiation Safety must be consulted before beginning any new use of radioactive material.
2. There must be no eating, gum/mint chewing, smoking, drinking, applying of cosmetics, or food preparation in any laboratory where radioactive material is used in dispersable form (e.g., liquid, powder, gas, etc.).
3. Food, drink, or personal effects must not be stored with radioactive material.
4. Pipetting of radioactive solutions by mouth is strictly prohibited.
5. Laboratory equipment (e.g., pipetting devices, centrifuges, etc.) used with radioactive material must be kept separate from other equipment and must be labeled with appropriate radiation hazard warning information.
6. Lab coats and disposable gloves must be worn during operations involving the handling of unsealed sources of radioactive material. The lab coat and gloves should be surveyed for radioactive contamination before leaving the laboratory. Shorts, skirts, open-toed shoes, and other articles of clothing that expose bare skin to possible radioactive contamination should not be worn while working with radioactive material.
7. Care must be taken such that other items (e.g., pens, pencils, notebooks, door knobs, telephones, etc.) are not handled with gloves that were used while working with radioactive material.
8. Work that may result in contamination of work surfaces must be done on plastic-backed absorbent paper or other materials that are approved by Radiation Safety. Trays made of impervious materials (e.g., stainless steel, porcelain-coated, etc.) and lined with absorbent paper provide excellent work surfaces to help prevent the spread of contamination.
9. Work surfaces and personnel must be monitored with appropriate survey equipment after working with radioactive material.
10. Objects and equipment that may have been contaminated with radioactive material must be surveyed and demonstrated to be free of contamination prior to their removal from a laboratory. Contaminated items must be controlled and decontaminated as soon as is practical.

11. If issued, radiation dosimetry must be worn at all times when working with radioactive material. Section 7 of this manual describes dosimetry policies in greater detail.
12. Radioactive material should be transported in shielded containers that can be sealed to minimize the possibility of causing a release of radioactive material. Containers of radioactive liquids being transported must be capped or sealed and transported in secondary containers to minimize the potential for a spill.
13. Personnel working with radioactive material should avoid working alone so that, in the event of a radiological emergency, a person is available to provide assistance.
14. Each individual is responsible for contacting Radiation Safety about any radiological spills, skin contamination, ingestion or inhalation of radioactive material, or similar emergencies.
15. All portable survey instruments must be calibrated annually. Permit Holders are responsible for ensuring meters in their possession are calibrated before use. Radiation Safety should be contacted if meters are broken, out of calibration, etc.
16. Permit Holders are responsible for maintaining an accurate inventory of all radioactive material possessed under their permits and present in their work spaces.
17. Permit Holders are responsible for ensuring that radiation hazard postings on doors to their laboratories are not covered up or marked out unless Radiation Safety has authorized such action.
18. Permit Holders are responsible for ensuring that radioactive material in storage is secured from unauthorized access or removal.
19. Permit Holders are responsible for ensuring that radioactive material in use is controlled and under constant surveillance.
20. All radioactive waste must be collected and submitted to Radiation Safety for disposal as described in Section 15 of this manual.
21. Use of more than 1000 μCi (37 MBq) of any radioiodine in the laboratory may require the worker to come to Radiation Safety for a thyroid bioassay between approximately 6 and 72 hours after use. The use of more than 80,000 μCi (2.96 GBq) of tritium may require the worker to submit a urine sample to Radiation Safety for bioassay within one week.

SECTION 11: SEALED AND UNSEALED RADIOACTIVE SOURCES

11.1 Location

1. Anyone requiring sealed sources (e.g., encased in epoxy, welded shut, etc.) must obtain permission for their use from the RSO.
2. All sealed sources must be registered with Radiation Safety.
3. Any radioactive material that is not permanently sealed is considered to be an unsealed source. The use of this radioactive material is restricted to qualified personnel approved by Radiation Safety.

11.2 Handling

1. A radioactive material label must be attached to each sealed source or source holder. The label information must state the radionuclide, activity, and date of assay. Lettering must be legible from a safe distance. Whenever possible, the source capsule itself should have the identity of the radionuclide engraved or etched on it. Unsealed sources should be stored in containers labeled with the above required information.
2. Remote handling equipment must be used at all times when manipulating sources having exposure rates higher than 100 millirem per hour at 1 meter. Mechanical manipulators or other remote control methods should accomplish movement of such sources from shielded positions to calibration positions. Methods of transfer that do not subject sources to repeated shocks, vibration, or pressure should be used.
3. All sealed sources must be leak-tested by Radiation Safety for possible surface contamination prior to initial use. Subsequent tests must be performed at least once every six months on beta/gamma sources containing more than 100 μCi (3.7 MBq) of any and every three months for alpha-emitting sources of greater than 10 μCi (0.37 MBq).

11.3 Transport of Sources

1. **External Transport**

   For sources to be transported to other institutions, contact Radiation Safety to arrange for proper shipping methodology.

2. **Internal Transport**

   a. Transport of sources within the facility must be accomplished using appropriate shielded containers. The shield design must be adequate to reduce personnel exposure as much as practicable. Call Radiation Safety if assistance is needed in selecting a proper shield. The container must be labeled with the following information: the words “Caution Radioactive Material,” the radiation warning hazard symbol, the date, the radionuclide and the estimated activity of radioactive material in the container.

   b. Sources must not be left unattended in hallways and must be secured against unauthorized removal at all times while in storage.

   c. Only persons who have received Radiation Safety training at VASDHS may transport sources.

11.4 Storage of Radioactive Material

Radioactive material must be stored such that it is secure from unauthorized removal.

1. Access to radioactive material must be restricted to authorized radiation workers.
2. Methods for restricting access includes, but is not limited to, the following:
   a. locking laboratory doors when no personnel are present;
   b. locking a corridor containing several rooms; and
   c. placing radioactive stock vials in a locked refrigerator or a lockbox to prevent removal.

SECTION 12: PROCEDURE FOR OBTAINING RADIONUCLIDES

12.1 Approval to Use Radioactive Material

Principal Investigator: Must apply for a permit through Radiation Safety by completing the required forms, in addition to supplying a copy of his/her CV. All forms are available through Radiation Safety. This permit must then be approved by the RSC.

Radiation Worker: Must complete appropriate training and be authorized to work with radioactive material.

12.2 Orders for Radioactive Material

Radiation Safety must pre-approve all radioactive material purchase requests with the exception of radioactive material ordered by the Nuclear Medicine Service.

1. Information required on a request includes: name of vendor, isotope required, chemical form, activity required (in microcuries or millicuries), catalog number, name of Permit Holder and permit number. The requested radioactive material and corresponding activities must be in accordance with the Principal Investigator's permit.
2. All shipments must be addressed to Radiation Safety/Name of the Permit Holder.
3. Radiation Safety will authorize (stamp and sign) only those purchase requests that are correctly prepared. If the permit limit is exceeded, the order will not be approved and the department will be notified.

12.3 Receipt of Radioactive Material

1. Upon arrival, all packages are surveyed and inspected by Radiation Safety.
2. A member of Radiation Safety will deliver all orders to the appropriate laboratory. The person receiving the material must be an authorized user and must sign a receipt log.
3. Radiation Safety must approve all radioactive material shipments, even if the material is offered to an authorized user at no cost. If radioactive material is to be obtained by other means, however, Radiation Safety is to be notified immediately. If radioactive material is to be transferred to another laboratory or to another investigator, prior approval from Radiation Safety must be obtained.

SECTION 13: OPENING RADIONUCLIDE CONTAINERS

1. Research packages bearing radioactive material are received by Radiation Safety, which will perform all required radiological surveys and inspections in accordance with federal regulations. If any of these packages is delivered directly to the laboratory by the courier, they must be taken to the Radiation Safety Office immediately for evaluation.
2. Proper personal protective equipment, including impermeable gloves and a laboratory coat, should be used when handling radioactive material containers. In addition, there should be no bare skin exposed that could become inadvertently contaminated; therefore, shorts, skirts, and open-toed shoes should not be worn.
3. Special handling procedures supplied by the vendor should be followed.
4. Stock vials and other radioactive material containers must be opened only in properly posted rooms.
5. Extreme caution should be used when opening the inner vial containing the radioactive material. Personnel and area monitoring for possible contamination should be performed after all use or handling of radioactive material.
6. Radiation Safety usually does not deliver stock vials in their original boxes, which usually includes the liner, shield, absorbent materials, and isotope container. If a package is delivered in its original box, all contaminated packaging materials must be managed as radioactive waste. (Any package placed in regular trash must be surveyed for contamination using appropriate monitoring techniques and have all radioactive labels removed or obliterated.)
7. Problems should be reported to Radiation Safety at ext. 3911.

SECTION 14: RADIOACTIVE WASTE DISPOSAL

The treatment and ultimate disposal of radioactive wastes depend on many factors and are strictly regulated by the NRC. To alleviate possible hazards involved in handling radioactive waste, disposal plans must be prepared before a research program is initiated.

14.1 General Rules

1. Minimization of radioactive and mixed (i.e., radioactive and hazardous) waste is a regulatory requirement and an important goal to minimize risk and concomitantly reduce costs. An important step in volume reduction is to segregate radioactive waste from nonradioactive waste.
2. Containers that present added hazards may require sorting before Radiation Safety will accept them. Such hazards include the presence of sharps (broken glass, hypodermic needles, razor blades, etc.), hazardous chemicals, and overly filled liquid waste containers.
3. All dry solid radioactive waste must be separated into long half-life and short half-life waste categories. Radiation Safety provides waste containers for solid waste disposal. No liquids are accepted with the solid waste. Short-lived radionuclides are those that may be stored for radioactive decay in accordance with the VA RAM Permit.
4. Animal carcasses containing radioactivity should be packaged based upon the species and size of the animal (i.e., multiple carcasses may be included in each container provided it will not break and it is easy to manage), and each package must be tagged securely with a waste tag indicating the amount of isotope present in μCi/gm of animal tissue.
5. All liquid waste must be accumulated in containers identified with a waste tag and contained by a secondary containment. The container should not be filled to more than three-quarters full.
6. Scintillation vials should be stored in separate containers.
7. Tags for labeling radioactive waste for disposal are available at no charge from Radiation Safety. The label for all radioactive waste must include
    a. date,
    b. radionuclide,
    c. estimated activity in microcuries,
    d. name of the Permit Holder and lab room number, and
    e. any secondary hazard that may exist (e.g., hazardous chemicals).
8. Needles, syringes, and sharps of any kind must be collected in a sharps container, not in the containers provided by Radiation Safety.
9. Disposal of any high-activity waste will be handled on an individual basis. Contact Radiation Safety to make arrangements.

10. All waste disposals should be recorded in the radioactive waste logbook. The amounts recorded should agree with the amount written on the waste tag.
11. All radioactive identification labels should be defaced or removed from radioactive containers and packages before disposal in radioactive waste containers. Containers and material that are not contaminated should be discarded as nonradioactive waste.

14.2 Radioactive Waste Storage, Processing, and Disposal

1. Short-lived (physical half-life <120 days) solid radioactive waste may be stored for radioactive decay and subsequently disposed of without regard to the radioactivity content. These wastes must be processed and then stored in Radiation Safety's waste processing and storage areas while awaiting disposal.
2. Long-lived (physical half-life $\geq$120 days) solid radioactive wastes must be sent for off-site treatment and/or disposal. They must be processed prior to shipment and then stored in Radiation Safety's waste processing and storage areas.
3. Liquid radioactive wastes must be transferred to Radiation Safety for radioactive decay or off site disposal, depending on the half-life of the nuclide(s) present.
4. Solid radioactive waste may be processed on-site by Radiation Safety via compaction and separation of solids and liquids.

SECTION 15: ANIMALS CONTAINING RADIOACTIVITY

1. No research involving animals may be conducted without receiving approval from the VASDHS Institutional Animal Care and Use Committee (IACUC) and Research and Development (R&D) committee.
2. Prior to commencing any research involving the administration of radioactive material into animals, the researcher must submit a VARSO 1010 Form to Radiation Safety and receive approval.
3. It has been VASDHS' practice not to house animals administered with radioactive material at VMU facilities. VMU may accommodate exceptions to this practice on a case-by-case basis subject to approval by VMU and the Radiation Safety Office.
4. Injections of radioactive material into animals must be performed over absorbent paper. The person conducting the injections must wear protective gloves to minimize the possibility of skin contamination.
5. All cages housing animals administered radioactive material must be marked with the radiation hazard symbol and a tag or label indicating the nuclide(s) and activity administered into each animal, the date(s) of administration, and the name of a contact person.
6. A radiation hazard caution sign must be hung on the door to any rooms in which radioactive animals are housed. This sign must remain on the door until Radiation Safety has cleared the room after completion of the experiment and removal of the animals.
7. It may be required to collect all animal bedding and excreta. Radiation Safety will make this determination. If such collection is necessary, Radiation Safety will provide radioactive waste containers.
8. All animals must be given to Radiation Safety for proper disposal after they have been sacrificed. They must be kept frozen until collected by or delivered to Radiation Safety.

SECTION 16: RADIOLOGICAL INCIDENTS

16.1 Incident Reporting

All incidents involving the use of radiation-producing devices or radioactive material, no matter how minor, must be reported immediately to Radiation Safety (ext. 3911). After hours and during weekends or holidays, contact Trouble Call (ext. 3301). The notification and reporting of incidents is mandatory according to federal regulations.

16.2 Radiological Incidents

A radiological incident is any event (defined below) involving radioactive contamination, high radiation levels, or the loss of radioactive material. Appropriate actions to take for some of these incidents are provided in the following sections.

All radiation workers are responsible for reporting incidents to Radiation Safety. These reports must be made at the earliest opportunity following discovery of the incident and no later than two hours afterward.

Examples of radiological emergencies include:

1. Missing radioactive material
2. Spills of radioactive material that could potentially lead to airborne or surface contamination levels which meet or exceed decontamination action limits
3. Release of radioactive material to the environment that could exceed allowable limits
4. Receiving a dose in excess of established limits
5. Unexpected airborne materials that could cause an environmental or safety concern
6. Malfunction of a radiation-producing device with personnel receiving a dose in excess of 1 rem
7. Personnel contamination
8. Fire or flood involving radioactive material

The general procedure to follow in the event of an incident is outlined below:

1. Stop the cause of the incident if this can be accomplished without additional risk to yourself or co-workers.
2. Warn others in the area and notify Radiation Safety and your Supervisor.
3. Isolate the affected areas by closing doors, putting up barriers, and/or guarding the entrances to the area.
4. Minimize your exposure to radiation and/or radioactive material.
5. If possible, secure local fans if they could spread radioactive material.

6. If you suspect that you are contaminated, stand fast and call for help. Minimize your movements to prevent the spread of contamination.

Under no circumstances must any untrained person attempt to examine or clean up any spilled radioactive material. Proper precautions taken immediately will protect the environment and worker health and safety.

Spill of Radioactive Material

A radioactive material spill is defined as the inadvertent release of radioactive material to an undesirable location with the potential of exceeding contamination limits. Radioactive spills are rarely a physical hazard in the research environment, but they have the potential to raise significant issues and incur considerable expense in the future (facility decommissioning). Spills of radioactive material may jeopardize ongoing and future research activities. All spills of radioactive material must be reported to Radiation Safety (ext. 3911) or Trouble Call (ext. 3301) within two hours of their occurrence. Research personnel involved in the spill must take the immediate actions noted below and must proceed with spill cleanup until Radiation Safety personnel arrive on the scene. At that time, Radiation Safety personnel may assume responsibility for continuing cleanup of the spill, may render assistance to laboratory personnel in completing spill cleanup, or may act in an advisory capacity. The immediate actions to be taken in the event of a radioactive material spill are outlined below.

Stop the spill by capping any open container(s) and placing absorbent materials on top of spilled liquids. The purpose of this step is to take actions to prevent the spill from worsening.

Warn others of the spill by announcing it to co-workers, posting a notice on the door to the laboratory (if appropriate), and contacting Radiation Safety or Security. These actions let others know of the spill so they can take appropriate actions such as rendering assistance, donning protective clothing, evacuating the area, or avoiding walking through the spill area, as appropriate for the specific instance.

Isolate the area by erecting boundaries, posting warning signs, or taking other actions as appropriate. This prevents the inadvertent contamination of personnel and limits the spread of contamination away from the spill area. No personnel may enter a spill area unless they don appropriate anti-contamination clothing such as shoe covers, a laboratory coat, and protective gloves. No personnel may leave a spill area until they have been surveyed and found to be free of contamination.

Minimize personnel exposure by carefully considering the extent of the spill, determining appropriate personal protective equipment, and conducting radiological surveys to delineate the spill area. This helps to maintain personal exposures as low as reasonably achievable.

Stop ventilation if possible and appropriate by turning off room or area ventilation, shutting ventilation dampers, or other appropriate measures. This reduces volatilization of liquid compounds and distribution of powdery solids.

Cleanup of the spill must commence immediately upon completion of the above immediate actions. Following decontamination, surveys must be performed using appropriate equipment to verify cleanup to appropriate levels has been accomplished. Copies of these surveys will be maintained by Radiation Safety and by the laboratory involved in the spill. These surveys must note the exact location and extent of spilled radioactive material prior to commencing decontamination efforts; the contamination levels noted at the time of the spill, and post-cleanup contamination levels (both fixed and removable). In general, use the following rules of thumb when cleaning up a radioactive spill:

1. Clean from top to bottom on vertical surfaces or when contamination is at several different levels.
2. Clean from the outside to the inside of a spill.
3. Clean from areas of low contamination toward areas of high contamination.

