March 5, 2010

The Honorable Edward J. Markey
Chairman, Subcommittee on Energy
and Environment
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter of January 14, 2010, in which you expressed concerns about NRC's regulations for the treatment of patients with radioisotopes and the criteria under which these patients are released from hospital care. Detailed responses to the questions contained in your letter are provided in the enclosure.

Please be assured that the Commission shares your concern for public health and safety. We continue to believe that our regulations for release of patients who have been treated with radioisotopes adequately protect the public from any unacceptable risk.

The NRC staff is available to provide a briefing for you or your staff and answer any remaining questions you may have, if you desire. If this would be helpful, please contact Rebecca Schmidt, Director, Office of Congressional Affairs, at 301-415-1776.

Sincerely,

/RA/

Gregory B. Jaczko

Enclosure:
Detailed Responses to Questions

ENCLOSURE

U.S. NUCLEAR REGULATORY COMMISSION RESPONSE
TO JANUARY 14, 2010, INFORMATION REQUEST

U.S. Nuclear Regulatory Commission (NRC) Response
to January 14, 2010, Information Request

Question 1:

> **In your letter to me you cite the 2006 report of the National Council on Radiation Protection (NCRP), No. 155, which found that with "adequate instructions," no member of the public is likely to be exposed to more than 5 millisieverts (mSv) of radiation by a released patient. However, NCRP No. 155 also says that for children and pregnant women, the acceptable dose rate is not 5 mSv, but one-fifth that: "Pregnant women and 'children *shall not* exceed 1 mSv." Later in your response, you state that "There is no distinction between the dose limits that apply to other members of the public and those that apply to pregnant women and young children," yet you also state that NRC's release requirements are consistent with NCRP. Can you please clarify the NRC position on this? Does NRC agree with the NCRP's recommendation for a lower dose limit to pregnant women and children? If not, why not? If so, then how is that recommendation factored into NRC's regulations regarding the release of patients treated with radionuclides?**

Response 1:

The NRC's dose limit to all members of the public from radiation from patients is 5 mSv. This is higher than the NRC's public dose limit of 1 mSv from other sources of radiation and NCRP's recommended level for pregnant women and children. The NRC incorporated this difference in dose limits into its regulations in response to several petitions received from the medical community between 1991-1994 that indicated lowering the dose limits from the release of patients would place an unacceptable burden on the medical community and interfere with medical treatment. These regulations were finalized in 1997.

In 2005, the agency received a petition for rulemaking that requested, among other things, that the NRC revoke the 1997 amendment, insofar as it allows the release of patients from radioactive isolation with more than the equivalent of 30 millicuries of I-131 in their bodies, and particularly mentioned the impacts on family members and children. In May 2008, the NRC denied the petition and stated that the rules did not require revision but that guidance on maintaining doses as low as reasonably achievable (ALARA) to other individuals would be strengthened.

The NRC believes it has incorporated the NCRP's objective into its regulations, which is to provide a reasonable set of measures to achieve adequate public protection. The NRC has done this by requiring the licensee to provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals ALARA if the total dose equivalent to any other individual is likely to exceed 1 mSv. The NRC believes that the application of the dose limits together with the principle of keeping all radiation exposures as low as reasonably achievable, results in an adequate degree of protection and a degree of protection that is significantly greater than could be attained by relying on the dose limit alone. This is one reason that NRC regulations under 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material," not only establish a dose limit for patient release but also a requirement to provide instructions on actions recommended to keep doses to others ALARA.

At the direction of the Commission, the agency is currently in the process of engagement with stakeholders and interested parties to obtain feedback on key issues and to develop the technical basis for possible revision of the NRC's radiation protection regulations, as appropriate and scientifically justified. A set of facilitated public workshops are planned for later this year. The staff has noted to the Commission that this topic may be raised by stakeholders as a point of discussion.

Question 2:

How many iodine-131 (I-131) licensee facilities are there in the United States?

Response 2:

There are an estimated 500 NRC and 3,200 Agreement State medical use licensees that use I-131 in therapeutic quantities (i.e., quantities that exceed 30 microcuries, which require a written directive).

Question 3:

How often does the NRC perform sampling inspections at each of these I-131 licensee facilities?

Response 3:

The NRC inspects its medical licensees that administer therapeutic doses of I-131 every two to three years. Inspection frequencies are based upon the type and scope of the program. Typically, large medical institutes and university-run medical facilities hold Medical Institution Broad Scope licenses. These licenses require an inspection frequency of once every two years. Another type of medical license that administers therapeutic doses of I-131, referred to as a Medical Institution - Written Directive Required, requires an inspection frequency of once every three years.

Question 4:

What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.

Response 4:

The NRC specifies the inspection criteria for a facility requiring written directives, including those facilities that administer I-131, in Inspection Procedure (IP) 87131 "Nuclear Medicine Programs, Written Directive Required" (Attachment 1). Regarding the release of patients, IP 87131 requires, in part, that the inspector determine by direct observations and, if needed, review of selected records that the licensee is knowledgeable about patient release criteria and is in compliance with the NRC patient release criteria in 10 CFR 35.75. NRC inspectors also verify that the licensee's evaluation for release of the patient meets the requirements in 10 CFR 35.75.

The inspectors review a sample of the licensee's written instructions to the patient to determine if the instructions meet current NRC requirements.

Question 5:

> **Appendix B of NCRP Report No. 155 includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients." For a patient receiving 175 millicuries of I-131, the patient is instructed not to hold or embrace children for more than 10 minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles; to wipe down the telephone with paper towels and then discard the paper towels; etc. What instructions has NRC given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?**

Response 5:

NRC guidance to medical use licensees, NUREG-1556 Volume 9, Revision 2, Appendix U "Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials," provides general objectives rather than prescriptive directions as provided in NCRP Report No. 155. The NRC requires the instructions to include actions that the licensee recommends to patients to meet the general objective of maintaining doses to other individuals as low as reasonably achievable. There are many ways of meeting these objectives, and the NCRP approach is one possible way. There is nothing that precludes the licensee from adopting the NCRP guidance.

NRC's Appendix U provides licensees with areas to consider in the instructions that they provide to patients who have received radiopharmaceutical administrations or implants. The instructions should be specific to the type of treatment, include information for individual situations, and include the name and telephone number of a knowledgeable contact person, in case the patient has any questions.

The guidance suggests that licensees provide instructions to patients on maintaining distance from other persons, including separate sleeping arrangements; minimizing or avoiding time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events); precautions to reduce the spread of radioactive contamination; and the length of time each of the precautions should be in effect. It also provides guidance concerning breast-feeding, and sample calculations to assist licensees in performing patient release calculations.

Additionally, in response to ICRP Publication 103 and to highlight concerns involving protection of infants and young children, the NRC provided supplemental guidance to NUREG-1556 Volume 9, Revision 2, Appendix U. This guidance is contained in Regulatory Issue Summary (RIS) 2008-11 "Precautions to Protect Children Who May Come in Contact with Patients Released After Therapeutic Administration of Iodine-131," dated May 12, 2008. The supplemental guidance recommends that in order to protect infants and young children from possible I-131 contamination, the licensee should recommend to patients that they avoid direct or indirect contact with infants and young children and maintain an adequate living space

(bedroom and bathroom) that can be used exclusively by the patient. The RIS also recommends that licensees inform patients of potential consequences, if any, from failure to follow these recommendations. The supplemental guidance also highlights that licensees should consider not releasing patients administered I-131 whose living conditions may result in the contamination of infants and young children.

Also, in July 2009, the NRC issued Supplement 1 to NRC Information Notice (IN) 2003-22 "Heightened Awareness for Patients Containing Detectable Amounts of Radiation From Medical Administrations" to provide additional information regarding medical-use licensees' provision of instructions and information to individuals released in accordance with 10 CFR 35.75 and to remind licensees of the importance of various NRC requirements, guidance, and communications on this topic. The IN stresses that under current regulations, a licensee may release a patient to any destination as long as the patient meets the release criteria in 10 CFR 35.75. However, licensees should consider the destination to which a patient may be released, consider the potential for exposure to others, and provide release instructions specific to the patient's circumstances.

Furthermore, over the years the NRC has worked with the Society of Nuclear Medicine and the Centers for Disease Control and Prevention (CDC) to enhance and better understand patient release issues. In 1987, the NRC and the Society of Nuclear Medicine co-published a pamphlet that provided information for patients receiving treatment with radioiodine, which contained blanks for the physician to fill in the length of time that each instruction should be followed. The NRC also collaborated with the CDC in 2006 and 2007 to assess how health care facilities informed patients released in accordance with 10 CFR 35.75 about radiation and public security checkpoints, such as border crossings. The findings from the study, which appeared in *The Journal of Nuclear Medicine* in December 2007, were the impetus for the NRC issuing IN 2003-22, Supplement 1, in July 2009.

Question 6:

> **In the past ten years, how many times has NRC, as part of these inspections, requested documentation from the licensee facilities that details the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with I-131 in excess of the default limits home, or to a hotel?**

Response 6:

During every inspection of I-131 programs at medical use facilities using quantities that require a determination of whether to release the patient under 10 CFR 35.75, NRC inspectors evaluate the licensee's patient release program to verify compliance with NRC requirements. This includes determining if the licensee is knowledgeable about release criteria, maintains appropriate records to document the basis for authorizing the individual's release, and provides adequate instructions to patients. Further documentation is requested if deficiencies are noted. These documents are reviewed at the licensee's site during the inspection. NRC does not keep a record of how many times inspectors have requested records.

Question 7:

In the past ten years, how many times has NRC, as part of these inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is released from licensee care?