Skin Contamination

Skin contamination refers to the presence of radioactive material in direct contact with a person's skin. Skin contamination is a concern because of the potential for very high-localized radiation dose and because of the potential for uptake of radioactive material attached to compounds that are absorbed through the skin and into the body. Skin contamination is almost entirely preventable through the proper use of protective clothing (gloves, lab coats, closed-toe shoes, wearing pants instead of shorts, and so forth). In the event that skin contamination does occur, the following procedure should be followed.

1. Notify Radiation Safety (ext. 3911) or Trouble Call (ext. 3301) immediately.
2. Estimate the amount of radioactive material on the skin. This may be done by using an appropriate meter and recording the count rate, type of detector, and isotope.
3. Commence decontamination efforts, beginning with mild soap and cool or warm water. In general, do not take measures that cause pain or that may degrade the skin's natural ability to act as a barrier. Decontamination efforts should continue until radiation safety personnel arrive, the decontamination is successful, or it is determined that continued efforts are inadvisable.

In the event of contamination with radioactive isotopes of iodine, a thyroid bioassay is required between approximately 6 and 72 hours after the contamination occurs. In the event of contamination with a beta-emitting nuclide (H-3, C-14, S-35, P-32, for example) a urine bioassay is required between 24 and 48 hours after the contamination occurred. The purpose of these bioassay measurements is to determine if uptake of radioactive material occurred. Personnel who are exposed to skin contamination must remain in or near their laboratory area until released by Radiation Safety personnel.

Ingestion or Inhalation of Radioactive Material

Potentially the most serious form of exposure to radioactive material is via ingestion or inhalation since this brings radioactive material into direct contact with living tissues, providing them a way to directly affect internal organs. Virtually all cases of ingestion or inhalation of radioactive material can be avoided through the use of proper laboratory safety equipment, including the use of fume hoods or face shields (when appropriate) and the elimination of eating and drinking in the laboratory environment. Personnel who may have ingested or inhaled radioactive material must remain in or near their laboratory area until released by Radiation Safety personnel. In the event there is a suspected intake of radioactive material through ingestion or inhalation, the following actions must be taken immediately:

1. Stop the source of exposure if possible (i.e., leave the room, move into fresh air, spit contaminated liquids out of the mouth, blow your nose, etc.).
2. Notify Radiation Safety (ext. 3911) or Trouble Call (ext. 3301) immediately.
3. Estimate the amount of intake to the best of your ability (save empty or partially empty stock vials, laboratory glassware, etc., that may help in this estimate).
4. Urine samples must be collected between 24 and 48 hours following any uptake of radioactive material for bioassay. Personnel working with radioactive isotopes of iodine must have thyroid bioassays performed between 6 and 72 hours following exposure.

Exposure to Abnormal and High Levels of X-ray, Beta, or Gamma Radiation

Abnormal levels of x-ray, beta, or gamma radiation in research applications are those levels that exceed 5 mrem/hr (0.05 mSv/hr) or that result in off-scale readings on the highest setting of any survey instrument. Radiation levels of 5 mrem/hr (0.05 mSv/hr) pose no immediate risk to personnel but are indicative of problems that may need to be investigated. In the event abnormal radiation levels are encountered, personnel must note the readings on their radiation survey instruments and immediately contact Radiation Safety (or Trouble Call at ext. 3301 after normal working hours). If radiation levels in research applications exceed 50 mrem/hr (0.5 mSv/hr), personnel must leave the area and assemble in a common area until released by Radiation Safety personnel. Depending on the perceived severity of the incident, Radiation Safety may send out radiation dosimetry for processing to determine whether or not personnel exposures exceeded applicable exposure limits.

Loss of Radioactive Material

Radioactive material is considered lost if it cannot be located within 4 hours after it was identified as missing. Loss of radioactive material is a serious concern that may have to be reported to the NRC. If any worker suspects they have lost radioactive material, they must inform Radiation Safety immediately and be prepared to provide the following information:

1. The radioisotope(s) involved and the approximate activity(ies)

2. The radioactive material stock vial log number(s)
3. The last time that particular stock vial(s) was/were used
4. The normal storage location(s)
5. Actions taken to locate the missing stock vial(s)

Upon arrival at the scene, Radiation Safety will assist with attempting to locate the missing radioactive material. If the material cannot be located, all involved parties will be required to write a report detailing the circumstances surrounding the loss of radioactive material and describing all actions taken. In addition, Radiation Safety will determine the risk posed, if any by the loss of radioactive material and will report the loss to the NRC as required by federal regulations.

Fire or Flooding Involving Radioactivity

If a room containing radioactive material is involved in fire or flooding, personnel working in the area or noticing the problem must take the following actions:

1. Exit the area if you feel your life is in danger.
2. Immediately report the emergency to Trouble Call (ext. 3301), including the fact that radioactive material is stored in the room in question.
3. During working hours, contact Radiation Safety at ext. 3911 to inform Radiation Safety of the emergency.
4. DO NOT try to combat a fire yourself unless you are trained and it is safe to do so.
5. If it is possible to isolate a source of flooding by operating an isolation valve or some other means, or to divert the water away from radioactive material, try to do so.

SECTION 17: STORAGE OF RADIOACTIVE MATERIAL

Radioactive material is stored as stock solutions, as experiments-in-progress, as radioactive waste, and for a variety of other reasons. Regardless of the form of the radioactive material and the reason for its storage, certain requirements must be met to fully comply with regulatory requirements and good radiation safety practices. These requirements are enumerated below.

1. Entrances to all areas in which radioactive material is stored must be posted with the words “Caution, Radioactive Material” and the radiation hazard symbol.
2. All radioactive material storage cabinets, lockers, refrigerators, freezers, etc., must be labeled with the words “Caution, Radioactive Material” and the radiation hazard symbol.
3. Each container of radioactive material must be labeled with the radiation hazard symbol, the words, “Caution, Radioactive Material,” the identity of the radioisotope, and the amount of radioactivity present.
4. All licensed radioactive material must be secured against unauthorized removal or access at all times.
5. Radioactive material storage locations must be shielded so that radiation levels are less than 2 mrem per hour at a distance of 1 meter from any accessible surface.
6. Bulk liquids must be stored in a sealed container. These containers must be kept in secondary containment to minimize the potential for contamination in the event the primary container is breached or damaged.

SECTION 18: TRANSPORTATION OF RADIOACTIVE MATERIAL

18.1 Incoming Radioactive Material Shipments

1. All incoming radioactive shipments to VASDHS, with the exception of radioactive material ordered by the Nuclear Medicine Service, must be received and inspected by Radiation Safety unless special arrangements approved by the RSO have been made. This includes radioactive material that is considered exempt or is generally licensed. Vendors delivering shipments to Nuclear Medicine after hours and on weekends must be escorted by Police Service to the radiopharmacy. Police Service must ensure that these shipments are left secured in this laboratory.
2. Numerous kinds of commercial equipment now contain radioactive material in such small quantities that labeling or special packaging is not required by governmental shipping regulations. Personnel should be aware, however, that radiation and leakage from these items may cause technical interference with the sensitive radiation measurements made in many hospital programs.
3. All radioactive material must be registered with Radiation Safety regardless of the amounts involved or the method or type of fabrication of such material. This specifically includes all radioactive material received from other-than-commercial vendors, such as universities, private research organizations, or government laboratories. A strict inventory is required by the VASDHS' radioactive materials permit, which limits the total amount of radioactive material that may be possessed.

18.2 Outgoing Shipments of Radioactive Material

Radiation Safety is responsible for ensuring that all shipments of radioactive material from VASDHS are in compliance with applicable regulations, policies, and procedures.

1. Any person to have radioactive material shipped from VASDHS should contact the Radiation Safety Office for assistance.
2. Radiation Safety must ensure that the institution receiving the radioactive material is properly authorized to possess the radioisotope in the form and quantity to be shipped. To accomplish this, Radiation Safety will obtain a copy of the institution's radioactive material license or permit prior to shipment.

18.3 Reports of Damaged Shipments

Any report of a damaged radioactive shipment from VASDHS must be promptly referred to Radiation Safety for investigation. Any decision to dispatch Radiation Safety personnel to the scene will depend upon such factors as the nature of the shipment, the extent of damage, the availability of competent personnel closer to the scene, and the requests of authorities having jurisdiction.

SECTION 19: TRAINING PROGRAMS

VASDHS is responsible for ensuring its personnel receive training respective to the radiation hazards present in the work areas. It should not be assumed that prior professional or occupational training has adequately covered radiation safety instruction. In addition to radiation workers, ancillary personnel (e.g., nursing, clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material need to be informed about radiation hazards and appropriate precautions.

Personnel will be instructed

1. before assuming duties with, or in the vicinity of, radioactive material;
2. during refresher training; and
3. whenever there is a significant change in duties, regulations, or the terms of the VASDHS radioactive materials permit.

19.1 Training and Experience for Medical Uses of Radioactive Material

Any human use of radioactive material (i.e., the internal or external administration of radioactive material or the radiations from said to human beings) must be carried out under the supervision of an authorized user. Such application of or order to apply radiation must be in the course of the practitioner's professional practice and must comply with applicable regulatory requirements and the provisions of the VASDHS radioactive materials permit. Physicians, technicians, and other persons involved in the medical use of radioactive material for the diagnosis and/or treatment of diseases in humans must meet the applicable training and experience requirements specified in 10 CFR 35. Physicians wishing to prescribe the use of radiation or radioactivity for the diagnosis or treatment of diseases in humans must be approved by the RSC. Physicians who have not been approved for such use by the RSC may work only under the supervision of an approved physician.

19.2 Training for Non-Medical Uses of Radioactive Material

Instruction will be provided initially and as refresher training. Areas to be covered during training will include, but are not limited to

1. Applicable regulations and radioactive materials permit conditions
2. Areas where radioactive material is used or stored
3. Potential hazards associated with radioactive material in each area where the employees will work
4. Appropriate radiation safety procedures
5. VASDHS radiation safety procedures and policies
6. Each individual's obligation to report unsafe conditions to the RSO

7. Appropriate response to emergencies or unsafe conditions
8. Worker's right to be informed of occupational radiation exposure and bioassay results
9. Locations where notices, pertinent regulations, and copies of pertinent permit and permit conditions are maintained.

All radiation workers are required to receive refresher training. This training may include any of the following:

1. Training administered by the Permit Holder. A short training syllabus and attendance sheet from such training must be forwarded to Radiation Safety.
2. Attendance at scheduled radiation safety training developed and administered by Radiation Safety.
3. Completion of a self-study package developed and administered by Radiation Safety.

SECTION 20: MEDICAL USE OF RADIOACTIVE MATERIAL

All physicians using unsealed radioactive material for diagnostic or therapeutic procedures must be approved by the RSC prior to first use. VASDHS is not authorized to use sealed sources for medical diagnosis, therapy, and research in humans.

20.1 Outpatients

1. Radiation Safety does not require records or notifications of outpatient administrations unless a medical event or an accident (e.g., spills or unexpected personnel exposure to radiation) occurs.
2. When the total effective dose equivalent to any individual from the release of a patient is likely to exceed 100 millirem, the patient or patient's responsible relative or guardian must be provided written information on risks of radiation and methods for reducing the exposure of individuals. Records of such patient releases must be maintained for 5 years.
3. At no time may a patient be provided outpatient treatment using radioactive material when a member of the general public may be reasonably expected to receive a dose in excess of 500 mrem from the treated patient.

20.2 Inpatients

1. When practical, a member of the Radiation Safety staff should attend the administration of therapeutic doses of radioactive material that are injected, or swallowed.
2. Radiation Safety or Nuclear Medicine will provide the patient or patient's responsible relative or guardian information regarding radiation safety precautions to be followed during treatment and after release from the hospital.
3. Radiation Safety or Nuclear Medicine personnel will measure radiation exposure rate levels near the patient to determine stay times for visitors and nursing staff, ensure the room is properly posted, and measure radiation levels in adjacent rooms and post as necessary.
4. A visitor's "safe line" should be marked on the floor with tape as far from the patient as possible.
5. A member of Radiation Safety or Nuclear Medicine will perform a radiation exposure rate survey following each administration of therapeutic doses of radiopharmaceuticals or implanted radioactive sources. Survey points may include, but are not limited to, the patient's bedside, one meter from the patient, and at the door.

6. Stay times for nursing staff will be set such that any nurse caring for radioactive patients will not exceed any annual occupational radiation dose limits.
7. Stay times for visitors will be set such that no visitor will receive a radiation dose in excess of 2 mrem in any hour and 50 mrem during the duration of the patient's stay.
8. Radiation Safety must post the patient's room door with a "Caution, Radioactive Material" sign bearing the radiation hazard symbol and a Radiation Safety Notice for nurses that lists visitor restrictions, nursing restrictions (including stay times), patient care instructions, important phone numbers, and radiation level measurements of the patient and surrounding areas.

20.3 Inpatient Radiopharmaceutical Therapy

1. Nuclear Medicine is required to keep records of all patients receiving radiopharmaceutical therapy.
2. The rooms must be set up to minimize the potential for contamination during the patient's stay by covering the floor, doorknobs, chairs, and other objects likely to be touched with plastic or plastic-backed absorbent material.
3. Patients should not bring any unnecessary personal effects into the room with them. Street clothing may be brought into the room but must remain in the closet until the patient dresses for discharge. Personal effects utilized by the patient will be considered contaminated and must be:
    - decontaminated to acceptable levels and returned to the patient at the time of release;
    - stored until the radioactivity has decayed away and the items can be returned to the patient; or
    - managed as radioactive waste upon the patient's discharge.
4. Disposable table service should be used for the duration of the patient's stay. Housekeeping personnel should be informed to stay out of the room when the room is posted with radiation hazard signage.
5. For radiation therapies performed on an inpatient basis, the following radiation safety policies and procedures apply:
    - The patient will remain hospitalized until either the residual radioactivity in the patient is less than or equal to 30 millicuries, the activity of the radionuclide is such that the total integrated dose at one meter from the patient will not exceed 0.5 rem during complete decay, or the total effective dose equivalent for an individual (other than the patient) is less than 500 millirem.

- Separate plastic-lined containers for linen, disposable waste, and non-disposable contaminated items will be provided.
- If urine is collected, a suitable leak-proof plastic container must be used. Collected urine must be disposed of via the toilet in the therapy suite.
- Nurses working with these patients may be required to wear radiation dosimetry.
- Radiation Safety must brief personnel annually on patient control, visitor control, contamination control, waste control, and emergency notifications.
- Radiation Safety or Nuclear Medicine must brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other applicable items.

6. All personnel entering the patient's room must wear shoe covers and protective gloves prior to entering the room. When exiting the patient's room, shoe covers and gloves must be removed in a manner such as that radioactive contamination does not leave the inside of the therapy suite. Used gloves and shoe covers must be placed inside a waste container in the therapy suite.
7. Only persons needed for medical, safety, or training purposes may be present during the administration of therapeutic doses of radiopharmaceuticals. Personnel must wear gloves, lab coats, and radiation dosimeters during therapy administrations. When handling volatile radiopharmaceuticals, personnel should use fume hoods (when practical) to control exposure to airborne radioactive material.
8. Personnel administering therapeutic doses of I-131 should have their thyroids checked between approximately 6 to 72 hours post administration to determine if radioiodine uptake occurred. Normally, Nursing staff do not require thyroid scans.
9. Sputum or emesis (i.e., vomit) from patients receiving therapeutic doses of unsealed radionuclides should discarded immediately via the toilet in the therapy suite.
10. After the therapy patient has been discharged, Radiation Safety will remove all surface coverings, contaminated items (e.g., used linens, food trays, etc.) and radioactive waste.
11. Radiation Safety will survey the therapy room and its contents for radioactive contamination. Before the patient's room can be used for general occupancy, it must be decontaminated and released by Radiation Safety.

20.4 Procedures Requiring Written Directives

1. Written procedures must be developed, implemented and maintained by Nuclear Medicine to provide high confidence that administrations of

radioactive drugs are in accordance to written directives (WDs). Such procedures must provide methods for verifying that each administration is in accordance with the WD.

2. Occasionally, patients who cannot be released under NRC regulations may have to be taken from the therapy suite to other areas of the hospital to undergo medical procedures. The transportation and treatment of these patients is authorized as long as Radiation Safety is promptly notified, the patient is escorted by a Nuclear Medicine technologist, personnel (physicians, nurses and technologists) that provide care for these patients receive proper instruction, the treatment area and all personnel involved are surveyed and decontaminated, and all radioactive waste generated is properly handled, surveyed and managed.

20.5 Radioactive Cadavers

1. If a controlled patient (e.g., undergoing radiopharmaceutical therapy) expires, it is the responsibility of the physician who pronounces such patient as dead to immediately notify both the physician in charge of the case and Radiation Safety to ensure the safe handling, transportation, and storage of the cadaver.
2. No autopsy of any cadaver containing more than 5 millicuries of any radioactive material can be performed without prior consultation with Radiation Safety.

20.6 Transport of Patients

1. A person from the administering department should accompany any patient with over 30 millicuries of any radioactive material.
2. Escort personnel, when used, must be instructed to handle the patient expeditiously and remain away from the patient if waiting periods arise.
3. Elevators used for transport must be cleared of all personnel not essential to the care or transport of that patient.

20.7 Surgical Removal or Biopsies of Tissues Containing Radioactivity

Studies performed at Veterans Healthcare Administration Medical Centers and other institutions such as the Mayo Clinic and Indiana University have shown that the radiation dose and risk to operating room staff is minimal during surgical procedures associated with patients injected with ^{99m}Technetium (Tc-99m). The amounts of radioactive material used during these procedures are very small. In order to maintain exposures to radiation as low as is reasonably achievable (ALARA), it is recommended that operating room and Pathology laboratory staff observes the following guidelines during surgery involving a patient who has had an injection of a Tc-99m pharmaceutical:

Surgery Personnel

1. Follow standard infection control precautions (e.g., wear disposable gloves, surgical scrubs and plastic aprons).
2. Use forceps to place all radioactive specimens removed from the patient in sealed containers.
3. In addition to the patient's name, nature of specimen and specimen number, label all resected primary site specimens with the name of the isotope (e.g., Tc-99m), and the date and time it was collected.
4. Upon completion of the surgical procedure, all instruments (e.g., forceps, scalpels, etc.) having had direct contact with the radioactive specimens should be cleaned following standard procedures.
5. All specimens should follow the normal biomedical waste management stream and be surveyed before disposal to ensure that radiation levels are indistinguishable from background.
6. Specimens must not be left unattended at any time and should be promptly transported to the pathology laboratory.

Pathology Personnel

1. Handle specimens following standard infection control precautions.
2. Maintain security of specimens at all times.
3. To dispose of specimens follow the normal biomedical waste management stream and survey them before disposal to ensure that radiation levels are indistinguishable from background.

20.8 Waste from Patients Treated with Radioactive Material

1. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material may be disposed of into the sanitary sewerage without being subject to any limitations.
2. Portal monitors are located at trash route areas to ensure that no waste containing detectable levels of radioactive material leave the facility. If while transporting waste, a monitor alarm goes off, workers are required to place it in room B194 for decay. The waste must not be disposed of following the regular waste stream until it no longer causes the portal monitor to alarm.

20.9 Errors in the Administration of Radioactive Material

1. Radiation Safety must be immediately notified following any errors in the administration of radiopharmaceuticals.

2. The referring physician of the affected patient must also be notified as well as the patient or a responsible relative or guardian, unless the referring physician

believes that, in his medical judgment, telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. Notification of parties must be done in a timely manner.

3. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, notification of the medical event will be made as soon as practicable.

20.10 Quarterly Audits

1. In order to ensure that safety rules are observed and that radioactive material has been adequately controlled and administered to patients, Radiation Safety conducts quarterly audits and surveys of the Nuclear Medicine Service.

2. During the course of the quarterly surveys, both external radiation levels and surface contamination levels are monitored. Other areas reviewed at this time include inventory and contamination survey records.

3. It is the responsibility of the Nuclear Medicine Service to have such records well organized, updated and readily available.

20.11 Minimizing Undue Radiation Dose to Patients

1. It is the responsibility of Nuclear Medicine to maintain undue radiation exposure to patients as low as possible and to ensure that proper radiological techniques are administered to the right patients.
2. Radiation exposure to the patient should be carefully restricted to the part under investigation.

SECTION 21: USE OF VOLATILE RADIOACTIVE MATERIAL

There are a number of radiolabeled molecules or compounds that can be volatile under certain conditions. When these molecules or compounds are volatilized, the risk of internal radioactive contamination to research and medical personnel is increased. Provided below is a partial list of volatile molecules or compounds which may be labeled with radioisotopes:

- ^{125}I or ^{131}I: Sodium iodide
- ^{35}S: Methionine
- ^{3}H: sodium borohydride, succinic anhydride, and acetic anhydride
- Compounds that are heated sufficiently that vapors may be released (e.g., heating tritiated water)

The potential for intake must be kept as low as is reasonably achievable. If a person experiences an intake of radioactive material, Radiation Safety must be contacted immediately so that any resulting internal contamination can be quantified, dose to critical organs or tissues calculated, and use of appropriate treatment options (if necessary).

21.1 Precautions for Working with All Volatile Compounds (Including Radioiodine)

1. All work with volatile compounds, such as radioiodinations in Research Service or venting of liquid radioiodine vials in Nuclear Medicine, must be performed in a fume hood in accordance with written procedures. Respiratory protection is not normally required if the fume hood is working properly.
2. Fume hoods must be checked for proper airflow rates at least annually.
3. The fume hood opening must not be obstructed in such a way that airflow is impeded or eddies formed that could result in the release of radioactive material from the fume hood.
4. Notify Radiation Safety immediately in the event of a spill or failure of a fume hood while working with these compounds. Radiation Safety will determine if a bioassay is necessary.
5. If stock solutions in excess of 5,000 μCi are to be used, contact Radiation Safety prior to such use. Radiation Safety will perform a dose assessment to determine if carbon filtration or other precautions are required.
6. Volatile radioisotope use limits are listed in Table 1 below. These limits may be adjusted by the RSO if a researcher can demonstrate that the physical or chemical forms of the compounds they are working with are not volatile.
7. Urine or thyroid bioassays may be required for personnel who handle stock vials containing more than one ALI of any volatile radionuclide or

radionuclide attached to a volatile chemical. Table 1 gives examples of some of these values.

Table 1

Volatile radioisotope use limits that may require bioassay. If a worker's radioisotope usage in a single application exceeds these limits, Radiation Safety must be contacted. Continued use of more than 1 ALI of radioiodines in any month may also require a thyroid bioassay. Fume hood filtration requirements are based on the single-use limit.

Nuclide	**1 ALI**
H-3	80,000 μCi
C-14	2,000 μCi
S-35	20,000 μCi
I-123	6000 μCi thyroid, 20000 μCi whole body
I-125	60 μCi thyroid, 200 μCi whole body
I-131	50 μCi thyroid, 200 μCi whole body

21.2 Additional Precautions for Working with Radioactive Iodine Compounds

1. Any research work with stock solutions in excess of 1,000 μCi of radioiodine must take place in the fume hoods approved by Radiation Safety. These hoods should contain a carbon-filtered exhaust system and ductwork upstream of the filter.
2. Personnel working with stock solutions containing more than 1,000 μCi of radioiodine, having skin contact with this radioisotope or involved in decontamination of a spill should receive a thyroid bioassay between 6 to 72 hours after such work.
3. Radiation Safety will review isotope-use records to verify that bioassays are performed as required.

SECTION 22: MAINTENANCE ON CONTAMINATED OR POTENTIALLY CONTAMINATED EQUIPMENT

Many laboratories contain equipment that may bear radioactive contamination. Such equipment may include, but not be limited to:

1. Refrigerators and freezers in which radioactive material is stored;
2. Fume hoods in which radioactive material is used or stored;
3. Centrifuges, incubation ovens, and other pieces of large analytical equipment; and
4. Ventilation ducts, fans, filters, and other equipment downstream of a fume hood where radioactive material is used.

Such equipment must be labeled the words “Caution, Radioactive Material” and the radiation hazard symbol.

When contaminated or potentially contaminated equipment requires repair or calibration, it must be surveyed and cleared by Radiation Safety prior to commencing repairs or (in the case of portable equipment) prior to removal from an authorized use or storage area. The sequence of operations required in such cases should be as follows:

1. Laboratory contacts Radiation Safety to request survey of broken equipment. Any qualified radiation worker may perform the equipment survey and decontamination in accordance with this section; however, all such surveys will be documented and verified by Radiation Safety.
2. Laboratory requests repair of equipment and notify repair personnel that equipment is used for radiological work.
3. Radiation Safety (or a qualified radiation worker) performs the survey and informs Maintenance of the results.
4. If the equipment is contaminated, Radiation Safety will either decontaminate the equipment, request the laboratory staff to decontaminate the equipment, or provide radiological coverage during maintenance work on it, according to the desires of the Permit Holder. If laboratory staff decontaminates the equipment, Radiation Safety may verify decontamination prior to repair work commencing.
5. Radiation Safety will tag the equipment with the date and time the survey, indicating it has been cleared for maintenance work.
6. Maintenance staff will perform repair work and inform Radiation Safety upon completion. Radiation Safety will remove the radiological clearance tag or sticker for return of the equipment to the laboratory.

Appendix A

VA San Diego Healthcare System ALARA Program

ALARA Policy

Personnel monitoring has been established under the VA San Diego Healthcare System ALARA (As Low As is Reasonably Achievable) Program that establishes the organizational structure, responsibilities and procedures to provide adequate confidence that doses to individuals and members of the general public are as far below the limits as is reasonably achievable. In meeting this objective, the following goals are to be met:

1. Enforcement of the maximum permissible dose level guidelines established in this manual.
2. Review quarterly all occupational exposures to determine if their exposures are in accordance with the provisions of the ALARA program.

Management Commitment

VASDHS Management is committed to the program described in this policy for keeping individual and collective exposures ALARA. In accordance with this commitment, we have established an administrative organization for radiation safety and have developed the necessary written policy, procedures and instructions to foster the ALARA concept within our institution. The organization includes a Radiation Safety Committee (RSC) and Radiation Safety Officer (RSO).

An annual review of the radiation safety program, including ALARA considerations, will be performed. This includes reviews of operating procedures and past exposure records, inspections, and consultations with the radiation protection staff or, if necessary, outside consultants.

Modification to operation and maintenance procedures and to equipment and facilities will be made where they will reduce exposures, unless the cost, in our judgment, is considered to be unjustified.

In addition to maintaining doses to individuals as far below the limits ALARA, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level.

Radiation Safety Committee

The RSC will review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied, to assure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

When considering a new use of radioactive material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and shall have considered incorporating the use of special equipment, such as syringe shields, rubber gloves, etc., in his proposed use.

The RSC will ensure that the user justifies his procedures and that doses (individual and collective) will be ALARA.

Delegation of Authority

The judicious delegation of RSC authority is essential to the enforcement of an ALARA program. The RSC will delegate authority to the RSO for enforcement of the ALARA concept.
The RSC will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's meeting.

Review of ALARA Program

The RSC will encourage all users to review current procedures and develop new procedures, as appropriate, to implement the ALARA concept. The RSC will perform, at its regular meeting, a review of occupational radiation exposure, with particular attention to instances where Investigational Levels in this manual are exceeded. The principal purpose of this review is to assess trends in occupational exposures as an index of the ALARA program quality and to decide if action is warranted when Investigational levels are exceeded. The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO and authorized users and workers, as well as those of Management.

Appendix B

VASDHS PRE-NATAL EXPOSURE POLICY FOR IONIZING RADIATION

PURPOSE

To establish a policy for monitoring pre-natal exposures to ionizing radiation from radioisotopes and x-ray producing machines and equipment.

POLICY

In compliance with Title 10, Code of Federal Regulations, Part 20 (10CFR20), "Standards for Protection Against Ionizing Radiation," this policy establishes the general guidelines for monitoring pre-natal exposures due to ionizing radiation.

GENERAL INFORMATION

The National Council on Radiation Protection and Measurements (NCRP) has recommended that special precautions be taken to limit exposure when an occupationally exposed woman could be pregnant. Specifically, the NCRP has recommended the maximum permissible dose to the fetus from occupational exposure of the mother should not exceed 500 mrem for the entire nine-month gestation period. This is approximately one-tenth of the maximum permissible occupational dose limit.

PROCEDURE

VA San Diego Healthcare System has adopted the conservative policy of restricting the dose of ionizing radiation to the fetus to 40 mrem per month or 400 mrem for the entire period of gestation.

If the employee works in an area where the anticipated dose is less than 400 mrem to the fetus for the gestation period, the employee may continue to work in the area with no restrictions. However, the Radiation Safety Officer (RSO) may make certain recommendations regarding the employee's work assignments.

If a situation is identified in which the anticipated dose to the fetus over the gestation period would exceed 400 mrem, the following two alternatives are possible:

- The employee may be assigned to another area involving less exposure to ionizing radiation.

- The employee may continue to work in the area with certain restrictions to limit exposure of the fetus to less than 40 mrem per month or 400 mrem for the entire gestation period. In some cases, the work environment or the work practices may require slight modifications to ensure that the pre-natal dose to the fetus does not exceed 400 mrem.

If the employee is unwilling to accept the increased risk to her unborn child due to her current level of radiation exposure, she may request reassignment to an area involving less exposure to ionizing radiation. VASDHS will make a good faith effort to accommodate her request in accordance with its general policy for reassignments. The employee must be aware that transfer to another area may result in a change of working hours. If it is not possible or practical to grant her request after a good faith effort has been made, then the employee may be placed on a leave in accordance with the medical center's general policies.

Individuals who are pregnant are not prohibited from working in or frequenting radiation use areas. These individuals may also operate sources of ionizing radiation such as diagnostic x-ray equipment and handle radioactive materials such as those that are present in the RIA Laboratory or Nuclear Medicine. The Radiation Safety Office will monitor the employee's exposure via the personnel dosimetry program.

Nuclide Safety Data Sheet
Hydrogen-3 [Tritium]

^{3}H

I. PHYSICAL DATA

Radiation:	Beta (100% abundance)	
Energy:	Max.: 18.6 keV; Average: 5.7 keV	
Half-Life [$T_{½}$] :	Physical $T_{½}$:	12.3 years
	Biological	10 - 12 days
	Effective $T_{½}$:	10 - 12 days*

* Large liquid intake (3-4 liters/day) reduces effective $T_{½}$ by a factor of 2+; ^{3}H is easily flushed from the body

Specific Activity:	9650 Ci/g [357 TBq/g] max.	
Beta Range:	Air:	6 mm [0.6 cm; 0.25 inches]
	Water:	0.006 mm [0.0006 cm; 3/10,000 inches]
	Solids/Tissue	insignificant [No ^{3}H betas pass through the dead layer of skin]

II. RADIOLOGICAL DATA

Radiotoxicity[1]:	Least radiotoxic of all nuclides; CEDE, ingestion or inhalation:
	Tritiated water: 1.73E-11 Sv/Bq (0.064 mrem/uCi) of ^{3}H intake
	Organic Compounds: 4.2E-11 Sv/Bq (0.16 mrem/uCi) of ^{3}H intake
Critical Organ:	Body water or tissue
Exposure Routes:	Ingestion, inhalation, puncture, wound, skin contamination absorption
Radiological Hazard:	External Exposure - None from weak ^{3}H beta
	Internal Exposure & Contamination - Primary concern

III. SHIELDING

None required - not an external radiation hazard

IV. DOSIMETRY MONITORING

Urine bioassay is the only readily available method to assess intake [for tritium, no intake = no dose]
Be sure to provide a urine sample to Radiation Safety whenever your monthly ^{3}H use exceeds 100 mCi, or after any accident/incident in which an intake is suspected

V. DETECTION AND MEASUREMENT

Liquid Scintillation Counting is the only readily available method for detecting ^{3}H
NOTE: PORTABLE SURVEY METERS WILL NOT DETECT LABORATORY QUANTITIES OF ^{3}H

VI. SPECIAL PRECAUTIONS

- Avoid skin contamination [absorption], ingestion, inhalation, & injection [all routes of intake]
- Many tritium compounds readily penetrate gloves and skin; handle such compounds remotely and wear double gloves, changing the outer pair at least every 20 minutes.
- While tritiated DNA precursors are considered more toxic that $^{3}H_{2}O$, they are generally less volatile and hence do not normally present a greater hazard
- The inability of direct-reading instruments to detect tritium and the slight permeability of most material to [tritiated] water and hydrogen [tritium] facilitates undetected spread of contamination. Use extreme care in handling and storage [e.g. sealed double or multiple containment] to avoid contamination, especially with high specific activity compounds.

---

[1] Federal Guidance Report No. 11 [Oak Ridge, TN; Oak Ridge National Laboratory, 1988], p. 122, 156; Radionuclide and Radiation Protection Data Handbook [Delacroix, et al; Radiation Protection Dosimetry, Kent, England: Nuclear Technology Publishing 1998], p. 19.