Response 7:

The NRC does not require licensees to keep a copy of the instructions provided to patients unless the patient is a breast-feeding female, and the dose to the infant or child from continued breast feeding would exceed 5 mSv; retention of these instructions in such a situation is required by 10 CFR 35.75(d). If the licensee does keep a copy of the instructions provided for an individual patient, the inspector may review it when the release methodology is reviewed. Also, many licensees have examples of the guidance they provide on hand for inspection. When the licensee does not keep copies of instructions for each patient or appropriate instruction models are not available at the licensee's facility, the inspector determines if the licensee is knowledgeable about release criteria and communicating adequate instructions to patients to determine if the licensee is in compliance with the regulations. NRC does not keep a record of how many times inspectors have requested records.

Question 8:

In the past ten years, how many times has NRC identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility? Please detail these problems.

Response 8:

In the past 10 years, the NRC has found a small number of cases in which a required dose calculation was not performed by the licensee or the licensee did not provide written instructions to the patient on how to maintain doses to other individuals as low as reasonably achievable. However, retrospective dose analysis has shown that the patients were allowed to be released per 10 CFR 35.75.

When these cases were identified, the NRC took enforcement action and required the licensee to implement corrective actions to prevent future occurrences. For example, the NRC issued Severity Level IV violations of 10 CFR 35.75 against the following licensees that failed to perform individualized analyses: South Jersey Hospital-Millville, Bridgeton, Newcomb (2001), Forbes Regional Hospital (2005), and Central Jersey Radiologists (2008). See Attachment 2 for detailed information on these violations.

Question 9:

In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require a knowledge of the layout of the hotel and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of a wall. Do you agree?

Response 9:

The NRC staff believes that a licensee can calculate conservative dose estimates using reasonable assumptions concerning occupancy, building geometry, and other factors.

Question 10:

> **Has the NRC ever attempted to determine how many patients treated with I-131 are a) sent home, b) sent to a hotel or c) kept in the hospital for additional time? If so, please provide the results. If not, why not?**

Response 10:

The NRC does not maintain records regarding the destinations of released patients from medical institutions. Instead, during onsite inspections at medical facilities, inspectors review a sample of cases involving therapeutic uses of radioactive materials to determine from patient records the circumstances whereupon the patient was released and the content of the counseling the patient received. These reviews are used to verify that public safety was ensured regardless of the patient's final destination.

Question 11:

> **In patients with doses in excess of the default limits, has the NRC ever attempted to determine whether these I-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has NRC ever encountered situations when individual analyses and/or dose calculations were not performed when they were required? Please provide reports and documentation relating to these cases.**

Response 11:

As discussed in response to questions four and six, NRC inspectors evaluate the licensee's program for patient release to verify compliance with NRC requirements. Included in this evaluation is a review of the licensee's process for performing individualized analysis, including patient-specific calculations. The NRC provides examples of violations of 10 CFR 35.75 in response to question eight.

Question 12:

> **What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?**

Response 12:

NRC guidance to medical use licensees provides general objectives rather than prescriptive directions. NRC requires the instructions to include actions the licensee recommends that meet the general objective of maintaining doses to other individuals as low as reasonably achievable, but licensees are not required to give patients explicit instructions to provide to hotel management. Guidance in NUREG-1556, Volume 9, Revision 2, Appendix U describes in

general terms how licensees can meet this performance-based objective. The NRC staff intends to review the guidance in this area, based on an existing internal commitment.

Question 13:

> **The health departments of Minnesota, Washington State, and New York City have all issued advisories warning licensees not to send radioactive patients to hotels. Is it the NRC's view that these advisories were uncalled-for? If not, why has the NRC issued no such guidance?**

Response 13:

The NRC has determined that issuance of an advisory warning NRC licensees not to send radioactive patients to hotels is not necessary given the regulation's flexibility to be applied to a variety of individual patient situations. The NRC believes that the current regulations provide adequate protection to members of the public. NRC regulations do not limit the location to which an individual may be released and allow a licensee to release a patient to any destination as long as the patient meets the release criteria in 10 CFR 35.75. However, as emphasized in a generic communication to licensees in a supplement to IN 2003-22, which was issued in July 2009, licensees should consider the destination to which a patient may be released, consider the potential for exposure to others, and provide release instructions specific to the patient's circumstances. The NRC has provided other considerable guidance to licensees about completing the required dose assessments. The principal guidance document is NUREG-1556, Volume 9, Revision 2 "Program-Specific Guidance About Medical Use Licenses" . This document has been supplemented by a 2008 generic communication (RIS 2008-11), and NRC staff intends to review the guidance relating to the release of I-131 therapy patients to hotels.

Question 14:

> **In 2002, the NRC Commissioners voted against receiving reports of instances in which released I-131 patients caused radiation exposure to family members or members of the public. How can NRC be confident that its rule is not causing harm when it has declared its unwillingness to be notified of events in which harm occurs? Do you believe that this proposal should be reconsidered? Why or why not?**

Response 14:

NCRP Report No. 155 summarizes the work of numerous investigators who have published on the subject of patient release. The report states that "the release of patients treated with therapeutic amounts of radiopharmaceuticals is not likely to expose any member of the public, inclusive of both external and internal dose contributions, [to] >5 mSv (0.5 rem) *provided that adequate instructions are provided at discharge to the patient and the family members*" [Emphasis added]. As such, the likelihood of a member of the public receiving a radiation exposure of 10 times (50 mSv or 5 rem) the allowable limit in 10 CFR 35.75 from a released patient appears to be very low. Therefore, the likelihood of a member of the public receiving a harmful radiation exposure (e.g., 1 Sv or 100 rem) is even more unlikely. As discussed in response to question four, the NRC does inspect to ensure patients are, in fact, given instructions. The Commission is not aware of any scenario in which a member of the public

received a 50 millisievert (5 rem) exposure from a released patient. Based on this information, the Commission does not believe that this proposal should be reconsidered.

Question 15:

> **Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.**

Response 15:

If documents required under 10 CFR 35.75 are missing or incomplete, this is considered to be a violation of NRC requirements and would be identified by NRC's inspectors. If the documentation is initially unclear, the inspector will ask additional questions to determine if a violation has occurred or not. Therefore, NRC's inspection reports provide a record of missing or incomplete documents.

Only a few cases were found where licensees violated 10 CFR 35.75. In some cases, licensees failed to perform surveys to assess I-131 patients prior to release. In other cases, licensees did not provide documentation for dose assessments because the licensee misinterpreted the guidance. These cases are documented in inspection reports in Attachment 2.

Two cases were identified in which patients were released to hotels. See Attachments 3-4 for detailed information on these cases.

Attachments:
1. NRC Inspection Manual – Inspection Procedure 87131
2. 10 CFR 35.75 Severity Level IV Violations for I-131 Therapy
3. Case 1 – Patient Release to Hotel
4. Case 2 – Patient Release to Hotel

There is an additional document that is Official Use Only that will come to you under separate cover.

ATTACHMENT 1
NRC INSPECTION MANUAL
INSPECTION PROCEDURE 87131

INSPECTION PROCEDURE 87131

NUCLEAR MEDICINE PROGRAMS, WRITTEN DIRECTIVE REQUIRED

PROGRAM APPLICABILITY: 2800

87131-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers, the general public and patients.

01.02 To determine if licensed activities are being conducted in accordance with U.S. Nuclear Regulatory Commission (NRC) requirements.

87131-02 INSPECTION REQUIREMENTS

The inspector should conduct the inspection in a manner that will allow him/her to develop conclusions about licensee performance relative to the following focus areas: 1) Security and control of licensed material; 2) Shielding of licensed material; 3) Comprehensive safety measures; 4) Radiation dosimetry program; 5) Radiation instrumentation and surveys; 6) Radiation safety training and practices; and 7) Management oversight. Based on selected observations of licensed activities, discussions with licensee staff, and as appropriate, a review of selected records and procedures, the inspector should determine the adequacy of a licensee's radiation safety program relative to each of the above focus areas. If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of the above focus areas, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are adequate, and a review of selected records maintained by the licensee documenting activities and outcomes. The above focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss or unauthorized use of radioactive material.

The NRC Inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be

conducted such that the inspector's presence does not interfere with patient care or a patient's privacy.

Discussion of the inspector's observations and interviews with the workers should not occur during the preparation for, or delivery of medical treatment, if possible. When practicable, the inspector should exercise discretion when interviewing licensee staff in the presence of patients so that the discussions do not interfere with licensee staff administering patient care. However, there may be cases when it is appropriate to discuss such matters at such times that would allow an inspector to ascertain the adequacy of the licensee's administration of the radiation safety program.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

02.01 Security and Control of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has controlled access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below NRC regulatory limits.

02.02 Shielding of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has maintained shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 Comprehensive Safety Measures. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has implemented comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 Radiation Dosimetry Program. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and a review of selected records, that the licensee's performance has implemented a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 Radiation Instrumentation and Surveys. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee has implemented radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 Radiation Safety Training and Practices. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has ensured that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

02.07 Management Oversight. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance for implementing a management system is appropriate for the scope of use and is able to ensure awareness of the radiation protection program, ALARA practices are implemented when appropriate, and assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

02.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, new emerging medical technologies are always on the forefront of providing optimal medical care to patients. In accordance with NRC regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part 35, if the licensee has submitted the information required by 10 CFR 35.12(b) through (d), and the licensee has received written approval from the NRC in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NRC considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during the inspection, the inspector may encounter new emerging technologies being used that have not been specifically amended to a licensee's license. If an inspector encounters such activity and uses, the inspector should contact NRC regional management as soon as practicable to independently verify that such use is authorized under NRC regulatory requirements. If further verification of such use is needed, the region should contact NMSS for further guidance.

87131-03 INSPECTION GUIDANCE

General Guidance

A determination regarding safety and compliance with NRC requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by NRC, independent measurements of radiation conditions at the licensee's facility, and where appropriate, a review of selected records. A direct examination of these licensed activities and discussions with cognizant workers should be a better indicator of the performance of a licensee's overall radiation safety program than a review of selected records alone.

Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, direct observations, and demonstrations by appropriate licensee personnel.

Once an inspector has conducted a review of the applicable elements of a focus area in a broad capacity (e.g., looked at the "big picture") and has not identified any safety significant concerns within that area, the inspector should conclude inspection of that focus area. The inspector should note that not all of the following elements outlined below in a particular focus area need to be reviewed by the inspector if he/she concludes from selected observations, discussions and reviews that the licensee's performance is adequate for ensuring public health and safety.

However, if the inspector during a review of selected elements of one of the focus areas concludes that there may be a significant safety concern, a more detailed review may be

appropriate. A more detailed review may include further observations, demonstrations, discussions and a review of selected records. In the records reviewed the inspector should look for trends in those areas of concerns, such as increasing radiation levels from area radiation and removable contamination surveys, and occupational radiation doses. Records such as surveys, receipt and transfer of licensed materials, survey instrument calibrations and training may be selectively examined until the inspector is satisfied that for those areas of concerns, the records may or may not substantiate his/her concerns. If the inspector substantiates a significant safety concern regarding a particular matter, it may be more appropriate to discuss this matter with NRC regional management. During the inspection, some records that are more closely related to health and safety (e.g., personnel occupational radiation exposure records, medical events and incident reports) may be examined in detail since a review of such records is necessary to ascertain the adequacy of the implementation the radiation safety program for that particular element of a focus area.

If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies from the licensee, while onsite, of all records that are needed to support the apparent violation. In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (e.g., licensee materials inventories), or make the licensing file more complete. In all cases where licensee documents are retained beyond the inspection, follow the requirements of MC 0620. Especially ensure that the licensee understands that the retained record will become publicly available, and give the licensee the opportunity to request withholding the information pursuant to the requirements of 10 CFR 2.790(b)(1).

The inspector should keep the licensee apprised of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management.

Whenever possible the inspector should keep NRC regional management informed of significant findings (e.g., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate NRC guidance under such circumstances.

03.01 Security and Control of Licensed Material

a. Adequate and Authorized Facilities. Descriptions of the facilities are generally found in the application for a license and subsequent amendments that are usually tied down to a license condition as submitted by the licensee in accordance with 10 CFR 35.13. Based on direct observations made during tours of the licensee's facility, the inspector should independently verify that access to licensed material received, used, and stored is secured from unauthorized removal, and the licensee uses processes or other engineering controls to maintain exposures as low as is reasonably achievable (ALARA).

b. Adequate Equipment and Instrumentation

1. Through discussion with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should ensure that equipment and instrumentation used by the licensee is appropriate to the scope of the licensed program. The inspector should independently verify through direct observations that

survey instruments have been calibrated in accordance with 10 CFR 35.61. The inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected.

2. If appropriate, the inspector should verify that the licensee has established and implemented procedures to identify and report safety component defects in accordance with 10 CFR 21.

c. Receipt and Transfer of Licensed Materials. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee has received and transferred licensed materials in accordance with NRC and applicable U.S. Department of Transportation (DOT) regulations and license conditions.

Through discussions with cognizant licensee representatives, direct observation of licensed activities, and if necessary, a review of selected records, the inspector should verify that the licensee has methods for picking up, receiving, and opening packages that address how and when packages will be picked up, radiation surveys and wipe tests of packages to be done on receipt, and procedures for opening packages (such as the location in the facility where packages are received, surveyed, and opened). From those discussions, observations and reviews, if necessary, the inspector should determine what actions are taken if surveys reveal that packages are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If packages arrive during the course of an inspection, the inspector should observe, when practical, personnel performing the package receipt surveys.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should review the licensee's materials accounting system. The inspector should note that sometimes, a relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility may need a sophisticated accounting system which provides accurate information on the receipt of material, its location, the quantity used and disposed of, the amount transferred to other laboratories operating under the same license, and the amount remaining after decay. From those discussions and reviews, if necessary, the inspector should determine if accounting systems consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees. In both types of accounting systems, the inspector should ensure that the licensee has performed routine audits of those systems to ensure the accuracy of the system.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that transfers of licensed material are made to recipients licensed to receive them (e.g., licensee obtains a copy of the recipient's current license before the transfer).

d. Transportation. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected transportation records, the inspector should verify that the licensee's hazardous material training, packages and associated documentation, vehicles (including placarding, cargo blocking, and bracing, etc.), and shipping papers are adequate and in accordance with NRC and DOT regulatory requirements for transportation of radioactive materials. Furthermore, from those discussions and reviews, if necessary, the inspector should verify if any incidents had occurred and that they were appropriately reported to DOT and NRC.

For further inspection guidance, the inspector should refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer closely to "Hazard Communications for Class 7 (Radioactive) Materials," the NRC field reference charts on hazard communications for transportation of radioactive materials, which contain references to the new transportation requirements, and are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings.

e. Material Security and Control. Through direct observations made during tours of the licensee's facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee has maintained adequate security and control of licensed material. From those observations, the inspector should note areas where radioactive materials are used and stored. From further observations and discussions, the inspector should verify that licensed material in storage, in controlled or unrestricted areas, is secured from unauthorized removal or access. Also, the inspector should verify that the storage areas are locked and have limited and controlled access. For licensed material not in storage, in controlled or unrestricted areas, the inspector should verify that such material is controlled and under constant surveillance or physically secured. Controls may include a utilization log to indicate when, in what amount, and by whom, radioactive material is taken from and returned to storage areas. In addition, the inspector should verify that access to restricted areas is limited by the licensee.

f. Written Directives. During the onsite inspection, the inspector should observe and interview individuals as they perform applicable duties to determine that individuals are knowledgeable about the need for written directives and if the licensee's written directives, as implemented, effectively ensure that radiation from byproduct material will be administered as directed by the authorized user in accordance with 10 CFR 35.41. The review should include consideration of the licensee's implementation of a continuous improvement in the following processes: monitoring, identification, evaluation, corrective action, and preventative measures. If necessary, the inspector should review selected records of written directives to confirm that these issues are adequately addressed in accordance with 10 CFR 35.2040.

g. Patient Release. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected records, the inspector should determine if a licensee is knowledgeable about patient release criteria and that a process exists to establish that a patient administered radiopharmaceuticals or therapeutic quantities of radioactive material is releasable from control in accordance with 10 CFR 35.75.

1. The inspector should note that the patient release criteria permits licensees to release individuals from control if the TEDE for any other individual is not likely to exceed 0.5 rem. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has taken adequate measures to ensure that patients have been released in accordance with 10 CFR 35.75.

2. Through further discussions the inspector should verify that the licensee is familiar with the requirements in 10 CFR 35.75(b) to provide instructions to released individuals if the dose to any other individual is likely to exceed 0.1 rem. The inspector should note that, in general, the licensee is required to give instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable. The inspector may determine how the licensee is demonstrating compliance with this requirement by discussing the content of the instructions with appropriate licensee staff. If concerns are identified from those discussions, the inspector may find it necessary to review the sample instructions given to patients. If the licensee is required by the rule to provide instructions to breast-feeding women, the inspector should verify through further discussions and reviews, if necessary, that the instructions include guidance on the interruption or discontinuation of breast-feeding and information on the potential consequences of failure to follow the guidance.

3. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that if the TEDE to a breast-feeding child could exceed 0.5 rem if the breast-feeding were continued, the licensee has maintained documentation that instructions were provided in accordance with 10 CFR 35.75(d).

h. Medical Events. Through discussions with cognizant licensee representatives, the inspector should determine if the licensee is knowledgeable of and in compliance with the requirements for identification, notification, reports, and records for medical events as required by NRC regulatory requirements. If necessary, the inspector should conduct a review of selected records to independently verify those discussions with such individuals. If from those reviews a previously unidentified medical event is identified by the inspector, the inspector should: 1) remind the licensee of the need to comply with the reporting requirements described in 10 CFR 35.3045, "Report and Notification of a Medical Event;" and 2) follow the procedure for reactive inspections and the guidance provided in Management Directive 8.10, "NRC Medical Event Assessment Program." Upon identification of such an event, the inspector should notify NRC regional management as soon as possible to ensure that appropriate guidance is given and matters are reviewed before completing the inspection.

i. Posting and Labeling. During tours of the licensee's facilities, the inspector should determine by direct observations whether proper caution signs are being used at access points to areas containing radioactive materials and radiation areas. During the conduct of the inspection the inspector should observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

During tours of the licensee's facilities, the inspector should verify that radiation areas have been conspicuously posted, as required by 10 CFR 20.1902. The

inspector should determine that areas occupied by radiation workers for long periods of time and common-use areas have been controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

During tours of the licensee's facilities, the inspector should observe locations where notices to workers are posted. The inspector should verify that applicable documents, notices, or forms are posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply in accordance with 10 CFR 19.11, 20.1902, and 21.6.

j. Inventories. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee is conducting a semi-annual inventory of all sealed sources in accordance with 10 CFR 35.67(g). If appropriate, the inspector should independently verify through direct observations or a review of selected records of receipt and transfer to determine that the quantities and forms of licensed material possessed and used by the licensee are as authorized in the license.

k. Waste Storage and Disposal. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that radioactive waste is stored and controlled in a secure and safe manner, and that radiation levels in unrestricted areas surrounding the storage area do not exceed NRC regulatory limits. Through further discussions, observations, and reviews, if necessary, the inspector should verify that disposals of decay-in-storage waste are performed in accordance with NRC regulatory requirements.

The inspector should note that generally, radionuclides used in nuclear medicine facilities have half-lives of 120 days or less and can be decayed in storage until surveys are indistinguishable from background, then be disposed of as non-radioactive waste.

Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify the following areas, when appropriate:

1. Waste disposed in accordance with 10 CFR 35.92;

2. Waste compacted in accordance with license conditions;

3. Waste storage containers properly labeled and area properly posted in accordance with 10 CFR 20.1902 and 20.1904; and

4. Waste was returned from a landfill due to radioactive contamination.

For further inspection guidance, the inspector should refer to IP 84850, "Radioactive Waste Management-Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61" and Information Notice (IN) 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20."

l. Effluents. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that releases into a public sanitary sewerage system and septic tanks , if any, are consistent with the form and quantity restrictions of NRC regulatory requirements. If the inspector determines that a review of selected records is necessary, the inspector should pay particular attention to the licensee's documentation for demonstrating that the material is readily soluble (or readily dispersible biological material) in water. If a review of selected records is necessary, the inspector should examine the waste release records generated since the last inspection, annual or semiannual reports, pertinent nonroutine event reports, and a random selection of liquid and airborne waste release records.

For liquid wastes, the inspector should determine through further discussions, observations and reviews, if necessary, if the licensee has identified all sources of liquid waste; evaluated treatment methods to minimize concentrations (such as the use of retention tanks); and complies with the regulatory requirements for disposal into sanitary sewerage.

Through further discussions, direct observations made during tours of the licensee's facility, and reviews, if necessary, the inspector should verify that waste-handling equipment, monitoring equipment, and/or administrative controls are adequate to maintain radioactive effluents within NRC regulatory requirements and are ALARA (This should include xenon or other gas waste, also).

In addition, from those discussions, observations and reviews, if necessary, the inspector should verify that effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity, and whether they are maintained, calibrated, and operated in accordance with the manufacturer's recommendations.

Furthermore, from those discussions, observations and reviews, if necessary, the inspector should verify that all significant release pathways are monitored, all unmonitored pathways have been characterized, and all surveillance procedures for effluents are being implemented by the licensee.

For further inspection guidance, the inspector should refer to IP 87102, "Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA).".

03.02 Shielding of Licensed Material

In an application for a license, a licensee must commit to develop, implement, and maintain procedures under 10 CFR 20.1101 and 10 CFR 20.1301 for safe use of unsealed byproduct material. Through observations and interviews, the inspector should assess the actual implementation of ALARA procedures which include shielding of licensed material.

a. Syringe and Vial Shields. Determine a sufficient number, type, and condition of syringe and vial shields are being used to protect workers and members of the public from unnecessary radiation. Verify labeling of syringe and vial shields required by 10 CFR 35.69.

b. Shielding in the Hot Lab. Determine use of shielding for waste receptacles, storage containers, generator systems, and work areas to protect workers in the hot lab.

c. Shielding for Nuclear Medicine Therapy. Determine use of shielding for administration of therapeutic quantities of byproduct material to protect workers and family members of the patient who may be present. To limit doses to workers and individual members of the public, a licensee may use portable shielding in patient rooms or the licensee may have installed permanent shielding in certain patient rooms designated for patients that cannot be released under 10 CFR 35.75. In an application for a license, the applicant would have described the shielding along with calculations to estimate dose levels. For portable shields, an applicant would also commit to develop administrative procedures for proper use and placement of the shields within a patient room.

If shielding is not evident, then the inspector should assess the licensee's procedure and further evaluation of radiation doses to workers and members of the public respectively under 10 CFR 20.1201, 20.1301, and 20.1302. The inspector should verify that the licensee instructed workers under 10 CFR 19.12 about shielding. The licensee may have determined that shielding was not indicated under certain conditions to protect the patient or human research subject from a non-radiological hazard which has significant health and safety consequences to the patient or human research subject.

03.03 Comprehensive Safety Measures

During tours of the licensee's facilities, the inspector should be aware of potential industrial safety hazards for referral to the U. S. Department of Labor's Occupational Safety and Health Administration.

During tours of the facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee's radioactive waste and licensed material are protected from fire and the elements, the integrity of packages containing licensed material is adequately maintained, areas used to store licensed material are properly ventilated, and adequate controls are in effect to minimize the risk from other hazardous materials.

03.04 Radiation Dosimetry Program

The inspector can find specific inspection guidance for this area in IP 83822, "Radiation Protection."

a. Radiation Protection Program. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has developed, implemented and maintained an adequate radiation protection program commensurate with the licensee's activities, that the program includes ALARA provisions, and that the program is being reviewed by the licensee at least annually, both for content and implementation in accordance with 10 CFR 20.1101.

b. Occupational Radiation Exposure. From a review of selected occupational radiation dosimetry reports and discussions with cognizant licensee representatives, the inspector should determine that occupational radiation exposures received by workers are within NRC regulatory limits (e.g., 10 CFR 20.1201, 1202, 1207, and 1208). If from those reviews and discussions the

inspector determines that a worker had exceeded an NRC regulatory limit, the inspector should immediately contact NRC regional management to discuss the matter and determine what steps need to be taken in following up on this matter.

10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Through discussions with cognizant licensee staff and management, the inspector should verify that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required. The licensee must advise these workers of doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. If the inspector cannot conclude from those discussions that workers had been advised of their occupational dose annually, then a records review may be more appropriate to confirm that the licensee had conducted this required task. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

c. Personnel Dosimeters. Through direct observations made during the onsite inspection, the inspector should independently verify that appropriate personal dosimetry devices are worn by appropriate licensee personnel. The inspector should verify that dosimetry devices appropriate to the type, energy of emitted radiation, and the anticipated radiation fields have been issued to facility personnel. In addition, the inspector should verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program approved and accredited processor.

Through discussions with cognizant licensee representatives and a review of selected records, the inspector should evaluate the adequacy of the licensee's methods used to assess the SDE to the portion of the skin of the extremity expected to have received the highest dose. The inspector should give particular attention to the distance between the location that is likely to have received the highest dose when sources are manipulated manually (even when shields are used) and where the extremity monitor is worn.

d. Internal Dosimetry. Through interviews with cognizant licensee representatives, and records review, if appropriate, verify that measurements for internal deposition of licensed materials are performed and evaluated in accordance with 10 CFR 20.1501.

03.05 Radiation Instrumentation and Surveys

a. Equipment and Instrumentation

1. During the conduct of the inspection, the inspector should verify through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, that equipment and instrumentation used to conduct licensed activities are appropriate to the scope of the licensed program, operable, calibrated, and adequately maintained in accordance with NRC regulatory requirements and the manufacturer’s recommendations. The inspector should verify that:

(a) The radiation survey instruments have been calibrated in accordance with10 CFR 35.61;

(b) The instruments used to measure the activity of unsealed byproduct material meet the requirements of 10 CFR 35.60;

(c) Licensees that use molybdenum-99/technetium-99m generators measure and record the molybdenum-99 concentration after the first eluate, in accordance with 10 CFR 35.204, to ensure that humans are not administered a pharmaceutical containing more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m.

The inspector should independently verify through direct observations that survey instruments have been calibrated at the required frequency in accordance with 10 CFR 35.61. The inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected. For those licensee's that calibrate their own instruments, the inspector should have cognizant licensee staff perform or demonstrate how those activities are conducted in order to demonstrate the technical adequacy of the licensee's calibration procedures.

2. When appropriate, the inspectors should confirm that the licensee is knowledgeable in identifying and reporting defects in accordance with Part 21. This will vary dependent upon the scope of the licensee's program.

b. Area Radiation Surveys. During tours of the licensee's facility, the inspector should verify by direct observations and independent measurements, that area radiation levels are within NRC regulatory limits, and that those areas are properly posted. The inspector should have the licensee spot-check area radiation levels in selected areas using the licensee's own instrumentation. However, the inspector must use NRC radiation survey instruments for independent verification of the licensee's measurements. (The inspector's instruments shall be calibrated and source-checked before he/she leaves the NRC regional office.) The inspector should conduct such surveys as further discussed in Section 0312.

If practical and when appropriate, the inspector should observe licensee staff conduct area radiation and removable contamination surveys, to determine the adequacy of such surveys. The inspector should verify the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured.

c. Leak Tests. During the conduct of the inspection, the inspector should verify that leak tests of sealed or contained sources are performed at the required frequency found in 10 CFR 35.67(b) or license conditions. Through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, the inspector should verify that the leak test is analyzed in accordance with 10 CFR 35.67(c). If records of leak test results show removable contamination in excess of the regulatory requirements of 0.005 microcuries (185 becquerels) or approved level included in a license condition, the inspector should verify that the licensee made the appropriate notifications per 10 CFR 35.67 (e) and removed the source from service.

03.06 Radiation Safety Training and Practices

a. General Training. During the onsite inspection, the inspector should discuss with cognizant licensee staff how, and by whom, training is conducted and the content of the training provided to workers.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify, pursuant to 10 CFR 19.12, that instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 milliSievert (100 mrem). The inspector should note that it is the licensee's management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NRC regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NRC requirements. Also, the inspector should verify that authorized users and workers understand the mechanism for raising safety concerns.

Of the training program elements, training given to authorized users and nuclear pharmacists, and those individuals under the supervision of authorized users and nuclear pharmacists is of primary importance. The inspector should interview one or more users of radioactive materials to independently verify that they have received the required training. The inspector should note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

If necessary, the inspector may need to review selected records of personnel training to the extent that the inspector is satisfied that the training program is being implemented as required.

During the inspection, the inspector should observe related activities and discuss the radiation safety training received by selected individuals to ensure that appropriate training was actually received by these individuals. From those observations and discussions, the inspector should verify that authorized users, authorized nuclear pharmacists and supervised individuals understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, "dry runs" for more complex or hazardous operations, and authorized nuclear pharmacists instruction in the preparation of drugs.

b. Operating and Emergency Procedures. During the conduct of the inspection, the inspector should verify through direct observations of licensed activities, if practical, licensee personnel perform tasks at selected work stations to verify that such licensed activities are performed in accordance with the licensee's operating procedures. Through discussions with cognizant licensee staff, the inspector should verify that for those individuals interviewed understand and implement procedures establish by the licensee and are aware of procedural revisions. If appropriate, the inspector should review the licensee's emergency procedures to determine that these procedures are adequate to ensure compliance to NRC regulatory requirements.