VII. GENERAL PRECAUTIONS

1. Maintain your occupational exposure to radiation As Low As Reasonably Achievable [ALARA].
2. Ensure all persons handling radioactive material and listed on an approved permit.
3. Review the nuclide characteristics on prior to working with that nuclide. Review the permit authorizing the procedure to be performed and follow any additional precautions in the protocol.
4. Plan experiments to minimize external exposure by reducing exposure time, using shielding and increasing your distance from the radiation source. Reduce internal and external radiation dose by monitoring the worker and the work area after each use of radioactive material, then promptly cleaning up any contamination discovered. Use the smallest amount of radioisotope possible so as to minimize radiation dose and radioactive waste.
5. Keep an accurate inventory of radioactive material, including records of all receipts, transfers and disposal. Perform lab surveys and record as required.
6. Provide for safe disposal of radioactive waste by following institutional Waste Handling and Disposal Procedures. Avoid generating mixed waste (combinations of radioactive, biological, and chemical waste). Note lab staff may not pour measurable quantities of radioactive material down the drain.
7. If there is a question regarding any aspect of the radiation safety program or radioactive material use, contact Radiation Safety at x3911

VIII. LAB PRACTICES

1. Disposable gloves, lab coats, and safety glasses are the minimum PPE [Personal Protective Equipment] required when handling radioactive material. Remove and discard potentially contaminated PPE prior to leaving the area where radioactive material is used.
2. Clearly outline radioactive material use areas with tape bearing the legend "radioactive". Cover lab bench tops where radioactive material will be handled with plastic-backed absorbent paper; change this covering periodically and whenever it's contaminated. Alternatively cover benches with thick plastic sheeting (i.e., painter’s drop cloth), periodically wipe it clean and replace it if torn.
3. Label each unattended radioactive material container with the radioactive symbol, isotope and activity. Place containers too small for such labels in larger labeled containers.
4. Handle radioactive solutions in trays large enough to contain the material in the event of a spill.
5. Never eat, drink, smoke, handle contact lenses, apply cosmetics, or take/apply medicine in the lab; keep food, drinks, cosmetics, etc. out of the lab entirely. Do not pipette by mouth.
6. Never store [human] food and beverage in refrigerators/freezers used for storing radioisotopes.
7. Prevent skin contact with skin-absorbable solvents containing radioactive material.
8. Fume hoods and biological safety cabinets for use with non-airborne radioactive material must be labeled "Caution Radioactive Material".
9. Use sealed containers and appropriate secondary containment to carry radioactive material between rooms.
10. Before taking any radioactive material off site, contact Radiation Safety at x3911.

VA SAN DIEGO HEALTHCARE SYSTEM A Division of VA Desert Pacific Healthcare Network	**Nuclide Safety Data Sheet** **Carbon-14**	**^{14}C**

I. PHYSICAL DATA

Radiation:	Beta (100% abundance)	
Energy:	Max.: 156 keV; Average: 49 keV	
Half-Life [$T_{½}$] :	Physical $T_{½}$:	5730 years
	Biological	12 days
	Effective $T_{½}$:	Bound - 12 days; unbound - 40 days
Specific Activity:	4.46 Ci/g [0.165 TBq/g] max.	
Beta Range:	Air:	24 cm [10 inches]
	Water/Tissue	0.28 mm [0.012 inches]
	[~1% of ^{14}C betas transmitted through dead skin layer, i.e. 0.007 cm depth]	
	Plastic:	0.25 mm [0.010 inches]

II. RADIOLOGICAL DATA

Radiotoxicity[1]:	0.023 mrem/uCi of $^{14}CO_2$ inhaled; 2.09 mrem/uCi organic compounds inhaled/ingested
Critical Organ:	Fat tissue [most labeled compounds]; bone [some labeled carbonates]
Exposure Routes:	Ingestion, inhalation, puncture, wound, skin contamination absorption
Radiological Hazard:	External Exposure - None from weak ^{14}C beta Internal Exposure and Contamination - Primary concern

III. SHIELDING

None required - mCi quantities not an external radiation hazard

IV. DOSIMETRY MONITORING

Urine bioassay is the most readily available method to assess intake [for ^{14}C, no intake = no dose]
Provide a urine sample to Radiation Safety whenever your monthly ^{14}C use exceeds 5 mCi, or after any accident/incident in which an intake is suspected

V. DETECTION AND MEASUREMENT

Portable Survey Meters: Geiger-Mueller [~10% efficiency];
Beta Scintillator [~5% efficiency]

Wipe Test: Liquid Scintillation Counting is the best readily available method for counting ^{14}C wipe tests

VI. SPECIAL PRECAUTIONS

- Avoid skin contamination [absorption], ingestion, inhalation, and injection [all routes of intake]
- Many ^{14}C compounds readily penetrate gloves and skin; handle such compounds remotely and wear double gloves, changing the outer pair at least every 20 minutes.

[1] Federal Guidance Report No. 11 [Oak Ridge, TN; Oak Ridge National Laboratory, 1988], p. 122, 156

VII. GENERAL PRECAUTIONS

1. Maintain your occupational exposure to radiation As Low As Reasonably Achievable [ALARA].
2. Ensure all persons handling radioactive material are trained and listed on an approved permit.
3. Review the nuclide characteristics on (reverse side) prior to working with that nuclide. Review the permit authorizing the procedure to be performed and follow any additional precautions in the protocol.
4. Plan experiments to minimize external exposure by reducing exposure time, using shielding and increasing your distance from the radiation source. Reduce internal and external radiation dose by monitoring the worker and the work area after each use of radioactive material, then promptly cleaning up any contamination discovered. Use the smallest amount of radioisotope possible so as to minimize radiation dose and radioactive waste.
5. Keep an accurate inventory of radioactive material, including records of all receipts, transfers and disposal. Perform and record regular lab surveys.
6. Provide for safe disposal of radioactive waste by following institutional Waste Handling and Disposal Procedures. Avoid generating mixed waste (combinations of radioactive, biological, and chemical waste). Note lab that staff may not pour measurable quantities of radioactive material down the drain.
7. If there is a question regarding any aspect of the radiation safety program or radioactive material use, contact Radiation Safety at x3911.

VIII. LAB PRACTICES

1. Disposable gloves, lab coats, and safety glasses are the minimum PPE [Personal Protective Equipment] required when handling radioactive material. Remove and discard potentially contaminated PPE prior to leaving the area where radioactive material is used.
2. Clearly outline radioactive material use areas with tape bearing the legend "radioactive". Cover lab bench tops where radioactive material will be handled with plastic-backed absorbent paper; change this covering periodically and whenever it's contaminated. Alternatively cover benches with thick plastic sheeting (i.e., painter's drop cloth), periodically wipe it clean and replace it if torn.
3. Label each unattended radioactive material container with the radioactive symbol, isotope and activity.
4. Place containers too small for such labels in larger labeled containers.
5. Handle radioactive solutions in trays large enough to contain the material in the event of a spill.
6. Never eat, drink, smoke, handle contact lenses, apply cosmetics, or take/apply medicine in the lab; keep food, drinks, cosmetics, etc. out of the lab entirely. Do not pipette by mouth.
7. Never store [human] food and beverage in refrigerators/freezers used for storing radioisotopes.
8. Prevent skin contact with skin-absorbable solvents containing radioactive material.
9. Fume hoods and biological safety cabinets for use with non-airborne radioactive material must be labeled "Caution Radioactive Material".
10. Use sealed containers and appropriate secondary containment to carry radioactive material between rooms.
11. Before taking any radioactive material off site, contact Radiation Safety at x3911.

VA SAN DIEGO HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

Nuclide Safety Data Sheet
Phosphorous-32

^{32}P

I. PHYSICAL DATA

Radiation:	Beta (100% abundance)	
Energy:	Maximum: 1,710 keV; Average: 695 keV	
Half-Life [$T_{½}$] :	Physical $T_{½}$:	14.29 days
	Biological	Bone ~ 1155 days; Whole Body ~ 257 days[1]
	Effective $T_{½}$:	14.29 days
Specific Activity:	286,500 Ci/g	[10,600 TBq/g] max.
Beta Range:	Air:	610 cm [240 inches; 20 feet]
	Water/Tissue	0.76 cm [0.33 inches]
	Plastic:	0.61 mm [3/8 inches]

II. RADIOLOGICAL DATA

Radiotoxicity[2]:	94.7 mrem/uCi [Lung] and 15.5 mrem/uCi [CEDE] of ^{32}P inhaled 29.9 mrem/uCi [Bone Marrow] and 8.77 mrem/uCi [CEDE] of ^{32}P ingested
Critical Organ:	Bone [soluble ^{32}P]; Lung [Inhalation]; GI Tract [Ingestion - insoluble compounds]
Exposure Routes:	Ingestion, inhalation, puncture, wound, skin contamination absorption
Radiological Hazard:	External Exposure [unshielded dose rate at 1 mCi ^{32}P vial mouth[3]: approx. 26 rem/hr], Internal Exposure and Contamination

III. SHIELDING

Shield ^{32}P with 3/8 inch Plexiglas and monitor for Bremstrahlung; If Bremstrahlung X-rays detected outside Plexiglas, apply 1/8 to 1/4 inch lead [Pb] shielding outside Plexiglas
The accessible dose rate should be background but must be < 2 mR/hr

IV. DOSIMETRY MONITORING

If required, always wear radiation dosimetry monitoring badge(s) whenever handling ^{32}P

V. DETECTION AND MEASUREMENT

Portable Survey Meters: Geiger-Mueller
Beta Scintillator
Wipe Test: Liquid Scintillation Counting is an acceptable method for counting ^{32}P wipe tests

VI. SPECIAL PRECAUTIONS

- Avoid skin contamination [absorption], ingestion, inhalation, and injection [all routes of intake].
- Store ^{32}P (including waste) behind Plexiglas shielding [3/8 inch thick]; survey (with GM meter) to check adequacy of shielding (accessible dose rate < 2 mR/hr; should be background); apply lead [Pb] shielding outside Plexiglas if needed.
- Use 3/8 inch Plexiglas shielding to minimize exposure while handling ^{32}P.
- Use tools [e.g. Beta Blocks] to handle ^{32}P sources and contaminated objects; avoid direct hand contact.
- Use eye protection for procedures that involve 10 mCi or more.
- Always have a portable survey meter present and turned on when handling ^{32}P.
- ^{32}P is not volatile, even when heated, and can be ignored as an airborne contaminant unless aerosolized.
- White wine vinegar can be an effective decontamination solvent for this nuclide in most forms.

---

[1] NCRP Report No. 65, p.88
[2] Federal Guidance Report No. 11 [Oak Ridge, TN; Oak Ridge National Laboratory, 1988], p. 122, 156
[3] Dupont/NEN, Phosphorous-32 Handling Precautions [Boston, MA; NEN Products, 1985]

VII. GENERAL PRECAUTIONS

1. Maintain your occupational exposure to radiation As Low As Reasonably Achievable [ALARA].
2. Ensure all persons handling radioactive material are trained and listed on an approved permit.
3. Review the nuclide characteristics on (reverse side) prior to working with that nuclide. Review the permit authorizing the procedure to be performed and follow any additional precautions in the protocol.
4. Plan experiments to minimize external exposure by reducing exposure time, using shielding and increasing your distance from the radiation source. Reduce internal and external radiation dose by monitoring the worker and the work area after each use of radioactive material, then promptly cleaning up any contamination discovered. Use the smallest amount of radioisotope possible so as to minimize radiation dose and radioactive waste.
5. Keep an accurate inventory of radioactive material, including records of all receipts, transfers and disposal. Perform lab surveys and record as required.
6. Provide for safe disposal of radioactive waste by following institutional Waste Handling and Disposal Procedures. Avoid generating mixed waste (combinations of radioactive, biological, and chemical waste). Note lab staff is not permitted to pour measurable quantities of radioactive material down the drain.
7. If there is a question regarding any aspect of the radiation safety program or radioactive material use, contact Radiation Safety at x3911.

VIII. LAB PRACTICES

1. Disposable gloves, lab coats, and safety glasses are the minimum PPE [Personal Protective Equipment] required when handling radioactive material. Remove and discard potentially contaminated PPE prior to leaving the area where radioactive material is used.
2. Clearly outline radioactive material use areas with tape bearing the legend "radioactive". Cover lab bench tops where radioactive material will be handled with plastic-backed absorbent paper; change this covering periodically and whenever it's contaminated. Alternatively cover benches with thick plastic sheeting (i.e., painter’s drop cloth), periodically wipe it clean and replace it if torn.
3. Label each unattended radioactive material container with the radioactive symbol, isotope and activity. Place containers too small for such labels in larger labeled containers.
4. Handle radioactive solutions in trays large enough to contain the material in the event of a spill.
5. Never eat, drink, smoke, handle contact lenses, apply cosmetics, or take/apply medicine in the lab; keep food, drinks, cosmetics, etc. out of the lab entirely. Do not pipette by mouth.
6. Never store [human] food and beverage in refrigerators/freezers used for storing radioisotopes.
7. Prevent skin contact with skin-absorbable solvents containing radioactive material.
8. Fume hoods and biological safety cabinets for use with non-airborne radioactive material must be labeled "Caution Radioactive Material".
9. Use sealed containers and appropriate secondary containment to carry radioactive material between rooms.
10. Before taking any radioactive material off site, contact Radiation Safety at x3911.

Nuclide Safety Data Sheet
Phosphorous-33

^{33}P

I. PHYSICAL DATA

Radiation:	Beta (100% abundance)	
Energy:	Maximum: 248.5 keV; Average: 76.4 keV	
Half-Life [$T_{½}$] :	Physical $T_{½}$:	25.3 days
	Biological	Bone ~ 1155 days; Whole Body ~ 257 days[1]
	Effective	25.3 days
Specific Activity:	156,000 Ci/g	[5,780 TBq/g] max.
Beta Range:	Air:	50 cm [~ 20 inches]
	Water/Tissu	0.06 cm [0.024 inches]
	Plastic:	0.05 cm [0.02 inches]

II. RADIOLOGICAL DATA

Radiotoxicity[2]:	15.6 mrem/uCi [Lung] and 2.32 mrem/uCi [CEDE] of ^{33}P inhaled 1.85 mrem/uCi [Bone Marrow] and 0.92 mrem/uCi [CEDE] of ^{33}P ingested
Critical Organ:	Bone [soluble ^{33}P]; Lung [Inhalation]; GI Tract [Ingestion - insoluble compounds]
Exposure Routes:	Ingestion, inhalation, puncture, wound, skin contamination absorption
Radiological Hazard:	External Exposure - mCi quantities not considered an external hazard Internal Exposure and Contamination - Primary concern

III. SHIELDING

None required - mCi quantities not an external radiation hazard

IV. DOSIMETRY MONITORING

Urine bioassay is the most readily available method to assess intake [for ^{33}P, no intake = no dose].
Provide a urine sample to Radiation Safety after any accident/incident in which an intake is suspected.
No dosimetry badges needed when working with ^{33}P [beta energy too low to be detected]

V. DETECTION AND MEASUREMENT

Portable Survey Meters: Geiger-Mueller
Beta Scintillator

Wipe Test: Liquid Scintillation Counting works well for counting ^{33}P wipe tests

VI. SPECIAL PRECAUTIONS

- Avoid skin contamination [absorption], ingestion, inhalation, and injection [all routes of intake]
- ^{33}P is not volatile, even when heated, and can be ignored as an airborne contaminant[3] unless aerosolized.
- White wine vinegar can be an effective decontamination solvent for this nuclide in most common chemical forms.

---

[1] NCRP Report No. 65, p.88
[2] Federal Guidance Report No. 11 [Oak Ridge, TN; Oak Ridge National Laboratory, 1988], p. 122, 156
[3] Bevelacqua, J. Contemporary Health Physics [New York; John Wiley & Sons, 1995], p. 282

VII. GENERAL PRECAUTIONS

1. Maintain your occupational exposure to radiation As Low As Reasonably Achievable [ALARA].
2. Ensure all persons handling radioactive material are trained, registered, and listed on an approved protocol.
3. Review the nuclide characteristics on (reverse side) prior to working with that nuclide. Review the permit authorizing the procedure to be performed and follow any additional precautions in the protocol.
4. Plan experiments to minimize external exposure by reducing exposure time, using shielding and increasing your distance from the radiation source. Reduce internal and external radiation dose by monitoring the worker and the work area after each use of radioactive material, then promptly cleaning up any contamination discovered. Use the smallest amount of radioisotope possible so as to minimize radiation dose and radioactive waste.
5. Keep an accurate inventory of radioactive material, including records of all receipts, transfers and disposal. Perform and document lab surveys as required.
6. Provide for safe disposal of radioactive waste by following institutional Waste Handling and Disposal Procedures. Avoid generating mixed waste (combinations of radioactive, biological, and chemical waste). Note that lab staff may not pour measurable quantities of radioactive material down the drain.
7. If there is a question regarding any aspect of the radiation safety program or radioactive material use, contact Radiation Safety at x3911.

VIII. LAB PRACTICES

1. Disposable gloves, lab coats, and safety glasses are the minimum PPE [Personal Protective Equipment] required when handling radioactive material. Remove and discard potentially contaminated PPE prior to leaving the area where radioactive material is used.
2. Clearly outline radioactive material use areas with tape bearing the legend "radioactive". Cover lab bench tops where radioactive material will be handled with plastic-backed absorbent paper; change this covering periodically and whenever it's contaminated. Alternatively cover benches with thick plastic sheeting (i.e., painter's drop cloth), periodically wipe it clean and replace it if torn.
3. Label each unattended radioactive material container with the radioactive symbol, isotope and activity.
4. Place containers too small for such labels in larger labeled containers.
5. Handle radioactive solutions in trays large enough to contain the material in the event of a spill.
6. Never eat, drink, smoke, handle contact lenses, apply cosmetics, or take/apply medicine in the lab; keep food, drinks, cosmetics, etc. out of the lab entirely. Do not pipette by mouth.
7. Never store [human] food and beverage in refrigerators/freezers used for storing radioisotopes.
8. Prevent skin contact with skin-absorbable solvents containing radioactive material.
9. Fume hoods and biological safety cabinets for use with non-airborne radioactive material must be labeled "Caution Radioactive Material."
10. Use sealed containers and appropriate secondary containment to carry radioactive material between rooms.
11. Before taking any radioactive material off site, contact Radiation Safety at x3911.

Nuclide Safety Data Sheet
Sulfur-35

^{35}S

I. PHYSICAL DATA

Radiation:	Beta (100% abundance)	
Energy:	Maximum: 167.47 keV; Average: 48.8 keV	
Half-Life [$T_{½}$] :	Physical $T_{½}$:	87.44 days
	Biological	623 days [unbound ^{35}S]; 90 days [bound ^{35}S]
	Effective $T_{½}$:	44 - 76 days [unbound ^{35}S]
Specific Activity:	42,707 Ci/g [1,580 TBq/g] max.	
Beta Range:	Air:	26 cm [10.2 inches]
	Water/Tissue	0.32 mm [0.015 inches]
	Plastic:	0.25 mm [0.010 inches]

II. RADIOLOGICAL DATA

Radiotoxicity[1]:	2.48 mrem/uCi [CEDE] of ^{35}S inhaled 0.733 mrem/uCi of ^{35}S ingested
Critical Organ:	Testis
Exposure Routes:	Ingestion, inhalation, puncture, wound, skin contamination absorption
Radiological Hazard:	External Exposure - None from weak ^{35}S beta Internal Exposure and Contamination - Primary concern

III. SHIELDING

None required - mCi quantities not an external radiation hazard

IV. DOSIMETRY MONITORING

Urine bioassay is the most readily available method to assess intake [for ^{35}S, no intake = no dose]
Provide a urine sample to Radiation Safety after any accident/incident in which an intake is suspected

V. DETECTION and MEASUREMENT

Portable Survey Meters: Geiger-Mueller [~10% efficiency]
Beta Scintillator [~5% efficiency]

Wipe Test: Liquid Scintillation Counting is the best readily available method for counting ^{35}S wipe tests

VI. SPECIAL PRECAUTIONS

- Avoid skin contamination [absorption], ingestion, inhalation, and injection [all routes of intake]
- Many ^{35}S compounds and metabolites are slightly volatile and may create contamination problems if not sealed or otherwise controlled. This occurs particularly when ^{35}S amino acids are thawed, and when they are added to cell culture media and incubated. Therefore vent thawing ^{35}S vials in a hood by inserting the needle of a charcoal packed syringe through the septum seal, and vent incubated ^{35}S-labelled tissue culture through charcoal-impregnated filter paper.

[1] Federal Guidance Report No. 11 [Oak Ridge, TN; Oak Ridge National Laboratory, 1988], p. 122, 156

VII. GENERAL PRECAUTIONS

1. Maintain your occupational exposure to radiation As Low As Reasonably Achievable [ALARA].
2. Ensure all persons handling radioactive material and listed on an approved permit.
3. Review the nuclide characteristics on prior to working with that nuclide. Review the permit authorizing the procedure to be performed and follow any additional precautions in the protocol.
4. Plan experiments to minimize external exposure by reducing exposure time, using shielding and increasing your distance from the radiation source. Reduce internal and external radiation dose by monitoring the worker and the work area after each use of radioactive material, then promptly cleaning up any contamination discovered. Use the smallest amount of radioisotope possible so as to minimize radiation dose and radioactive waste.
5. Keep an accurate inventory of radioactive material, including records of all receipts, transfers and disposal. Perform lab surveys and record as required.
6. Provide for safe disposal of radioactive waste by following Waste Handling and Disposal Procedures. Avoid generating mixed waste (combinations of radioactive, biological, and chemical waste). Note that lab staff may not pour measurable quantities of radioactive material down the drain.
7. If there is a question regarding any aspect of the radiation safety program or radioactive material use, contact Radiation Safety.

VIII. LAB PRACTICES

1. Disposable gloves, lab coats, and safety glasses are the minimum PPE [Personal Protective Equipment] required when handling radioactive material. Remove and discard potentially contaminated PPE prior to leaving the area where radioactive material is used.
2. Clearly outline radioactive material use areas with tape bearing the legend "radioactive". Cover lab bench tops where radioactive material will be handled with plastic-backed absorbent paper; change this covering periodically and whenever it's contaminated. Alternatively cover benches with thick plastic sheeting (i.e., painter's drop cloth), periodically wipe it clean and replace it if torn.
3. Label each unattended radioactive material container with the radioactive symbol, isotope and activity. Place containers too small for such labels in larger labeled containers.
4. Handle radioactive solutions in trays large enough to contain the material in the event of a spill.
5. Never eat, drink, smoke, handle contact lenses, apply cosmetics, or take/apply medicine in the lab; keep food, drinks, cosmetics, etc. out of the lab entirely. Do not pipette by mouth.
6. Never store [human] food and beverage in refrigerators/freezers used for storing radioisotopes.
7. Prevent skin contact with skin-absorbable solvents containing radioactive material.
8. Fume hoods and biological safety cabinets for use with non-airborne radioactive material must be labeled "Caution Radioactive Material".
9. All volatile, gaseous, or aerosolized radioactive material must be used only in a properly operating charcoal and/or HEPA filtered fume hood or Biological Safety Cabinet bearing a Caution Airborne Radioactivity label.
10. Take special precautions when working with radioactive compounds that tend to become volatile [e.g. ^{35}S labeled amino acids tend to volatilize in acidic solutions]. These precautions may include: using the materials only within an approved fume hood, protecting the house vacuum system with primary and secondary vapor trapping devices, and covering active cell cultures with carbon-impregnating paper.
11. Use sealed containers and appropriate secondary containment to carry radioactive material between rooms.
12. Before taking any radioactive material off site, contact Radiation Safety at x3911.

VA SAN DIEGO HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

Nuclide Safety Data Sheet
Technetium - 99m

^{99m}Tc

I. PHYSICAL DATA

Radiation: Gamma: 141 keV (89% abundance)
X-rays: 18 keV (6% abundance), 21 keV (1.2% abundance)

Gamma Constant: 0.77 R/hr at 1 cm from an unshielded 1 mCi point source[1]

Half-Life [$T_{½}$] : Physical $T_{½}$: 6.0 hours
Biological ~ 1 day[2]
Effective $T_{½}$: ~ 4.8 hours

Specific Activity: 5.27E6 Ci/g [1.95E17 Bq/g]

II. RADIOLOGICAL DATA

Radiotoxicity: 63 mrem/mCi [1.7E-8 mSv/Bq] of ^{99m}Tc ingested [CEDE][3]
27 mrem/mCi [7.21E-9 mSv/Bq] of ^{99m}Tc inhaled [CEDE][3]

Critical Organ: Thyroid Gland[3]; Upper GI tract[1]

Exposure Routes: Ingestion, inhalation, puncture, wound, skin contamination absorption

Radiological Hazard: External and Internal Exposure; Contamination

III. SHIELDING

	Half Value Layer (HVL)	Tenth Value Layer (TVL)
Lead [Pb]	<1 mm	1 mm

- The accessible dose rate should be background but must be < 2 mR/hr

IV. DOSIMETRY MONITORING

- If required, always wear radiation dosimetry monitoring badges whenever handling ^{99m}Tc
- Submit a urine sample to Radiation Safety two to 24 hours [i.e. As Soon As Possible] after any suspected intake of ^{99m}Tc; alert Radiation Safety of the short half-lived nuclide involved.

V. DETECTION AND MEASUREMENT

Portable Survey Meters: Geiger-Mueller to assess shielding effectiveness
Low Energy Gamma Detector for contamination surveys

Wipe Test: Liquid Scintillation Counter

VI. SPECIAL PRECAUTIONS

- Store ^{99m}Tc behind ¼-inch [~ 0.6 cm] thick lead (Pb) shielding
- Use tools to indirectly handle unshielded sources and potentially contaminated vessels; avoid direct hand contact
- Ensure that an appropriate, operational survey meter is present in the work area and turned on whenever ^{99m}Tc is handled, so that any external exposure issues will be immediately apparent and hence quickly addressed
- Shield waste containers as needed to maintain accessible dose rate ALARA and < 2 mR/hr

---

[1] Dupont/NEN, Technetium-99m Handling Precautions (Boston, MA: NEN, 1985)
[2] Delacroix et al, Radiation Protection Dosimetry - Radionuclide and Radiation Protection Data Handbook (Kent, England: Nuclear Technology Publishing, 1998), p. 71
[3] Federal Guidance Report No. 11 (Oak Ridge, TN; Oak Ridge National Laboratory, 1988), p. 130, 162

VII. GENERAL PRECAUTIONS

1. Maintain your occupational exposure to radiation As Low As Reasonably Achievable [ALARA].
2. Ensure all persons handling radioactive material are trained and listed on an approved permit.
3. Review the nuclide characteristics prior to working with that nuclide. Review the permit authorizing the procedure to be performed and follow any additional precautions in the protocol.
4. Plan experiments to minimize external exposure by reducing exposure time, using shielding and increasing your distance from the radiation source. Reduce internal and external radiation dose by monitoring the worker and the work area after each use of radioactive material, then promptly cleaning up any contamination discovered. Use the smallest amount of radioisotope possible so as to minimize radiation dose and radioactive waste.
5. Keep an accurate inventory of radioactive material, including records of all receipts, transfers and disposal. Perform lab surveys and record as required.
6. Provide for safe disposal of radioactive waste by following institutional Waste Handling and Disposal Procedures. Avoid generating mixed waste (combinations of radioactive, biological, and chemical waste). Note that lab staff may not pour measurable quantities of radioactive material down the drain.
7. If there is a question regarding any aspect of the radiation safety program or radioactive material use, contact Radiation Safety at x3911.

VIII. LAB PRACTICES

1. Disposable gloves, lab coats, and safety glasses are the minimum PPE [Personal Protective Equipment] required when handling radioactive material. Remove and discard potentially contaminated PPE prior to leaving the area where radioactive material is used.
2. Clearly outline radioactive material use areas with tape bearing the legend "radioactive". Cover lab bench tops where radioactive material will be handled with plastic-backed absorbent paper; change this covering periodically and whenever it's contaminated. Alternatively cover benches with thick plastic sheeting (i.e., painter's drop cloth), periodically wipe it clean and replace it if torn.
3. Label each unattended radioactive material container with the radioactive symbol, isotope and activity. Place containers too small for such labels in larger labeled containers.
4. Handle radioactive solutions in trays large enough to contain the material in the event of a spill.
5. Never eat, drink, smoke, handle contact lenses, apply cosmetics, or take/apply medicine in the lab; keep food, drinks, cosmetics, etc. out of the lab entirely. Do not pipette by mouth.
6. Never store [human] food and beverage in refrigerators/freezers used for storing radioisotopes.
7. Prevent skin contact with skin-absorbable solvents containing radioactive material.
8. All volatile, gaseous, or aerosolized radioactive material must be used only in a properly operating charcoal, HEPA filtered fume hoods or Biological Safety Cabinets bearing a Caution Airborne Radioactivity hood label.
9. Use sealed containers and appropriate secondary containment to carry radioactive material between rooms.
10. Before taking any radioactive material off site, contact Radiation Safety at x3911.

Nuclide Safety Data Sheet
Iodine-125

^{125}I

I. PHYSICAL DATA

Radiation:	Gamma - 35.5 keV (7% abundance)
	X-ray - 27 keV (113% abundance)
Gamma Constant:	0.27 mR/hr per mCi @ 1.0 meter [7.432E-5 mSv/hr per MBq @ 1.0 meter][1]
Half-Life [$T_{½}$] :	Physical $T_{½}$: 60.14 days
	Biological 120-138 days (unbound iodine)
	Effective $T_{½}$: 42 days (unbound iodine)
Specific Activity:	1.73E4 Ci/g [642 TBq/g] max.

II. RADIOLOGICAL DATA

Radiotoxicity[2]:	3.44E-7 Sv/Bq (1273 mrem/uCi) of ^{125}I ingested [Thyroid]
	2.16 E-7 Sv/Bq (799 mrem/uCi) of ^{125}I inhaled [Thyroid]
Critical Organ:	Thyroid Gland
Intake Routes:	Ingestion, inhalation, puncture, wound, skin contamination (absorption);
Radiological Hazard:	External and Internal Exposure; Contamination

III. SHIELDING

	Half Value Layer [HVL]	Tenth Value Layer [TVL]
Lead [Pb]	0.02 mm (0.0008 inches)	0.07 mm (0.003 inches)

- The accessible dose rate should be background but must be < 2 mR/hr

IV. DOSIMETRY MONITORING

- If required, always wear radiation dosimetry monitoring badges whenever handling ^{125}I
- Conduct a baseline thyroid scan prior to first use of radioactive iodine
- If required, ensure a thyroid scan is performed no earlier than 6 hours, but within 72 hours of handling 1 mCi or more of ^{125}I or after any suspected intake

V. DETECTION AND MEASUREMENT

Portable Survey Meters:	Geiger-Mueller to assess shielding effectiveness
	Low Energy Gamma Detector [e.g. Ludlum 44-21, ~19% eff. for ^{125}I] for contamination surveys
Wipe Test:	Liquid Scintillation Counter

VI. SPECIAL PRECAUTIONS

- Avoid skin contamination [absorption], ingestion, inhalation, and injection [all routes of intake]
- Use shielding [lead or leaded Plexiglas] to minimize exposure while handling mCi quantities of ^{125}I
- Avoid making low pH [acidic] solutions containing ^{125}I to avoid volatilization
- For Iodinations:
    - Use a cannula adapter needle to vent stock vials of ^{125}I used; this prevents puff releases
    - Cover test tubes used to count or separate fractions from iodinations with Parafilm or other tight caps to prevent release while counting or moving outside the fume hood.

---

[1] Health Physics and Radiological Health Handbook, 3rd Ed. [Baltimore, MD; Williams and Wilkins, 1998], p. 6-11

[2] Federal Guidance Report No. 11 [Oak Ridge, TN; Oak Ridge National Laboratory, 1988], p. 136, 166

VII. GENERAL PRECAUTIONS

1. Maintain your occupational exposure to radiation As Low As Reasonably Achievable [ALARA].
2. Ensure all persons handling radioactive material and listed on an approved permit.
3. Review the nuclide characteristics on prior to working with that nuclide. Review the permit authorizing the procedure to be performed and follow any additional precautions in the protocol.
4. Plan experiments to minimize external exposure by reducing exposure time, using shielding and increasing your distance from the radiation source. Reduce internal and external radiation dose by monitoring the worker and the work area after each use of radioactive material, then promptly cleaning up any contamination discovered. Use the smallest amount of radioisotope possible so as to minimize radiation dose and radioactive waste.
5. Keep an accurate inventory of radioactive material, including records of all receipts, transfers and disposal. Perform lab surveys and record as required.
6. Provide for safe disposal of radioactive waste by following institutional Waste Handling and Disposal Procedures. Avoid generating mixed waste (combinations of radioactive, biological, and chemical waste). Note that lab staff may not pour measurable quantities of radioactive material down the drain.
7. If there is a question regarding any aspect of the radiation safety program or radioactive material use, contact Radiation Safety at x3911.

VIII. LAB PRACTICES

1. Disposable gloves, lab coats, and safety glasses are the minimum PPE [Personal Protective Equipment] required when handling radioactive material. Remove and discard potentially contaminated PPE prior to leaving the area where radioactive material is used.
2. Clearly outline radioactive material use areas with tape bearing the legend "radioactive". Cover lab bench tops where radioactive material will be handled with plastic-backed absorbent paper; change this covering periodically and whenever it's contaminated. Alternatively cover benches with thick plastic sheeting (i.e., painter's drop cloth), periodically wipe it clean and replace it if torn.
3. Label each unattended radioactive material container with the radioactive symbol, isotope and activity. Place containers too small for such labels in larger labeled containers.
4. Handle radioactive solutions in trays large enough to contain the material in the event of a spill.
5. Never eat, drink, smoke, handle contact lenses, apply cosmetics, or take/apply medicine in the lab; keep food, drinks, cosmetics, etc. out of the lab entirely. Do not pipette by mouth.
6. Never store [human] food and beverage in refrigerators/freezers used for storing radioisotopes.
7. Prevent skin contact with skin-absorbable solvents containing radioactive material.
8. All volatile, gaseous, or aerosolized radioactive material must be used only in charcoal filtered fume hoods or Biological Safety Cabinets bearing a Caution Airborne Radioactivity label, unless otherwise specified by the Radiation Safety Officer. In particular, radioactive iodinations must be performed only in specially designed and authorized fume hoods.
9. Take special precautions when working with radioactive compounds that tend to become volatile [e.g. ^{125}I - iodine tends to volatilize in acidic solutions]. These precautions may include: using the materials only within an approved fume hood, protecting the house vacuum system with primary and secondary vapor trapping devices, and covering active cell cultures with carbon-impregnating paper.
10. Use sealed containers and appropriate secondary containment to carry radioactive material between rooms.
11. Before taking any radioactive material off site, contact Radiation Safety at x3911.

VA SAN DIEGO HEALTHCARE SYSTEM
A Division of VA Desert Pacific Healthcare Network

Nuclide Safety Data Sheet
Iodine-131

^{131}I

I. PHYSICAL DATA

Radiation: Gammas and X-rays: primary 364 keV (81% abundance); others 4 – 723 keV
Betas: primary 606 keV (89% abundance); others 248 – 807 keV

Gamma Constant: 0.28 mR/hr per mCi @ 1.0 meter [7.647E-5 mSv/hr per MBq @ 1.0 meter][1]

Half-Life [$T_{½}$] : Physical $T_{½}$: 8.04 days
Biological 120-138 days (unbound iodine)
Effective $T_{½}$: 7.6 days (unbound iodine)

Specific Activity: 1.24E5 Ci/g [4,600 TBq/g] max.