Discuss with cognizant licensee representatives, or if practicable, observe licensee personnel conduct periodic tests, especially for scenarios involving events that would require reporting to the NRC under 10 CFR 20.2202.

Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. The inspector should discuss with cognizant licensee representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

c. Safety Instruction for Personnel Caring for Non-Releasable Patients. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee provides radiation safety instruction for all personnel caring for patients who cannot be released under 10 CFR 35.75, in accordance with10 CFR 35.310. The inspector should note that radiation safety instruction must be conducted initially and at least annually an be commensurate with the duties of the personnel.

d. Protective Clothing. Through direct observations of licensed activities and discussions with cognizant licensee representatives, the inspector should verify that radiation workers are provided with, and wear, the appropriate protective clothing commensurate with activities being performed. The observation of the protective clothing that licensee staff wear during their work activities should provide the inspector with an acceptable means of reviewing this requirement. If the inspector identifies a concern with this practice, the inspector should discuss this practice with appropriate licensee representatives to ensure that licensee staff are following licensee procedures for wearing adequate protective clothing.

03.07 Management Oversight

The inspector should interview cognizant licensee representatives to gain information concerning organization, scope, and management oversight of the radiation safety program.

a. Organization. During the conduct of the inspection, the inspector should interview cognizant licensee representatives to discuss the current organization of the licensee's program. The licensee's organizational structure will usually be found in the license application and may involve one or more individuals. The inspector should review with cognizant licensee representatives the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Through discussions with cognizant licensee representatives, the inspector should determine the reporting structure between executive management and the RSO. Through discussions with cognizant licensee staff, the inspector should determine whether the RSO has sufficient access to licensee management. Through further discussions with cognizant licensee representatives, the inspector should determine if changes in ownership or staffing have occurred. If the owner or individuals named in the license have changed, the inspector should determine whether the licensee has submitted appropriate notification to NRC. This information must be provided whenever changes in ownership or personnel named in the license are made. Through discussions with cognizant licensee management the inspector should determine if changes have occurred, or are anticipated, and ask personnel to confirm (to the inspector's satisfaction) that no changes have taken place. If there

have been no changes in the organization since the previous inspection, there is no need to pursue this element in further detail. If there have been changes in ownership, the inspector should discuss this matter with appropriate licensee representatives and NRC regional staff (e.g., license reviewers) to ensure that proper actions will be taken in response to the changes in ownership.

Through discussions with cognizant licensee representatives, the inspector should review any organizational change in the RSO position, authorities, responsibilities, and reporting chains. The inspector should be sensitive to changes that reduce the ability of the RSO to resolve concerns or issues related to the safe conduct of the radiation protection program. The inspector should discuss with cognizant licensee management representatives and the RSO about the RSO's authority and about any changes that may impact upon the RSO's duties, responsibilities, or effectiveness.

b. Scope of Program. Through discussions with cognizant licensee staff and direct observations of licensed activities, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc. From those discussions and direct observations made during tours of the licensee's facilities, the inspector will be able to discern the actual size and scope of the licensee's program, and to determine if significant changes have occurred since the previous inspection. Through further discussions inspector should determine if multiple places of use are listed on the license. In cases where there are multiple sites/satellite facilities, the inspector should determine if inspections should be performed at all sites. This decision should be based on MC 2800, "Materials Inspection Program," and regional policy for performing inspections at satellite facilities. From those observations and discussions, the inspector should verify that the locations of use are as authorized in the license. If the inspector determines that there are locations of use not authorized under the license, the inspector should discuss this matter with appropriate licensee representatives to ensure that the license is amended to allow the unauthorized location of use in accordance with 10 CFR 35.13 and/or 35.14. Furthermore, the inspector should determine if licensed activities conducted at such locations were conducted in accordance with NRC regulatory requirements and the licensee's license.

In reviewing the scope of the licensee's program in this area, the inspector should discuss information that includes lab personnel, locations of use, human research and medical use activities, mobile nuclear medicine services, distribution of pharmaceuticals under 10 CFR Part 35 license, and principal types and quantities of licensed materials used.

c. Radiation Program Administration. In the course of interviewing cognizant licensee personnel, the inspector should determine if management oversight is sufficient to provide the licensee's staff with adequate resources and authority to administer the licensed program. In the review to verify implementation of the radiation safety program, the inspector should pay particular attention to the scope of the program, frequency of licensee audits, and the use of qualified auditors. If necessary, the inspector should review selected procedures for recording and reporting deficiencies to management; and methods and completion of follow-up actions by management.

1. RSO. The RSO is the individual, appointed by licensee management and identified on the license, who is responsible for implementing the radiation

safety program. The inspector should independently verify through discussion and direct observations of licensed activities that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. The inspector should verify authority, without prior approval of the that, when deficiencies are identified, the RSO has sufficient authority to implement corrective actions, including termination of operations that pose a threat to health and safety.

2. Audits. The frequency and scope of audits of the licensed program will vary. However, the inspector should note that at a minimum, medical licensees are required by 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. The results of audits should be documented. If time permits, the inspector should examine these records with particular attention to deficiencies identified by the auditors, and note any corrective actions taken as a result of deficiencies found. If no corrective actions were taken, the inspector through discussions with cognizant licensee representatives should determine why the licensee disregarded deficiencies identified during audits, and whether the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

d. Authorized Users. Authorized users (physicians, nuclear pharmacists, and medical physicists) are named on the license. The inspector should noted that the regulations in 10 CFR 35.11(b) allow an individual to receive, possess, use, or transfer byproduct material for medical use "under the supervision of" the authorized user, unless prohibited by license condition. Also, these regulations do not specifically require that the authorized user be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, pursuant to 10 CFR 35.27(a), and is responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent.

e. Authorized Uses. The inspector should determine from observing the use of licensed material, discussing the activities with cognizant licensee personnel, and if necessary, from a review of selected records, that the type, quantity, and use of licensed material at the licensee's facility are as authorized by the license. From those observations, discussions, and reviews, if necessary, the inspector should verify that the total activity of licensed material does not exceed the maximum activity authorized either in the license or in the design specifications of the device's sealed source device registration certificate.

f. Financial Assurance and Decommissioning. The decommissioning recordkeeping requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in 10 CFR 30.35(g). These records should contain, among other information: 1) records of unusual occurrences involving the spread of contamination in and around the facility, equipment, or site; 2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination; and 3) records of the cost estimate performed for a decommissioning funding plan or the amount certified for decommissioning. This list is not all-inclusive of the information and requirements given in 10 CFR

30.35(g). The inspector should ensure that the licensee has such decommissioning records, that the records are complete, that they are updated as required, and that the decommissioning records are assembled or referenced in an identified location.

Some licensees may release rooms within a building for unrestricted use, without a license amendment. The release of these areas may fall outside of the reporting requirements in the Decommissioning Timeliness Rule if the licensee continues to conduct other activities in the same building. During the onsite inspection, the inspector should identify the rooms that have been released since the last inspection and perform random confirmatory measurements for selected rooms (e.g., randomly sample selected areas, not survey 100%), to verify that radiation and contamination levels are below release limits. Licensee survey records and other documentation should be reviewed to verify that the basis for releasing each room is adequately documented in the licensee's decommissioning records. If during the confirmatory survey, the inspector identifies levels above release limits, the inspector should inform appropriate licensee representatives as soon as practicable to review the matter, determine what appropriate actions need to be taken to address the matter, determine if members of the public have been received radiation exposures that exceeded NRC regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded NRC regulatory limits, the inspector should immediately contact NRC regional management for further guidance.

Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions. Occasionally, those conditions may change over time and the licensee may not notify NRC. The inspector should be aware of changes, in radiological conditions, while inspecting a licensee's facility, that would necessitate a change in the financial assurance instrument and/or decommissioning plan, especially where the radiological conditions deteriorate and the financial assurance instrument or decommissioning plan may no longer be sufficient. In preparation for the inspection, the inspector should determine the dates that the financial assurance instrument and decommissioning plan (if applicable) were submitted to NRC. During the inspection, through observations made during tours of the facilities, discussions with cognizant licensee personnel, and a review of selected records, the inspector should determine whether the radiological conditions at the licensee's facility have changed since the documents were submitted to NRC. If conditions have changed and the adequacy of the financial assurance instrument and/or decommissioning plan is in doubt, the inspector should contact regional management as soon as practicable from the licensee's site to discuss the situation.

Additionally, some licensees are required to maintain decommissioning cost estimates and funding methods on file. If the licensee uses a parent company guarantee or a self-guarantee as a funding method, the inspector should verify that the licensee has a Certified Public Accountant certify each year that the licensee passes a financial test. The financial test ratios for parent company guarantees and self-guarantees are specified in Section II, Appendix A and Appendix C, respectively, to Part 30.

g. Decommissioning Timeliness. Through discussions with cognizant licensee representatives and direct observations, the inspector should determine whether

the license to conduct a principal activity has expired or been revoked. If the license remains in effect, the inspector should determine if the licensee has made a decision to cease principal activities at the site or in any separate building. Finally, the inspector should determine if there has been a 24-month duration in which no principal activities have been conducted in such areas. A principal activity is one which is essential to the purpose for which a license was issued or amended, and does not include storage incidental to decontamination or decommissioning. If the licensee meets any of the above conditions, the decommissioning timeliness requirements apply.

The inspector should note that the requirements of 10 CFR 30.36, 40.42 and 70.38 do not apply to released rooms within a building where principal activities are still on-going in other parts of the same building. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect.