II. RADIOLOGICAL DATA

Radiotoxicity[2]: 4.76 E-7 Sv/Bq (1.76 rem/uCi) of ^{131}I ingested [Thyroid]
2.92 E-7 Sv/Bq (1.08 rem/uCi) of ^{131}I inhaled [Thyroid]

Critical Organ: Thyroid Gland

Intake Routes: Ingestion, inhalation, puncture, wound, skin contamination (absorption);

Radiological Hazard: External and Internal Exposure; Contamination

III. SHIELDING

	Half Value Layer [HVL]	Tenth Value Layer [TVL]
Lead [Pb][3]	3 mm (0.12 inches)	11 mm (0.43 inches)

→ The accessible dose rate should be background but must be < 2 mR/hr

IV. DOSIMETRY MONITORING

- If required, always wear radiation dosimetry monitoring badges whenever handling ^{131}I
- Conduct a baseline thyroid scan prior to first use of radioactive iodine
- If required, ensure a thyroid scan is performed no earlier than 6 hours, but within 72 hours of handling 1 mCi or more of ^{131}I or after any suspected intake

V. DETECTION AND MEASUREMENT

Portable Survey Meters: Geiger-Mueller to assess shielding effectiveness and contamination. The efficiency is about 8% for GM pancake survey probes with 15.5 cm^2 surface area.

Wipe Test: Liquid Scintillation Counter or Gamma Counter

VI. SPECIAL PRECAUTIONS

- Avoid skin contamination [absorption], ingestion, inhalation and injection [all routes of intake]
- Use shielding [lead or leaded Plexiglas] to minimize exposure while handling mCi quantities of ^{131}I
- Avoid making low pH [acidic] solutions containing ^{131}I to avoid volatilization
- For Iodinations:
  - Use a cannula adapter needle to vent stock vials of ^{131}I used; this prevents puff releases
  - Cover test tubes used to count or separate fractions from iodinations with Parafilm or other tight caps to prevent release while counting or moving outside the fume hood.

---

[1] Health Physics and Radiological Health Handbook, 3rd Ed. [Baltimore, MD; Williams and Wilkins, 1998], p. 6-11
[2] Federal Guidance Report No. 11 [Oak Ridge, TN; Oak Ridge National Laboratory, 1988], p. 136, 166
[3] HVL and TVL values from: Delacroix, D. et al. Radionuclide and Radiation Protection Handbook [*Radiation Protection Dosimetry*, vol.76, nos 1-2, 1998, Nuclear Technology Publishing, Ashford, Kent, England, 1998], p. 90

VII. GENERAL PRECAUTIONS

1. Maintain your occupational exposure to radiation As Low As Reasonably Achievable [ALARA].
2. Ensure all persons handling radioactive material are trained, authorized and listed on an approved permit.
3. Review the nuclide characteristics on (reverse side) prior to working with that nuclide. Review the permit authorizing the procedure to be performed and follow any additional precautions in the protocol.
4. Plan experiments to minimize external exposure by reducing exposure time, using shielding and increasing your distance from the radiation source. Reduce internal and external radiation dose by monitoring the worker and the work area after each use of radioactive material, then promptly cleaning up any contamination discovered. Use the smallest amount of radioisotope possible so as to minimize radiation dose and radioactive waste.
5. Keep an accurate inventory of radioactive material, including records of all receipts, transfers and disposal. Perform lab surveys and record as required.
6. Provide for safe disposal of radioactive waste by following institutional waste handling and disposal procedures. Avoid generating mixed waste (combinations of radioactive, biological, and chemical waste). Note that lab staff is not permitted to pour measurable quantities of radioactive material down the drain.
7. If there is a question regarding any aspect of the radiation safety program or radioactive material use, contact Radiation Safety at x3911.

VIII. LABORATORY PRACTICES

1. Disposable gloves, lab coats, and safety glasses are the minimum PPE [Personal Protective Equipment] required when handling radioactive material. Remove and discard potentially contaminated PPE prior to leaving the area where radioactive material is used.
2. Clearly outline radioactive material use areas with tape bearing the legend "radioactive". Cover lab bench tops where radioactive material will be handled with plastic-backed absorbent paper; change this covering periodically and whenever it's contaminated. Alternatively cover benches with thick plastic sheeting (i.e., painter's drop cloth), periodically wipe it clean and replace it if torn.
3. Label each unattended radioactive material container with the radioactive symbol, isotope and activity. Place containers too small for such labels in larger labeled containers.
4. Handle radioactive solutions in trays large enough to contain the material in the event of a spill.
5. Never eat, drink, smoke, handle contact lenses, apply cosmetics, or take/apply medicine in the lab; keep food, drinks, cosmetics, etc. out of the lab entirely. Do not pipette by mouth.
6. Never store [human] food and beverage in refrigerators/freezers used for storing radioisotopes.
7. Prevent skin contact with skin-absorbable solvents containing radioactive material.
8. Fume hoods and biological safety cabinets for use with non-airborne radioactive material must be approved (through the protocol) and must be labeled "Caution Radioactive Material".
9. All volatile, gaseous, or aerosolized radioactive material must be used only in a properly operating charcoal and/or HEPA filtered fume hood. In particular, radioactive iodination must be performed only in specially designed and authorized fume hoods. Take special precautions when working with radioactive compounds that tend to become volatile. These precautions may include: using the materials only within an approved fume hood, protecting the house vacuum system with primary and secondary vapor trapping devices, and covering active cell cultures with carbon-impregnating paper.
10. Use sealed containers and appropriate secondary containment to carry radioactive material between rooms.
11. Before taking any radioactive material off site, contact Radiation Safety at x3911.

3350 La Jolla Village Drive
San Diego, CA 92161
Phone: 858.552.8585

Radiation Safety Office Personnel
René Michel, RSO ……..x1059
Mike Zorn, Assist. RSO ……..x7215
M/C 151, x3911

VA SAN DIEGO HEALTHCARE SYSTEM

A Division of VA Desert Pacific Healthcare Network

Procedure for the Completion of Nuclear Medicine Written Directives (WDs)

Overview: The purpose of this procedure is to ensure written directives for the administration of radioactive drugs by Nuclear Medicine Personnel are completed correctly as required by 10 CFR 35.41 (a)(2).

Steps:

1. Obtain a copy of the latest version of form VARSO 5001 (Nuclear Medicine Written Directive form).

2. In the section titled, "Authorized Attending Nuclear Medicine (ANM) Physician Written Directive," complete the following:
   a) Write down the patient's full name,
   b) write down the patient's Social Security Number (SSN),
   c) write down the patient's date of birth (DOB),
   d) indicatethe patient's gender by checking the correct box,
   e) write down the name of the authorized ANM physician (i.e., AU),
   f) write down the name of the physician ordering the administration (i.e., referring physician),
   g) select the radioactive drug prescribed (if the drug is not listed, write down, in the space provided, the correct name of the radioactive drug (make sure to identify both the radioisotope and the chemical form),
   h) write down the name of the procedure to be performed (e.g., radioiodine thyroid ablation for cancer),
   i) specify the prescribed route of administration by checking one of the boxes (if the correct route of administration is not listed, write down the correct route in the space provided, and check the box next to it),
   j) write down the dosage ordered in mCi,
   k) have the authorized ANM Physician review the written directive for accuracy,
   l) ensure that the ANM Physician signs his/her name in the space provided, and
   m) ensure that the ANM Physician records the date he/she signed the form.

3. In the section titled, "Radioactive Drug Dosage Verification," document the following information:
   a) Indicate if the radioactive drug being administered to the patient is the one prescribed in the WD above by checking one of the boxes (if the answer is no, do not perform the administration and consult with the ANM Physician to have the WD revised),
   b) if the answer for a) was yes, write down in the space provided the drug lot # for the radioactive drug to be administered,
   c) record the calibrated activity of the radioactive drug in mCi,
   d) record the date and time when the drug was calibrated,
   e) make sure to administer the radioactive drug as indicated in the WD, following the proper procedure (e.g., service or manufacturer), and check the correct box,
   f) record the date and the time the administration was performed,
   g) sign your name in the space provided.

4. The patient's identity has to be verified prior to the administration of the radioactive drug by two members of the staff. In the section titled, "Radioactive Drug Administration," document the following information:
   a) the two methods used to identify the patient (select by checking the correct boxes from the available list),
   b) ensure that the two members of the staff write down or sign their names in the spaces provided.

5. For female patients between the ages of 13 and 60 who have not had a hysterectomy, indicate by checking the correct box the patient's pregnancy status (which must be verified and documented via urine pregnancy test) and breast feeding status.

6. Indicate if the patient is breast feeding by checking the correct box. If the answer is yes, provide her with nursing instructions and check the “yes” box.

7. If the patient is undergoing radiation therapy, provide him/her with the appropriate release instructions and check the correct box.

8. In the section titled, “Review After Administration for Unintended Deviations,” document the following information if unintended deviations occurred:
   a) describe the unintended deviations in the space provided,
   b) ensure that the ANM Physician signs his/her name and records the date in the space provided,
   c) ensure that the Radiation Safety Officer reviews this form, signs his/her name and records the date in the space provided.

9. Affix the radioactive drug dose calibration to the area shown at the bottom of the VARSO 5001 form.

10. File the completed form in the patient’s file.

THERAPY FOR THYROID CANCER
(I-131 as Sodium Iodide)

Overview

- I-131 therapy for Thyroid Cancer, of the papillary-follicular type, is intended to ablate residual functioning thyroid tissue, either remaining normal thyroid tissue in the thyroid bed or functioning thyroid cancer anywhere in the body. The maximum effect is achieved when the residual functioning tissue is maximally stimulated by a high thyroid stimulating hormone (TSH) level and when the circulating non radioactive iodine level is relatively low. Thyroid cancer that has become undifferentiated will take up relatively little radioiodine.

Indications

- Ablation of residual normal thyroid tissue post subtotal thyroidectomy in (1-5):
  1. Patients with a primary cancer larger than 1-1.5 cm.
  2. Patients with a primary cancer of any size with extrathyroidal spread or multicentricity.

- Treatment of residual functioning thyroid cancer (1-7).

- Treatment for a rising serum thyroglobulin antibody level in the absence of abnormal uptake on the whole body I-131 study (1,8-10).

Procedure Time

- Initially: 20 minutes for obtaining informed consent and administering the dose.

- Later (if the patient is hospitalized): 20 minutes per day, or more often, for monitoring the patient's I-131 body burden until it is below approximately 30 mCi (1110 MBq) and less than 7 mR/hr. at a distance of one meter as measured by an appropriate survey meter.

Patient Preparation

- The patient must discontinue iodide containing preparations and medications that could potentially affect the ability of thyroid tissue to accumulate iodide (6,7).

Medication	Time of withdrawal
Antithyroid medication (propylthiouracil, methimazole, carbimazole)	3 dy
Multivitamins	7 wk
Expectorants, kelp, agar, carageen, topical iodide	3 wk

Reviewed and Approved
November 25, 2009
Ernest V. Belezzuoli, M.D.
Chief Nuclear Medicine Service
VA San Diego Healthcare System

Radiographic contrast agents	3 wk
Amiodarone	3 mo

- The patient must undergo thyroid stimulating hormone (TSH) stimulation by either:
  1. Withdrawal of thyroid hormone for a period of time.

Hormone	Time of withdrawal
Triiodothyronine (T-3)	2 wk
Thyroxine (T-4)	4-6 wk

  2. Pretreatment with recombinant TSH (rTSH) over two days (1,11).

- For women of child bearing age, a pregnancy test should be performed prior to treatment. Pregnancy is an absolute contraindication.

- The nuclear medicine physician explains the expected benefits and possible complications (6).

- The nuclear medicine physician obtains written informed consent for treatment and for treatment as an outpatient [see consent forms at end of section].

Post Treatment Restrictions

- Outpatient treatment (for those patients whose home living situation allows them to meet the requirements for keeping exposure to relatives and the public below the 0.5 rem limit) (12):
  1. A member of the nuclear medicine department reviews the requirements established by the treating institution with the patient. If the patient agrees to follow all of the requirements, the patient may be discharged following administration of the radiopharmaceutical.
  2. Sample requirements are given in the form at the end of this section.

- Hospitalization (for those patients who cannot meet the requirements for outpatient treatment) (13):
  1. Room location: Should be a corner room at the end of a hallway.
  2. Room preparation:
     a) tape absorbent paper to:
        i surface patient will eat on.
        ii floor around toilet.
        iii likely walkways on floor.
     b) place plastic sheets:
        i under bed sheet and pillow case.
     c) wrap plastic or absorbent paper around:
        i telephone base and hand set.

ii television and bed controls; nurse call button.
iii faucet and toilet handles; toilet seat.

d) place plastic bags in room for disposal of waste, i.e. paper plates, tissues, soiled linens.

e) put cart by door with disposable gloves, shoe covers, and gowns for nurses to wear.

f) place tape on floor to indicate line visitors should stay behind.

g) remove patient's personal belongings so they will not become contaminated.

3. The patient should wear either a disposable gown or surgical scrub suit rather than personal night clothes.

Radiopharmaceutical, Dose, & Technique of Administration

- Radiopharmaceutical: I-131 as sodium iodide (6).

- Dose :
  > Ablation of residual functioning thyroid tissue post thyroidectomy: 100-200 mCi (3700-7,400 MBq) (7,13-16).
  > Treatment of persistent or recurrent functioning thyroid cancer: 100- 300 mCi (3,700-11,100 MBq) (1-8,13-16).

- Technique of administration:
  a) Capsule – oral
  b) Liquid – oral
     1. The vial containing the liquid iodine must be vented in an approved fume hood.
     2. The radioiodine dose will be drawn up in the fume hood.
     3. Appropriate shielding will be provided during transportation to the patient.
     4. The radioiodine dose will be administered to the patient using the sipping device provided by the radiopharmacy.
  c) Liquid via <u>single</u> lumen gastrostomy tube
     1. The vial containing the liquid radioiodine must be vented in an approved fume hood.
     2. The radioiodine dose will be drawn up in the fume hood.
     3. Appropriate shielding will be provided during transportation to the patient.
     4. The gastrostomy tube port will be flushed before the administration of the radioiodine dose to determine patency.
     5. The gastrostomy tube port will be flushed after administration of the radioiodine dose.
  d) Liquid via <u>multi-port</u> gastrostomy tube
     1. Every attempt will be made to replace the multi-port gastrostomy tube with a single lumen gastrostomy tube. (see part c. above)

2. In the case where replacement is not possible, and the need for therapy is urgent, the nuclear medicine physician, the nuclear medicine technologist, and the radiation safety officer (or designee) will participate in a "time-out" exercise. All participants will agree on the port to be utilized prior to administration of the radionuclide via the multi-port gastrostomy tube.
3. The vial containing the liquid radioiodine must be vented in an approved fume hood.
4. The radioiodine dose will be drawn up in the fume hood.
5. Appropriate shielding will be provided during transportation of the radioiodine dose to the patient.
6. The gastrostomy tube port to be utilized for the radioiodine administration (see part d. #2 above) will be flushed before the administration of the radioiodine dose to determine patency.
7. The gastrostomy tube port will be flushed after the administration of the radioiodine dose.

- Any required manipulation of liquid radioiodine doses, such as transfer to an alternate syringe, must be performed under an approved fume hood. The dose must then be re-assayed prior to patient administration.

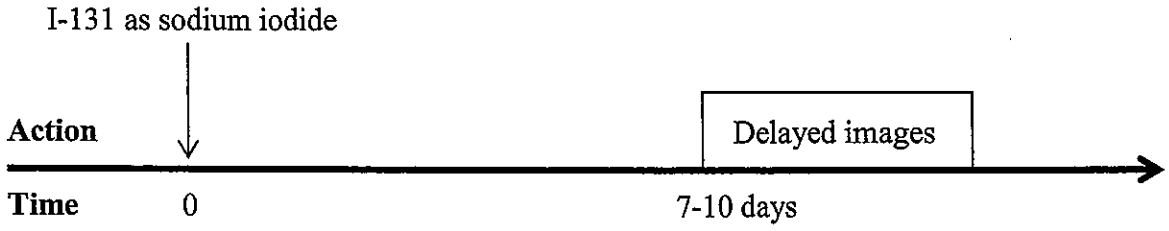
Monitoring

- All patients receiving therapeutic radioiodine as an inpatient will be monitored daily to assess for appropriate biological distribution and excretion of the radioiodine. The monitoring results will be recorded in the patient's electronic medical record (CPRS). Monitoring at 24 hours following I-131 therapeutic administration should reveal a decrease in exposure level of approximately 50% as compared to the initial post-therapy exposure reading. If this expected decrease in exposure level is not achieved, the Nuclear Medicine Service Chief and the Radiation Safety Officer (RSO) will be notified.

Acquisition Protocol

- Perform whole body imaging 7-10 days following administration of the treatment dose of I-131 (6,7).