The Decommissioning Timeliness Rule became effective on August 15, 1994. If the license has expired or been revoked, or if the licensee has made a decision to permanently cease principal activities, and the licensee provided NRC notification before August 15, 1994, then August 15, 1994, is considered to be the date for initiating the decommissioning calendar (i.e., date of notification). If there has been a 24-month duration in which no principal activities have been conducted at the location before the effective date of the rule, but the licensee did not notify NRC, then the 24-month time period of inactivity is considered to be initiated on August 15, 1994, and the licensee must provide notification to NRC within either 30 or 60 days of August 15, 1996 (depending on whether the licensee requests a delay).

The inspector should note that the NRC has a stringent enforcement policy with respect to violations of the decommissioning timeliness requirements. Failure to comply with the Decommissioning Timeliness Rule (failure to notify NRC, failure to meet decommissioning standards, failure to complete decommissioning activities in accordance with regulation or license condition, or failure to meet required decommissioning schedules without adequate justification) may be classified as a Severity Level III violation and may result in consideration of monetary civil penalties or other enforcement actions, as appropriate.

Decommissioning timeliness issues can be complex. For situations where an inspector has questions about the licensee's status and whether the decommissioning timeliness standards apply, he/she should contact NRC regional management as soon as practicable for further guidance.

For planning and conducting inspections of licensees undergoing decommissioning, the inspector should refer to MC 2602, "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees"; IP 87104, "Decommissioning Inspection Procedure for Materials Licensees"; and NUREG/BR-0241. “NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees.”

h. Generic Communications of Information. Through discussions with cognizant licensee management and the RSO as well as through direct observations made during tours of the licensee’s facility, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, NMSS Newsletter, etc.,

and that the information contained in these documents is disseminated to appropriate staff personnel. The inspector should also verify that the licensee has taken appropriate action in response to these NRC communications, when a response is required.

i. Notifications and Reports. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should determine the licensee's compliance for notifications and reports to the Commission. The licensee may be required to make notifications following loss or theft of material, overexposures, incidents, high radiation levels, safety-related equipment failure, medical events, dose to an embry/fetus or a nursing child, etc.

From those discussions and reviews, the inspector should verify that notifications and/or reports were appropriately submitted to NRC and individuals, if applicable. If the inspector determines that the licensee failed to submit such notifications and/or reports, the inspector should bring this matter to the attention of appropriate licensee representatives as soon as practicable for followup and compliance to the appropriate NRC regulatory requirements.

j. Special License Conditions. Some licenses will contain special license conditions that are unique to a particular practice or procedure, such as the use of equipment for non-medical purposes. In these instances, through discussions with cognizant licensee representatives, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license conditions. The inspector should also note that some special license conditions may state an exemption to a particular NRC requirement.

k. Research Involving Human Subjects. If applicable, the inspector must verify that this type of research satisfy the following conditions: 1) All research is conducted, supported, or regulated by another Federal Agency that has implemented “Federal Policy for Protection of Human Subjects” (10 CFR 35.6), or the licensee is authorized to conduct such research; 2) the licensee obtains informed consent from the subjects, as defined and described in the Federal Policy; and 3) the licensee obtains prior review and approval from an Institutional Review Board, as defined and described in the Federal Policy.

03.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, a variety of new medical uses of byproduct material or radiation from byproduct material are always on the forefront of providing optimal medical care to patients. Due to the increase in these various new medical uses of byproduct material or radiation from byproduct material, the regulations were revised to allow licensees the ability to use such uses in order to provide optimal patient care. In accordance with the regulations in 10 CFR 35.1000, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if the licensee has submitted the information required by 10 CFR 35.12(b) through (d); and the licensee has received written approval from the NRC in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NRC considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during inspections, the inspector may encounter various new medical uses of byproduct material or radiation from byproduct material being used that have not been specifically amended to a licensee’s license. If an inspector encounters such a use, the inspector should contact regional management as soon as practicable to independently

verify that such use is authorized under the regulations. If further verification of such use is needed, the region should contact NMSS for further guidance.

For further inspection guidance, refer to MC 2800.

END

ATTACHMENT 2

10 CFR 35.75 SEVERITY LEVEL IV VIOLATIONS FOR I-131 THERAPY

NRC FORM 591 PART 1
(8-1997)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY AND COMPLIANCE INSPECTION

1. LICENSEE	2. REGIONAL OFFICE
SOUTH JERSEY HOSPITAL MILLVILLE, BRIDGETON AND NEWCOMB 1200 NORTH HIGH STREET MILLVILLE, NJ 08332 REPORT NUMBER(S) 0001-001	REGION I US NUCLEAR REGULATORY COMMISSION 475 ALLENDALE ROAD KING OF PRUSSIA PA 19406-1415

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030 02578	29-18911-01	8-16+17-2001

LICENSEE:
The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☐ 1. Based on the inspection findings, no violations were identified.

☐ 2. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied. _____ non-cited violation(s) were discussed involving the following requirement(s): _____

☒ 3. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which is required to be posted in accordance with 10 CFR 19.11.

10 CFR 35.75 REQUIRES THAT THE LICENSEE SHALL MAINTAIN A RECORD FOR 3 YEARS THAT INSTRUCTIONS WERE REQUIRED AND THE BASIS FOR RELEASING THE INDIVIDUAL

CONTRARY TO THE ABOVE YOU DID NOT MAINTAIN A RECORD OF THE BASIS FOR RELEASE OF AN INDIVIDUAL

THE LICENSEE STATED THAT WILL REVIEW ALL ADMINISTRATIONS IN ACCORDANCE WITH THE INSTRUCTIONS IN REG GUIDE 8.39 AND WILL INSURE ALL INDIVIDUALS INVOLVED IN ADMINISTRATION

STATEMENT OF CORRECTIVE ACTIONS

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE	WAYNE SCHIFFNER		8.17.01
NRC INSPECTOR	DAVID S EUGENHAUT		8-17-01

APPENDIX A
NUCLEAR MEDICINE INSPECTION RECORD (IP 87115)

REGION I					
Report #	2001-001	License #	29-13911-01	Docket #	030-02578
Licensee Name	South Jersey Hospital System, Millville, Bridgeton and Newcomb				
Street Address	1200 North High Street				
City, State, Zip	Millville, New Jersey 08332				
Location (Authorized Site) Being Inspected	Bridgeton and Newcomb				
Licensee Contact Name	Paul Chase, DO, RSO.			Phone #	856 825-3500
Priority	3	Program Code	2120	Description	
Last Inspection:	Sept. 27 & 28. 2000	This Inspection	Aug. 16 & 17, 2001		
Type of Insp.	Announced		Unannounced	**XX**	
	Routine	**XX**	Special	Initial	
Next Insp. Date	8/2004	Normal	**X**	Reduced	Extended
Justification for change in normal inspection frequency:					

Summary of Findings and Actions

No violations, Clear 591 or letter issued		Non-cited violations	
Violation(s), 591 issued	**X**	Violation(s), letter issued	
Follow up on previous violations:	**None**		

Inspector -Signature	***/RA/***	10/13/01
- Printed Name	**David B. Everhart**	Date
Approved - Signature	***/RA/***	10/10/01
- Printed Name	**William H. Ruland**	Date

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES

License amendments issued since last inspection, or program changes noted in the license.

AMENDMENT #	DATE	SUBJECT
46	4/30/01	Relocate Nuclear Medicine
45	1/17/01	Add use and storage of Brachytherapy sources at Newcomb
44	10/4/2000	Add the use of Xenon133 at Bridgeton facility

2. INSPECTION AND ENFORCEMENT HISTORY

Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders.

None

3. INCIDENT/EVENT HISTORY

List any incidents or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.

None

PART II (NUCLEAR MEDICINE- 87115) - INSPECTION DOCUMENTATION

NOTE: References that correspond to each inspection documentation topic are in Inspection Procedure 87115, Appendix B, "Nuclear Medicine Inspection References."

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in this part are required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section, where applicable. All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

1. ORGANIZATION AND SCOPE OF PROGRAM

Management organization; authorities and responsibilities; authorized locations of use; type, quantity, and frequency of byproduct material use; staff size; mobile nuclear medicine service; limited distribution of pharmaceuticals; and research involving human subjects.

This inspection was conducted to review the effect of the addition of Newcomb Hospital as a place of use on their license and to make all the facilities inspection dates current. The license currently has a total of three locations of use, an increase from two locations of use since the last inspection . The last inspection of the Newcomb license was in 1998. The last inspection of the rest of the facilities on the license was in September, 2000. The inspection also evaluated any change in oversight due to the additional facility and a review of the move of the brachytherapy program to the Newcomb facility. The inspection included a limited review of the Nuclear Medicine program at the Bridgeton location of use.

The RSO reports directly to management for al radiation safety needs. Management is very responsive to the RSO for radiation safety needs. The RSO has appropriate authority and responsibility to fulfill the required responsibilities. The license lists three locations of use and these were noted during the inspection. The licensee performs routine nuclear medicine procedures including bone and cardiac studies and lung scans using Xenon and thyroid uptakes and scans and therapy for hyperthyroidism. The Newcomb facility has three full-time technologists with three cameras. The licensee does not provide mobile nuclear medicine services, limited distribution of radiopharmaceuticals nor do they perform research involving human subjects.

2. MANAGEMENT OVERSIGHT

Management support to radiation safety; Radiation Safety Committee; Radiation Safety Officer; and program audits, including as low as is reasonably achievable (ALARA) reviews.

Management is supportive of radiation safety. The RSO has good support from medical physics and administrative technologists in nuclear medicine. The inspector reviewed the RSC meetings since the last inspection and found proper representation

and good discussions of pertinent issues. The RSC also reviewed the ALARA review of the monthly dosimetry reports. Program audits were performed by a consultant health physicist and reviewed by the RSC.

3. FACILITIES

Facilities as described; uses; control of access; and engineering controls.

The facilities and uses were as described. Control of access to the hot lab at both the Bridgeton facility is accomplished by direct supervision and keypad locked doors. Control of access at the Newcomb facility is accomplished through keyed locks and direct oversight. Management discussed the feasibility of adding keypad locks to the Newcomb facility. Surveys of xenon trap effluent and room negative pressure tests were performed monthly.

4. EQUIPMENT AND INSTRUMENTATION

Dose calibrator; instrumentation for assaying alpha- emitting and beta-emitting radionuclides; generators; syringes and vials; survey instruments; 10 CFR Part 21 procedures; and special equipment and instrumentation.

The licensee possesses and uses an Capintec CRC-7 which has had linearity and accuracy performed as required from 1998 to the present. The licensee has not moved the dose calibrator an has not performed a geometry evaluation since the last inspection. The licensee does not use a generator but syringe and vial shields were noted and observed in use during the inspection. The inspector noted one operable and properly calibrated survey instrument. Records indicate the licensee obtains a replacement survey meter from the radiopharmacy when they send their survey instrument in for calibration. No Part 21 procedures implemented or required.

5. MATERIAL USE, CONTROL, AND TRANSFER

Materials and uses authorized; use of radiopharmaceuticals; security and control of licensed materials; and procedures for receipt and transfer of licensed material.

Materials noted in use through direct observation and records reviews were authorized. Control over licensed material was noted to be adequate throughout the inspection at all facilities. Interviews with individuals revealed an adequate understanding of requirements and good radiation safety practices, commensurate with their level of use.

6. RADIOPHARMACEUTICAL THERAPY

Safety precautions; surveys; and release criteria of patients and rooms.

No patients were hospitalized in compliance with 10 CFR 35.75. Three patients were given doses greater than 33 mCi of I^{131} and released with instructions in July of 2001. Patients were counseled and this was well documented. The authorized user was not aware of the need for performing a calculation to assure compliance with 35.75. Subsequent calculations revealed that the release of these patients met the release criteria in Regulatory Guide 8.39 which is used to show compliance with 10 CFR 35.75.

These administration had not been reviewed with the consultant physicist. The authorized user is now fully aware of the requirement and will train all other individuals of this requirement. All technologists involved in thyroid treatments will also be in-serviced in the requirement. This was an isolated incident and was not indicative of a breakdown in the overall radiation safety program. The corrective actions proposed were acceptable and the inspector cited the violation on the NRC Form 591.

7. QUALITY MANAGEMENT PROGRAM (QMP) AND MISADMINISTRATIONS

QMP - written directives, implementation, reviews, and records; misadministrations - identification, notifications, reports, and records.

The licensee performed a QMP audit in January of 2001. Individuals interviewed exhibited an adequate understanding of procedures, requirements and good safety practices. A review of 48 (100% of the administrations in 98 to 01) I^{131} therapy administrations in the Newcomb facility revealed no misadministrations and no recordable or reportable events. A review of 12 of the 29 administrations at the Bridgeton facility revealed no misadministrations and no recordable or reportable events.

8. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; records; and public doses.

Surveys were reviewed for both the Newcomb and the Bridgeton facilities. Surveys were performed as required and the results were documented, including minor spills with appropriate follow-up. Leak tests and inventories were performed and recorded as required. Observations and interviews with individuals revealed an adequate understanding and implementation of radiation safety requirements when handling radioactive materials. Public dose was not inspected.

9. TRAINING AND INSTRUCTIONS TO WORKERS

Interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Part 20 requirements; therapy training and postulated emergency situations; supervision by authorized users.

Interviews and observations revealed an adequate understanding of requirements and good safety practices commensurate with their level of use. Individuals revealed an adequate understanding of Part 20 requirements and normal and postulated emergency situations. Supervision of individuals by authorized users was adequate.

10. RADIATION PROTECTION

Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose records; and patient release.

The licensee supplies monthly dosimetry. The RSO performs an ALARA review at each RSC meeting . A review of the dosimetry records from 1/98 to 6/01 revealed a maximum reading of:1680 mRem per year, extremity dose; and 280 mRem whole body TEDE dose per year. See Item 6 regarding patient release.

11. RADIOACTIVE WASTE MANAGEMENT

Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment incinerators, hoods, vents and compactors; and records.

The licensee disposes of radioactive materials using decay-in-storage and disposal as hazardous waste.

12. DECOMMISSIONING

Records of radiological conditions; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements.

Not inspected.

13. TRANSPORTATION

Quantities and types of licensed material shipped; packaging design requirements; hazardous materials (HAZMAT) communication procedures; unit dose return; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports.

The licensee receives unit doses and returns used and unused doses to the radiopharmacy. Interviewed individuals exhibited an adequate understanding of proper receipt requirements and procedures as well as proper transfer procedures including limited quantity limits. HAZMAT training not inspected.

14. NOTIFICATIONS AND REPORTS

Theft; loss; incidents; overexposures; change in Radiation Safety Officer (RSO), authorized user, or nuclear pharmacist; and radiation exposure reports to individuals.

No theft, loss, incidents, overexposures or changes in RSO or authorized user.

15. POSTING AND LABELING

Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material.

Posting of radiation areas and labeling of containers was noted as required. Notices bulletins and generic information was received, reviewed and filed appropriately. Licensee documents were available as required.

16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date.

Surveys were performed with a Ludlum 14C with an end window probe. NRC number 033504, last calibrated January, 2001. Surveys of the brachytherapy patient room revealed 0.2 mR/hr at the door, 0.7 mR/Hr in the adjacent room and 0.4 mR/hr in the stairway. Background was measured at 0.04 mR/hr. Surveys of the outside adjacent areas of the brachytherapy room were equal to background. Surveys were also performed at Newcomb facility. Background was noted at 0.03 mR/hr. Readings of the hot lab, camera rooms stress rooms and adjacent areas revealed reading equal to background. Readings were compatible with readings noted on area surveys.

17. VIOLATIONS, NON-CITED VIOLATIONS (NCVs) AND OTHER SAFETY ISSUES

State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.

The licensee performed three I^{131} thyroid therapy administrations in July of 2001, with greater than 33 mCi, the limit in Reg Guide 8.39, and failed to perform calculations to ensure that the dose to the individual likely to receive the highest dose was less than 500 mRem in accordance with 10 CFR 35.75. The licensee initially was not aware of the requirement to perform the calculation and the consultant physicist had not visited the site since the therapies and when the inspection occurred. The consultant physicist was aware of the requirement and subsequently performed the calculation which showed that the dose to the individual would be less than 500 mRem. The RSO is now aware of the requirement and will train all authorized users who might perform therapies and also train the technologists who might participate in the therapy to ensure this does not occur in the future. The inspector cited the violation on Form 591 since this was not a programmatic breakdown and corrective action proposed was adequate to resolve the violation and prevent recurrence. 10 CFR 35.75 requires that the licensee shall maintain a record for three years that instructions were provided and the basis for releasing the individuals. Contrary to the above the licensee did not maintain a record of the basis of the release of the individual.

18. PERSONNEL CONTACTED

Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).
Use **#** to indicate individual present at entrance meeting.
Use ***** to indicate individual present at exit meeting.

	Name	Title	Phone No.	In Person or By phone
*	**Wayne Schiffner**	**Chief Operating Officer**		**Person**
*	**Paul V. Chase, DO**	**Radiation Safety Officer**		**Person**

*	Maria Phillips	Admin Dir Radiology		Person
*	Mario Sergi	Dir, Rad Oncology		Person
*	Marcia Ostroff	Lead Nuc Med Tech		Person
	Sandy Gabriel	Physicist		Person
	Lester	Physicist		Person
	Chris Redington	Nuc Med Tech N		Person
	Teresa Pimpinella	Nuc Med Tech N		Person
	Luz Melendez	Nuc Med Tech N		Person
	Kathy Sinisacki	Contractor Tech N		Person
	Suzanne Ramsey	Contractor Tech B		Person
	Deepak Parikh	Nuc Med Tech B		Person

19. PERFORMANCE EVALUATION FACTORS

A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight.			Y		N	X
B.	RSO too busy with other assignments.			Y		N	X
C.	Insufficient staffing.			Y		N	X
D.	RSC fails to meet or functions inadequately.	N/A		Y		N	X
E.	Inadequate consulting services or inadequate audits conducted.	N/A		Y		N	X

REMARKS: (Consider the above assessment and/or other pertinent Performance Evaluation Factors (PEFs) with regard to the licensee's oversight of the radiation safety program.)

PART III - POST- INSPECTION ACTIVITIES

1. REGIONAL FOLLOWUP ON PEFs

None

2. DEBRIEF WITH REGIONAL STAFF

Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer.

Reviewed with Branch Chief

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES

License amendments issued since last inspection, or program changes noted in the license.

AMENDMENT # DATE SUBJECT

See Nuc Med Inspection Record

2. INSPECTION AND ENFORCEMENT HISTORY

Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders.

See Nuc Med Inspection Record

3. INCIDENT/EVENT HISTORY

List any incidents or events reported to NRC since the last inspection. Citing “None” indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.

See Nuc Med Inspection Record

PART II (BRACHYTHERAPY - 87118) - INSPECTION DOCUMENTATION

NOTE: References that correspond to each inspection documentation topic are in Inspection Procedure (IP) 87118, Appendix B, “Brachytherapy Inspection References.”

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in this part are required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or “Not Applicable”) should be made in each section, where applicable.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

1. ORGANIZATION AND SCOPE OF PROGRAM

Management organizational structure; Radiation Safety Officer (RSO) and chairman of Radiation Safety Committee (RSC); authorized locations of use; type, quantity, and frequency of byproduct material use.

The main purpose of this inspection was to review the administrative oversight changes since the actual change of control occurred which included the Newcomb facility on the license and including the move of the brachytherapy program to the Newcomb facility. See the Nuclear Medicine Inspection Record for more information.