Protocol Summary Diagram



Reviewed and Approved
November 25, 2009
Ernest V. Belezzuoli, M.D.
Chief Nuclear Medicine Service
VA San Diego Healthcare System

Post Treatment Restrictions (6)

- There are post-treatment restrictions for the patient to follow which will be discussed with the patient by the nuclear medicine physician/technologist and/or the radiation safety officer. Written instructions will also be provided to the patient (see handout titled "Discharge Information for Patients Receiving NaI I-131 Thyroid Ablation Radiotherapy on an Inpatient Basis" at the end of this section).

Complications

- In general, the risk of complications from I-131 therapy increases as the cumulative dose from I-131 increases and as the amount of residual post-operative thyroid tissue increases (6,17).

Complication	Time of onset	Frequency (%)	Reference
Acute radiation sickness, e.g. nausea	< 24 hr	30	6
Prolonged I-131 retention	< 24 hr	rare	17
Thyroid tissue pain & swelling	< 48 hr	20	17
Salivary and lacrimal gland dysfunction	< 1 wk	20-30	18-20
Taste dysfunction	< 1 wk	20	21
Hyperthyroidism	< 1 wk	rare	22
Radiation pneumonitis	< 1 wk	rare*	6
Impaired spermatogenesis	< 2 wk	common	23
Facial nerve palsy	< 2 wk	rare	24
Marrow suppression	years	1	6
Solid cancers	years	1	25
Miscarriages, birth defects	years	rare	26,27

- Only in patients with diffuse lung metastases.

Optional Maneuvers

- Low iodine diet: Some improvement in uptake of radioactive iodine in functioning thyroid tissue can be obtained by placing the patient on a low iodine diet for approximately 1 week prior to treatment (28,29).

- Pretreatment with diuretics: Pretreatment with diuretics may lower the blood iodide level more than a low iodine diet (30).

- Individualized dose based treatments: The treatment dose may be determined by calculating the maximum safe amount of radioiodine based empirically on an

upper limit of 200 rads to the blood and a maximum of 120 mCi of I-131 retained at 48 hours (80 mCi if the patient has pulmonary metastases) (6,31).

- Semi-automatic administration of I-131 by pipette: I-131 may be admistered by pipette in patients with severe swallowing difficulties (32).

- Pretreatment of dedifferentiated thyroid cancer with isotretinoin: Pretreatment of dedifferentiated thyroid cancer with isotretinoin may restore the cancer's ability to take up iodine (33).

- Renal failure/dialysis: Patients in renal failure may be treated with I-131 with some modifications in the protocol (34).

- Radioprotection of salivary glands: Give 300 mg/m2 of amifostine (Ethyol)

- Letter documenting radioactive treatment: If the patient triggers a radiation detector in a public facility, it is useful for him/her to have a letter documenting the cause (36).

Principle Radiation Emission Data - I-131 (37)

- Physical half-life = 8.04 days.

Radiation	Mean % per disintegration	Mean energy (keV)
Beta-4	89.4	191.5
Gamma-14	81.2	364.5

Dosimetry - I-131 as Sodium Iodide (38,39)

Organ	rads/150 mCi	mGy/5,550 MBq
Thyroid	39,000.0	390,000.0
Stomach wall	255.0	2,550.0
Salivary glands	105.0	1,050.0
Total body	36.0	360.0
Red marrow	21.0	210.0
Ovaries	21.0	210.0
Testes	12.6	126.0

References

1. Intenzo CM, Jabbour S, Dam HQ, et al: Changing concepts in the management of differentiated thyroid cancer. Sem Nucl Med 35:257-265, 2005.
2. Sawka AM, Thephamongkhol K, Brouwers M, et al: Postoperative radioactive iodine therapy may reduce the risk of recurrence of papillary and follicular carcinoma. J Clin Endocrinol Metab 89:3668-3678, 2004.

Reviewed and Approved
November 25, 2009
Ernest V. Belezzuoli, M.D.
Chief Nuclear Medicine Service
VA San Diego Healthcare System

3. Randolph GW, Daniels GH: Radioiodine-induced thyroid lobectomy is an alternative to completion thyroidectomy in patients with thyroid carcinoma. Thyroid 12: 989-996, 2002.
4. Hay ID, Thompson GB, Grant CS, et al: Changes in surgical practice and use of postoperative radioiodine therapy have had limited effect on outcome in patients with papillary thyroid carcinoma. World J Surg 26:879-885, 2002.
5. Jarzab B, Junak DH, Wloch J, et al: Multivariate analysis of prognostic factors for differentiated thyroid carcinoma in children. Eur J Nucl Med 27:833-841, 2000.
6. Tuttle RM, Becker DV, Hurley JR: Radioiodine treatment of thyroid disease. In Diagnostic Nuclear Medicine, MP Sandler, RE Coleman, JA Patton, et al, eds, Lippincott Williams & Wilkins, Philadelphia, 2003, pp 653-670.
7. Meier CA, Brill DR, Becker DV, et al: Procedure guideline for therapy of thyroid disease with iodine-131. J Nucl Med 43:856-861, 2002.
8. Kabasakal L, Sewlcuk NA, Shafipour H, et al: Treatment of iodine-negative thyroglobulin-positive thyroid cancer: Differences in outcome in patients with macrometastases and patients with micrometastases. Eur J Nucl Med 31:1500-1504, 2004.
9. Kim TY, Kim WB, Kim ES, et al: The risk of tumor recurrence is low in patients with thyroid carcinoma who have low serum thyroglobulin concentrations after surgery. J Clin Endocrinol Metab 90:1440-1445, 2005.
10. Mazzaferri EL: Empirically treating high serum thyroglobulin levels. J Nucl Med 46:1079-1088, 2005.
11. de Keizer B, H Koekstra A, Konijnenberg MW, et al: Bone marrow dosimetry and safety of high I-131 activities given after recombinant human thyroid-stimulating hormone to treat metastatic differentiated thyroid cancer. J Nucl Med 45:1549-1554, 2004.
12. Grigsby PW, Siegel BA, Baker S, et al: Radiation exposure from outpatient radioactive iodine (I-131) therapy for thyroid carcinoma. J Am Med Assoc 283:2272-2274, 2000.
13. Marcus CS, Aldrich R: Avoiding solid waste contamination problems from iodine-131 patients. J Nucl Med 38:26N,1997.
14. Robbins RJ, Schlumberger MJ: The evolving role of I-131 for the treatment of differentiated thyroid carcinoma. J Nucl Med 46 28-37, 2005.
15. Silberstein EB: A randomized study of the value of dosimetry in the use of I-131 for ablation of post-operative thyroid remnants. Eur J Nucl Med 42:350P, 2001.
16. Werkooijen RBT, Stokkel MPM, Smit JWA, et al: Radioiodine-131 in differentiated thyroid cancer: A retrospective analysis of an uptake-related ablation strategy. Eur J Nucl Med 31:499-506, 2004.
17. DiRusso G, et al: Complications of I-131 radioablation for well-differentiated thyroid cancer. Surgery 116:1024-1030, 1994.
18. Nakada K, Ishibashi T, Takei T, et al: Does lemon candy decrease salivary gland damage after radioiodine therapy for thyroid cancer? J Nucl Med 46:261-266, 2005.
19. Alexander C, Bader JB, Schaefer A, et al: Intermediate and long-term side effects of high-dose radioiodine therapy for thyroid carcinoma. J Nucl Med 39:1551-1554, 1998.

Reviewed and Approved
November 25, 2009
Ernest V. Belezzuoli, M.D.
Chief Nuclear Medicine Service
VA San Diego Healthcare System

20. Solans R, Bosch Ja, Galofre R, et al: Salivary and lacrimal gland dysfunction (Sicca syndrome) after radioiodine therapy. J Nucl Med 42:738-743, 2001.
21. Varma VM, Dai WL, Henkin RE, et al: Taste dysfunction in patients with thyroid cancer following treatment with I-131. J Nucl Med 33:996, 1992.
22. Cerletty JM, Listwan WJ: Hyperthyroidism due to functioning metastatic thyroid carcinoma: Precipitation of thyroid storm with therapeutic radioactive iodine. JAMA 242:269, 1979.
23. Wichers M, Bnez E, Palmedo H, et al: Testicular function after radioiodine therapy for thyroid carcinoma. Eur J Nucl Med 27:503-507, 2000.
24. Levenson D, Gulec S, Sonenberg M, et al: Peripheral facial nerve palsy after high-dose radioiodine therapy in patients with papillary thyroid carcinoma. Ann Intern Med 120:576-578, 1994.
25. Berthe E, Henry-Amar M, Michels JJ, et al: Risk of second primary cancer following differentiated thyroid cancer. Eur J Nucl Med Mol Imaging 31:685-691, 2004.
26. Schlumberger M, De Vathaire F, Ceccarelli C, et al: Exposure to radioactive iodine-131 for scintigraphy or therapy does not preclude pregnancy in thyroid cancer patients. J Nucl Med 37:606-612, 1996.
27. Vini K, Hyer S, Al-Saadi A, et al: Fertility is not impaired after radioiodine therapy in women with thyroid carcinoma. Postgrad Med J 78:92-93, 2002.
28. Pluijmen MJ, Eustatia-Rutten C, Goslings BM, et al: A low-iodine diet increases the efficacy of initial iodine-131 therapy in patients with thyroid carcinoma. Clin Endocrinol 58:428-435, 2003.
29. Lakshmanan M, Schaffer A, Robbins J, et al: A simplified low iodine diet in I-131 scanning and therapy of thyroid cancer. Clin Nucl Med 13:866-888, 1988.
30. Kapucu OL, Azizoglu FY, Ayvaz g: Effects of diuretic on iodine uptake in non-toxic goiter: Comparison with low iodine diet. Eur J Nucl Med 30:1270-1272, 2003.
31. Dorn R, Kopp J, Vogt J, et al: Dosimetry-guided radioactive iodine treatment in patients with metastatic differentiated thyroid cancer: Largest safe dose using a risk-adapted approach. J Nucl Med 44:451-456, 2003.
32. Karam M, Dansereau RN, Smith HS: Oral administration of I-131 by semiautomatic pipette to a patient with severe swallowing difficulties. J Nucl Med Technol 31:161-162, 2003.
33. Sandrock D, Kettner B, Munz DL: Radioiodine treatment after redifferentiation, hormone withdrawal and recombinant human thyrotropin in patients with dedifferentiated thyroid carcinoma. Eur J Nucl Med 27:930, 2000.
34. Mello AM, Isaacs R, Petersen J, et al: Management of thyroid papillary carcinoma with radioiodine in a patient with end stage renal disease on hemodialysis. Clin Nucl Med 19:776-781, 1994.
35. Bohuslavizki KF, Brenner W, Klutmann S, et al: Radioprotection of salivary glands by amifostine in high-dose radioiodine therapy. J Nucl Med 39:1237-1242, 1998.
36. Buettner C, Surks MI: Police detainment of a patient following treatment with radioactive iodine. JAMA 288:2687, 2002.

Reviewed and Approved
November 25, 2009
Ernest V. Belezzuoli, M.D.
Chief Nuclear Medicine Service
VA San Diego Healthcare System

37. 53-I-131. In MIRD: Radionuclide data and decay schemes, DA Weber, KF Eckerman, LT Dillman, JC Ryman, eds, Society Nuclear Medicine, New York, 1989, p 228.
38. MIRD Dose Estimate Report No. 5: Summary of current radiation dose estimates to humans from I-123, I-124, I-126, I-130, I-131, I-132 as sodium iodide. J Nucl Med 16:857-860, 1975.
39. Stabin MG: Radiation dose to the upper spine from therapeutic administrations of iodine-131-sodium iodide. J Nucl Med 34:695-696, 1993.

Reviewed and Approved
November 25, 2009
Ernest V. Belezzuoli, M.D.
Chief Nuclear Medicine Service
VA San Diego Healthcare System

VA SAN DIEGO HEALTHCARE SYSTEM

A Division of VA Desert Pacific Healthcare Network

Discharge Information for Patients Receiving NaI I-131 Thyroid Ablation Radiotherapy on an Inpatient Basis

When you leave the hospital, you will have some radioactive material in your body. Therefore, you should adhere to the following precautions to minimize the radiation levels to which yourself and your family members are exposed.

Diet and Nutrition, Including Drug-Food Interactions

1. Drink plenty of clear liquids (e.g., water, coffee, tea, fruit juices and/or soft drinks) for at least the first 2 days following administration.
2. Suck on hard candy or lemon wedges frequently for 2 days following administration.
3. Use disposable cups, plates, dishes, and utensils for 3 days following treatment.

Minimizing Radiation Exposures to Others

1. Maintain a prudent distance from others, especially children and pregnant women, for 3 days following treatment.
2. Try to sleep alone in a room for the first 3 nights following administration.
3. Avoid travel on a prolonged automobile trip with others for first 2 days following administration.
4. Avoid travel by airplane or mass transportation for 3 days following treatment.
5. Friends, family members, etc., should wash their hands after touching you for 3 days following treatment.

Personal Hygiene and Grooming

1. Try to use your own bathroom for at least the first 2 days following treatment. Urinate frequently (every 2-3 hours if possible) for 2 days. **Sit down** when urinating. Flush the toilet twice after each use.
2. Wash your hands frequently and thoroughly, especially after using the toilet.
3. Shower daily and use separate towels for 5 days. Rinse the shower area thoroughly after each use.
4. Wear clothing that can be laundered (not dry cleaned) for 5 days following treatment.
5. Collect your worn clothing for 5 days after treatment and launder them separately from other clothing. Put them through the wash/rinse cycles twice.

Contact the Nuclear Medicine Department at 858-552-7511 should you have any comments, questions, or concerns regarding the information provided.

Reviewed and Approved
November 25, 2009
Ernest V. Belezzuoli, M.D.
Chief Nuclear Medicine Service
VA San Diego Healthcare System

Subpart M--Reports

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in--

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following--

(i) An administration of a wrong radioactive drug containing byproduct material;

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center[3] no later than the next calendar day after discovery of the medical event.

By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.

(1) The written report must include--

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardi

(g) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(i) Name of the individual who is the subject of the event; and

(ii) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

[68 FR 58805, Oct. 10, 2003]

[3] The commercial telephone number of the NRC Operations Center is (301) 951-0550.

VA SAN DIEGO HEALTHCARE SYSTEM

A Division of VA Desert Pacific Healthcare Network

Safe Handling of Therapeutic I-131 Liquid Doses in Nuclear Medicine

Overview: The purpose of this procedure is to ensure the proper handling of I-131 liquid dosages for therapeutic procedures performed prior to gastrostomy administrations. Handling must be performed in such a way that any manipulation, transfers and transportation of these materials is performed in such a way that the risks of spillage, contamination and occupational doses to personnel are minimized.

Steps:

1. Go to the Radiotherapy Suite and examine the ports to the patient's gastrostomy tube and positively ID the port designed for administration of medication. If possible, have another member of the treatment team review and confirm the correct port for medication administration.
2. Using brand new syringes (of the same type that can be used to administer the therapy dose), identify the syringe that couples completely and securely to the medication port. Return to Nuclear Medicine.
3. Don lab coat, whole body dosimeter, finger ring dosimeter, and nitrile gloves.
4. Ensure work surfaces are covered with Chux or other suitable removable bench covering.
5. Turn on a calibrated Victoreen 451P and verify it is operating properly.
6. Ensure a calibrated contamination meter is nearby, turned on, and working properly.
7. Upon receipt, and if it is practical and safe to do so, place the dose vial in elongated locking tongs (such that the label is readable) to reduce extremity doses.
8. Measure the radiation exposure rate of the vial at a distance of approximately 1-2 inches so that you are aware of the radiation levels present.
9. Remove the dose vial from the tongs (if applicable).
10. Assay the dose and compare the measured activity to that identified on the vial label and written directive. The measured activity should be within +/- 10% of the prescribed dose. Note: Due to the potential for loss of activity (residual activity in dose vial, residual activity in syringe, etc.) via this route of administration, the measured activity prior to administration should be within +/- 10% of the prescribed dose. If the activity actually administered (e.g., measured activity – vial activity losses – straw activity losses) is not within +/- 20% of the activity prescribed, a **NRC medical event** will have occurred and you need to contact the Radiation Safety Officer immediately.
11. Place the dose vial inside a properly working fume hood/mini-hood that is authorized for use with volatile radioactive materials and is compliant with USP 797 use criteria.
12. Open the vial and allow any volatilized radioiodine to off-gas and be captured/exhausted by the hood.
13. Attach the correct gauge needle to the syringe that will be used to administer the therapy dose to the patient.
14. Place the syringe into a syringe shield.
15. Draw-up the therapy dose using the shielded syringe with the correct gauge needle.
16. Using another clean syringe/needle combination, carefully rinse the inside of the dose vial with 1-2 ml of sterile saline/distilled water.
17. Using the shielded syringe/needle that contains the therapy dose, draw-up the 1-2 ml of rinse liquid in the dose vial. Remove the needle and discard it inside sharps containers labeled for radioactive material.
18. Transport the dose vial to the patient therapy suite.
19. After the administration is completed, discard the syringe inside a sharps container labeled for radioactive material.
20. Return dose vial/hood set-up to Nuclear medicine, perform surveys, complete documentation.

RADIATION SAFETY PROCEDURES FOR PERFORMING NON-ROUTINE PROCEDURES ON CONTROLLED NUCLEAR MEDICINE PATIENTS

INTRODUCTION

Each year, the VASDHS Nuclear Medicine Service treats approximately 8-12 patients with radioactive materials in such quantities that these patients may not be immediately released due to radiation safety considerations. When such treatments are necessary, they are performed in the Radiotherapy Suite (Room 3365) located on 3-North, C-Pod. Following treatment, patients are required to remain within the Radiotherapy Suite until radiation exposure rates have reduced to acceptable levels.

VASDHS policy allows the transportation of these patients to other areas of the hospital to undergo certain medical procedures. Due to the elevated radiation levels emanating from these patients and the high risk of radioactive contamination leaving the Radiotherapy Suite, Radiation Safety and Nuclear Medicine personnel must follow the below procedures, unless a life-threatening emergency exists.

I. RSO NOTIFICATION (Nuclear Medicine)

Nuclear Medicine personnel must immediately notify the Radiation Safety Office when patients staying in the Radiotherapy Suite must be taken to other areas of the hospital to undergo medical procedures. René Michel is the facility's Radiation Safety Officer (RSO). He may be reached via his office phone (x1059) or his work cell phone (858-518-5220). If Mr. Michel is unavailable, contact Michael Zorn, the facility's Assistant RSO. Mr. Zorn may be reached via his office phone (x7215) or his work cell phone (858-337-1184). When contacting them, be prepared to provide them with the following information:

- Your Name
- Your Contact Information
- The Name of the Patient
- The Reason(s) Why the Patient has to Leave the Radiotherapy Suite
- The Date and Time when the Patient will Leave the Radiotherapy Suite
- The Location (Service/Section/Department and room #) Where the Patient will be Going
- The Date and Time when the Patient will be Returned to the Radiotherapy Suite

II. PERSONNEL INSTRUCTION (Radiation Safety)

Anyone who is going to be involved with a medical procedure involving a restricted Nuclear Medicine patient must be informed of the hazards expected to be present as well as protective measures that must be employed to control radiological exposures. To comply with this requirement, Radiation Safety will set-up a training session with personnel expected to be present and review the following before the medical procedure is initiated:

- The training guide titled "Radiation Safety Training for Personnel Caring for Controlled Patients"
- The procedure to be performed and the reason why it is being performed;
- Discuss the types and quantities of radioactive material present and anticipated radiation levels;
- Describe methods for minimizing radiological exposures, such as:
    - Covering work surfaces with removable layers to minimize radioactive contamination;
    - Wearing disposable garb (e.g., aprons, head covers, shoe covers, gloves, etc.);
    - Minimizing time around the patient/items removed from the patient;
    - Maximizing distance from the patient/items removed from the patient;
    - Using mobile shields when proximal to the patient (if necessary) and place radioactive items in shielded receptacles;
    - Using dosimeters, if needed, to monitor occupational exposures to ionizing radiation; and
    - Performing radiological surveys of personnel and work surfaces during and after the procedure to monitor for radioactive contamination.
- Personal bioassays may be performed to monitor internal exposures to ionizing radiation;
- Methods for maintaining radioactive material/waste secure from unauthorized access or removal; and
- Management of radioactive items/waste.

III. PREPARATION OF THE TREATMENT/EVALUATION AREA (Radiation Safety)

Due to the amount and nature of the radioactive material present inside the patient, Radiation Safety should prepare the treatment/evaluation area to prevent it from getting contaminated. The degree to which the area should be prepared is based upon the status of the patient (e.g., is the patient feeling nauseous, is the patient incontinent, etc.) and the likelihood that the procedure will generate dispersible radioactive material (e.g., blood, urine, tissues, etc.).

For example, if a patient is in good spirits, is not feeling nauseous, and will simply have an image taken of his body, minimal preparation is needed (e.g., removable layer of plastic or blue under pads (Chux) on the imaging table, etc.). However, if there is a strong likelihood of fluid loss, tissue/specimen, collection, etc., then the treatment/evaluation area should be set-up much like the Radiotherapy Suite:

- Tarps on the floor
- Plastic liners on the walls
- Plastic liners/Chux on treatment surfaces
- Radiation Hazard signs on entrances
- Radioactive Waste Receptacle
- Radioactive Linen Receptacle

Radiation Safety will establish a "Clean Zone" inside the room near an exit but away from the treatment/evaluation area. This area must be kept clear of any radioactivity before, during, and after the procedure. Place the following items inside the "Clean Zone:"

- Several contamination meters suitable for the radiations expected to be present
- One or more exposure rate meters
- Wipe supplies (e.g., vials, filter paper circles, etc.)
- Decontamination supplies (e.g., survey sheets/diagrams, Fantastik, disposable gloves, disposable shoe covers, paper towels, plastic-backed bench paper, China markers, etc.)

Radiation safety will also establish a small "Transition Zone" right in front of the "Clean Zone" by placing Chux, plastic-backed bench paper, or a poly tarp on the floor. The "Transition Zone" is the area where personnel are surveyed for radioactive contamination after they have removed their protective garb.

IV. PATIENT TRANSPORTATION FROM THE RADIOTHERAPY SUITE (Nuclear Medicine)

The following steps must be taken by a Nuclear Medicine technologist to prevent the spread of radioactive contamination:

- Have the patient use the restroom before he/she leaves the Radiotherapy Suite.
- Obtain a wheelchair. Cover the seat, back rest, and arm rests with a removable layer of material (e.g., plastic sheet, Chux, etc.). Place the wheel chair just outside the entrance to the Radiotherapy Suite.
- Obtain a disposable gown, disposable head cover, disposable shoe covers, and disposable gloves. With the patient standing just inside the entrance to the Radiotherapy Suite, have him or her don the disposable gloves, then the disposable gown, then the disposable head cover.
- After orienting the wheel chair so it is facing into the Radiotherapy Suite, have the patient sit down onto the wheel chair with his/her feet on the floor inside the Radiotherapy Suite.
- Have the patient raise his/her foot, place a disposable shoe cover on it, then set it in the foot rest. Repeat this process with the patient's other foot.
- Move the patient a couple of feet towards the Emergency Exit.
- Lock the Radiotherapy Suite.

The Nuclear Medicine technologist must accompany the patient at all times until he/she is returned to his/her suite.

V. PATIENT TRANSPORTATION TO THE TREATMENT/EVALUATION AREA (Nuclear Medicine)

Using a brisk but safe pace, the Nuclear Medicine technologist will transport the patient to the treatment/evaluation area using the most direct route available. If it is necessary to change floors, use a service elevator and do not allow other people to ride with you. Periodically, check behind you to ensure that nothing (e.g., fluid/urine) has dropped from the patient onto the floor. When passing through doorways or tight spots, ask for help from your fellow employees (if needed) and have the patient keep his or her hands in their lap.

VI. TREATMENT AND EVALUATION OF THE PATIENT (Nuclear Medicine/Radiation Safety)

Upon your arrival at the treatment/evaluation location, the Nuclear Medicine technologist must keep the patient in the wheelchair and position him/her inside the room. Don the appropriate attire as required by the procedure and that will allow for sufficient radiological protection. Remain in the room throughout the procedure/evaluation to ensure radiological precautions are being followed. It is important that only essential healthcare personnel are present during the treatment/evaluation and that they are wearing protective clothing. No visitors, pregnant workers or unessential personnel should be allowed in the diagnostic/treatment room.

VII. PATIENT TRANSPORTATION BACK TO THE RADIOTHERAPY SUITE (Nuclear Medicine)

Once the treatment/evaluation has concluded, it is important to return the restricted patient to the Radiotherapy Suite. The Nuclear Medicine technologist should use a similar approach to that used when leaving the Radiotherapy Suite:

- Ensure that the patient is wearing a disposable gown, head covering, shoe covers, and gloves.
- Have the patient sit in the covered wheel chair.
- Position the patient in the wheel chair at the treatment/evaluation room exit.
- Put on disposable shoe covers and gloves.
- Using a brisk but safe pace, transport the patient to the Radiotherapy Suite using the most direct route available. Should you have to change floors, use a service elevator and do not allow other people to ride with you. Periodically, check behind you to ensure that nothing (e.g., fluid/urine) has dropped from the patient onto the floor. When passing through doorways or tight spots, ask for help from your fellow employees (if needed) and have the patient keep his or her hands in their lap.
- Unlock the door to the Radiotherapy Suite.
- Position the patient in wheelchair in front of the entrance to the Radiotherapy Suite.
- Have the patient place his/her feet on the covered floor inside the Radiotherapy Suite.
- Have the patient stand-up and walk into the Radiotherapy Suite.
- Close the door to the Radiotherapy Suite.

VIII. RADIOLOGICAL SURVEYS AND CONTAMINATION CONTROL (Radiation Safety)

Radiation Safety must ensure that security and control over any radioactive items remaining in the room is maintained at all times and that contamination surveys of personnel and the work area are performed after the procedure is completed. After the patient has left the room, radiation levels should drop to background so radiological surveys can begin. If this is not the case, make sure that any radioactive items/wastes are placed inside shielded receptacles at the distal end of the room and away from the “clean zone.” Perform and document a quick exposure rate survey of radioactive items/waste under shielded and unshielded conditions to ascertain the magnitude of radiation levels.

Personnel Monitoring

Before anyone is allowed to leave the room, surveys must be performed and documented by Radiation Safety to ensure radioactive contamination is contained. Ensure each person does not track radioactive contamination into the “Clean Zone” by having them, one at a time:

- Stand right next to the “Transition Zone.”
- Carefully remove their outer layer of gloves and dispose of them in the waste receptacle.
- Carefully remove their head covering and disposable gown and throw them in the waste receptacle.
- Raise one shoe, remove the shoe cover, and keep that shoe in the air so you can survey it (document results).
- If the shoe is not contaminated, the person places that foot in the “Clean Zone.”
  Note: If the shoe is contaminated, remove and store it, and survey the person’s foot (document results). Disposable shoe covers may be worn on bare feet.
- Raise the other shoe, remove the shoe cover, and keep that shoe in the air so you can survey it (document results).
- If the shoe is not contaminated, the person places that foot in the “Clean Zone.”
  Note: If the shoe is contaminated, remove and store it, and survey the person’s foot (document results). Disposable shoe covers may be worn on bare feet.
- Carefully remove their gloves and dispose of them in the waste receptacle.
- Hold their hands out so you can survey them (document results).

Note: If either hand is contaminated, have the person scrub their hands with a suitable decontamination agent over the waste receptacle. Survey the person's hands for contamination (document results). If it is difficult to decontaminate the hands, have the person put on a pair of disposable gloves to make them sweat. This may help remove the contamination from the skin.

- Stand facing you so you can survey their head, torso, arms, and legs (document results).
- Stand facing away from you so you can survey their head, torso, arms, and legs (document results).
  Note: If any articles of clothing are contaminated, remove and store them, and have the person put on clean scrubs or a disposable gown. If the person's skin is contaminated, use suitable decontamination agents to remove the radioactive material.

Once the person has been verified as not having radioactive contamination, he/she may step to the "Clean Zone" and leave the area.

Removal of Area Coverings

Once unnecessary personnel have been cleared from the area, Radiation safety will carefully remove disposable coverings from equipment, work surfaces, etc., such that you do not spread radioactive contamination. When removing the floor covering, stay on the covering itself and roll it up into a ball. Once you've made the floor covering as small as you can:

- Carefully remove your outer layer of gloves
- Carefully remove one shoe cover, keeping your foot in the air
- Place a new shoe cover on your shoe and step onto the uncovered floor
- Carefully remove your other shoe cover, keeping your foot in the air
- Place a new shoe cover on your shoe and step onto the uncovered floor
- Dispose of the wadded up floor covering into the waste receptacle
- Remove your inner layer of gloves and survey your hands for contamination
- Put on two layers of disposable gloves

Area Monitoring/Decontamination

Initiate the survey of the evaluation/treatment area. Survey all work surfaces with a suitable contamination meter. Mark any areas measuring more than 3X background with a China marker and record the results. Be very careful to avoid spreading radioactive contamination from identified "hot" spots. After the initial contamination survey has been completed, use an exposure rate meter to measure and record radiation levels in units of millirem per hour or microrem per hour.

Using Fantastik or another suitable decontamination agent, treat all of the identified "hot" spots to try and reduce radioactive contamination to less than 3X background on the contamination meter. Once each spot has been decontaminated to background or no further radioactive material can be removed, resurvey each spot with a contamination meter and exposure rate meter and record the results. Collect wipe samples from each spot and analyze them on a suitable scintillation counter. Retain the wipe test results with the survey meter monitoring results. Any "hot" spots bearing high levels of fixed contamination must be covered, labeled, and re-evaluated periodically.

Bioassays

Within 72 hours of the procedure, bioassays should be performed on all involved personnel to determine if there were any intakes of radioactive material and, if so, the resulting dose equivalents to critical organs as well as the whole body.

IX. WASTE MANAGEMENT (Radiation Safety)

Due to the likelihood of radioactive contamination, all waste generated inside the study/treatment area must remain inside until it is removed by Radiation Safety personnel. Radiation Safety will store the contaminated waste until it has decayed to background radiation levels. Once decayed, Radiation Safety shall properly dispose of the waste.

VA SAN DIEGO HEALTHCARE SYSTEM

A Division of VA Desert Pacific Healthcare Network

RADIATION SAFETY TRAINING FOR PERSONNEL CARING FOR CONTROLLED PATIENTS

INTRODUCTION

VASDHS Nuclear Medicine Service performs a number of treatments, including in-house therapies of patients with thyroid cancer or hyperthyroidism that involve the administration of radioactive drugs into patients. These treatments are usually performed in the Radiotherapy Suite (Room 3365) located on 3-North, C-Pod, where the patients stay until radiation levels drop below regulatory limits and they are released. These patients may have to be taken to other areas of the hospital to undergo medical procedures that cannot be performed in the therapy suite. This training was developed for VASDHS personnel, such as physicians, nurses and technologists that may be required to provide care for these patients.

TRAINING REQUIREMENT

U.S. Nuclear Regulatory Commission Regulations (10 CFR 35.310) require that VASDHS provide radiation safety instruction to all personnel caring for controlled patients (those individuals that cannot be released per 10 CFR 35.75). Such training must cover VASDHS the following areas:

RSO NOTIFICATION

In order to ensure that medical procedures are performed safely, and in accordance with applicable regulations, the Radiation Safety Office (also referred to as Radiation Safety) must be promptly notified when patients have to be taken to other areas of the hospital. René Michel is the facility's Radiation Safety Officer (RSO). He may be contacted at x1059 or via his cell phone at 858-518-5220. If Mr. Michel is unavailable, make sure to contact Mike Zorn, the Assistant RSO at x1059 or via his cell phone at 858-337-1184.

PATIENT CONTROL

Patients that cannot be released per 10 CFR 35.75 are instructed to stay in the Radiotherapy Suite at all times during their stay. If a patient has to be transported to other areas of the hospital to undergo a medical procedure, he/she must be escorted by a Nuclear Medicine technologist. This individual must accompany the patient at all times until he/she is returned to his/her suite. Radiation Safety is responsible for overseeing all radiation safety aspects (i.e., contamination control, keeping occupational doses ALARA, radioactive waste management, contamination surveys, etc.).

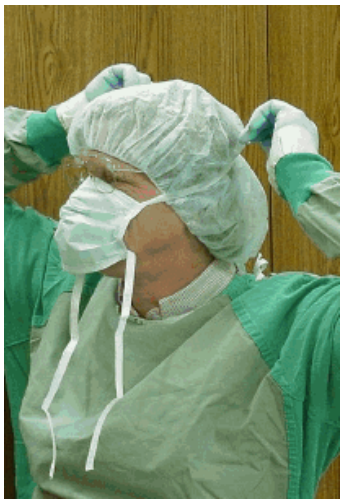
VISITOR CONTROL

Only essential healthcare personnel that have completed this training are authorized to provide medical care to the patient. No visitors, pregnant workers or unessential personnel must be allowed in the diagnostic/treatment room.

CONTAMINATION CONTROL

Virtually every surface the patient and his/her body fluids touch can become contaminated with radioactive material. Practically everything (materials, equipment, etc.) that goes into the diagnostic/treatment area must STAY in it until released by Radiation Safety. The following contamination control precautions must be followed:

- When entering the treatment/diagnostic area, you must wear surgical gloves, booties and gowns to keep your shoes, hands and body from becoming contaminated.



- Keep your exposure to radiation ALARA by minimizing the time you spend working with the patient and increasing your distance from him/her as much as possible, without compromising patient care.

- Follow any instructions provided by Radiation Safety.

- Remove booties, gloves and gown as you exit the study/treatment area such you do not allow radioactive contamination to leave the room.

- To ensure your hands and feet do not bear radioactive contamination, make sure they are monitored with a portable survey meter such as the one shown in the picture below.

After the study/treatment is completed, the Radiation Safety must ensure that radioactive contamination does not leave the study/treatment area. If needed, this area may be temporarily secured (appropriate "Caution-Radioactive Material" and "Do Not Enter" postings must be placed at all access to the study/treatment room) until released by Radiation Safety.

WASTE CONTROL

Due to the likelihood of radioactive contamination, all waste generated inside the study/treatment area must remain inside until it is removed by Radiation Safety personnel. Radiation Safety will store the contaminated waste until it has decayed to background radiation levels. Once decayed, Radiation Safety will properly dispose of the waste.