2. MANAGEMENT OVERSIGHT

Management support to radiation safety; RSC; RSO; program audits or inspections; as low as reasonably achievable (ALARA) reviews; control and supervision by authorized users.

See Nuclear Medicine Inspection Record

3. FACILITIES

Facilities as described; uses; control of access; engineering controls; shielding; maintenance by authorized persons; remote afterloader facilities; pulsed-dose-rate afterloader facilities; low-dose-rate afterloader facilities; interlocks; patient monitoring; approved locations of use.

The inspector reviewed the new storage location for brachytherapy sources including surveys performed in the storage room and surrounding locations. The licensee was also performing a brachytherapy procedure the inspection an d the inspector performed surveys and compared the results with the surveys performed by the licensee.

4. EQUIPMENT AND INSTRUMENTATION

Operable and calibrated survey instruments and dosimetry; procedures; 10 CFR Part 21 procedures; calibration records; fixed radiation monitors; backup power supplies for monitors and afterloaders; equipment inspected as scheduled; emergency equipment; calibration and maintenance by authorized persons.

See Nuclear Medicine Inspection Record

5. MATERIAL USE, CONTROL, AND TRANSFER

Materials and uses authorized; afterloader sources approved; security and control of licensed materials; procedures for receipt and transfer of licensed material; source installation and replacement by authorized persons; patient surveys and release.

See Nuclear Medicine Inspection Record

6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

Radiological survey locations and frequencies; leak tests; inventories; handling of radioactive materials; records and reports; public doses; unrestricted area surveys; use of protective clothing; proper waste disposal; shielding.

See Nuclear Medicine Inspection Record

7. TRAINING AND INSTRUCTIONS TO WORKERS

Training and retraining requirements for authorized users and operators; documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency response and training for operators, physicians, nurses, and medical physicists; use and supervision by authorized users.

See Nuclear Medicine Inspection Record

8. OPERATING AND EMERGENCY PROCEDURES FOR REMOTE AFTERLOADERS

Operating and emergency procedures posted; procedures approved; required persons present during afterloader use; surveys in unrestricted areas; leak testing; inventories.

Not applicable

9. RADIATION PROTECTION

Radiation protection program with ALARA provisions; access control; dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications.

See Nuclear Medicine Inspection Record

10. QUALITY MANAGEMENT (QM) PROGRAM, MISADMINISTRATIONS, AND REPORTABLE EVENTS

Verify QM program administration and records and reports of misadministrations and events.

See Nuclear Medicine Inspection Record

11. RADIOACTIVE WASTE MANAGEMENT

Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents and compactors; license conditions for special disposal methods.

See Nuclear Medicine Inspection Record

12. DECOMMISSIONING

Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted.

See Nuclear Medicine Inspection Record

13. TRANSPORTATION

Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials HAZMAT communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports.

See Nuclear Medicine Inspection Record

14. NOTIFICATIONS AND REPORTS

Overexposure and misadministration reports; administrative changes in RSO, authorized users, and physicist; reports to individuals.

See Nuclear Medicine Inspection Record

15. POSTING AND LABELING

Notices; license documents; regulations; bulletins and generic information; area postings; and labeling of containers of licensed material.

See Nuclear Medicine Inspection Record

16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

Areas, both restricted and unrestricted, surveyed, and comparison of data with licensee's results and regulations; and instrument type and calibration date.

See Nuclear Medicine Inspection Record

17. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES

State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.

See Nuclear Medicine Inspection Record

18. PERSONNEL CONTACTED

Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).
Use # to indicate individual present at entrance meeting.
Use * to indicate individual present at exit meeting.

Name	Title	Phone No.	In Person or By phone

See Nuclear Medicine Inspection Record

18. PERFORMANCE EVALUATION FACTORS (PEFs)

A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight			Y		N
B.	RSO too busy with other assignments			Y		N
C.	Insufficient staffing			Y		N
D.	Radiation Safety Committee fails to meet or functions inadequately	N/A		Y		N
E.	Inadequate consulting services or inadequate audits conducted	N/A		Y		N

REMARKS: (Consider the above assessment and/or other pertinent PEFs with regard to the licensee's oversight of the radiation safety program.)

PART III - POST- INSPECTION ACTIVITIES

1. REGIONAL FOLLOWUP ON PEFs

None

2. DEBRIEF WITH REGIONAL STAFF

Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer.

See Nuclear Medicine Inspection Record

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

February 2, 2005

Docket No. 03014474 License No. 37-18104-01

Darlette Tice
Vice President of Operations & Chief Nursing Officer
Forbes Regional Hospital
2570 Haymaker Road
Monroeville, PA 15146-3592

SUBJECT: INSPECTION 03014474/2005001, FORBES REGIONAL HOSPITAL, MONROEVILLE, PENNSYLVANIA SITE AND NOTICE OF VIOLATION

Dear Ms. Tice:

On January 24 and 25, 2005, Richard McKinley of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with you and others of your staff at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Your cooperation with us is appreciated.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Stephen R. DeLong, M.D., Radiation Safety Officer
Commonwealth of Pennsylvania

Distribution:
D. J. Holody, RI

DOCUMENT NAME: E:\Filenet\ML050340142.wpd
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	RmcKinley RWM1		Phenderson PJH1					
DATE	2/2/05		2/2/05					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Forbes Regional Hospital
Monroeville, PA

Docket No. 03014474
License No. 37-18104-01

During an NRC inspection conducted on January 24 and 25, 2005, one violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violation is listed below:

A. 10 CFR 35.75(a) states that a licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

Contrary to the above, the licensee failed to ensure that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). Specifically, on July 23, 2004, and September 3, 2004, the licensee administered 149.5 mCi and 159.4 mCi, respectively, of iodine-131 to patients and released them from its control without doing the calculations necessary to ensure that the total effective dose equivalent to any other individual from exposure to the released individual was not likely to exceed 5 mSv (0.5 rem).

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Forbes Regional Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the 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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site at http://www.nrc.gov/reading-rm.html. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made

publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This _2_ day of _February_ 2005

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

October 14, 2008

Docket No. 03035600 License No. 29-30606-01

Jill Baer
Administrator
Central Jersey Radiologist
2128 Kings Hwy. & Route 35
Oakhurst, NJ 07755

SUBJECT: INSPECTION 03035600/2008001, CENTRAL JERSEY RADIOLOGIST, OAKHURST, NEW JERSEY SITE AND NOTICE OF VIOLATION

Dear Ms. Baer:

On September 16, 2008, Michelle Simmons of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with Jill Baer, John Phander of your organization at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications Page.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC; How We Regulate; Enforcement;** then **Enforcement Policy.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Michelle Simmons at 610-337-6921 if you have any questions regarding this matter.

Sincerely,

Original signed by Sandra Gabriel for

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure
Notice of Violation

cc:
Irving Stein, D.O., Radiation Safety Officer
State of New Jersey

Please contact Michelle Simmons at 610-337-6921 if you have any questions regarding this matter.

Sincerely,

Original signed by Sandra Gabriel for

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure
Notice of Violation

cc:
Irving Stein, D.O., Radiation Safety Officer
State of New Jersey

Distribution:
D. J. Holody, RI

DOCUMENT NAME: G:\WordDocs\Current\Insp Letter\L29-30606-01.2008001.doc

ML082940298
SUNSI Review Complete: MSimmons
After declaring this document "An Official Agency Record" it **will** be released to the Public.

To receive a copy of this document, indicate in the box: "**C**" = Copy w/o attach/encl "**E**" = Copy w/ attach/encl "**N**" = No copy

OFFICE	DNMS/RI	N	DNMS/RI					
NAME	MSimmons/MS		PHenderson/SG f/					
DATE	10/16/08		10/20/08					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Central Jersey Radiologist
Oakhurst, NJ

Docket No. 03035600
License No. 29-30606-01

During an NRC inspection conducted on September 16, 2008, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 20.1501(a)(2) states in part, that each licensee shall make or cause to be made, surveys that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels and the potential radiological hazards.

10 CFR 35.75(a) states that a licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

Contrary to the above, the licensee did not make or cause to be made, surveys that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels. Specifically, on November 28, 2007, June 12, 2008, and July 1, 2008, the licensee did not perform surveys in accordance with 10 CFR 35.75(a), on a patient after being administered sodium iodide iodine -131 in quantities exceeding 33 millicuries to determine if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

This is a Severity Level IV violation (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, Central Jersey Radiologist is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the 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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This _14_ day of _October_ 2008

ATTACHMENT 3
CASE 1
PATIENT RELEASE TO HOTEL

	Initial		Announced	x	Unannounced	x	Routine		Special

NRC FORM 591M PART 3
(10-2003) 10 CFR 2 201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
MedStar Georgetown Medical Center, Inc. **3800 Reservoir Road, N.W.** **Washington, D.C. 20007** REPORT NOS 2007-001	**U.S. Nuclear Regulatory Commission** **Region I, 475 Allendale Road** **King of Prussia, Pennsylvania 19406-1415**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-35409	08-30577-01	August 9-10, 2007, 9-4-2008

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS	8. INSPECTOR
87134; 87122	03.01-03.07	P. Lanzisera

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2110, 3510, etc.	2	Jason Dunavant, RSO	202-444-4534

[x] Main Office Inspection — Next Inspection Date: 8/2009

[ ] Field Office _____

[ ] Temporary Job Site _____

PROGRAM SCOPE

Broad Scope medical facility performing primarily clinical activities in nuclear medicine, radiation oncology, and cardiology. 5-6 authorized users in the nuclear medicine department use unit and bulk dosages of primarily Tc-99m. Radiopharmaceutical therapy includes: 1-2 Zevalin treatments/year, a research protocol for Bexxar, and 30 I-131 carcinoma treatments/year. Holmium 166 is on the license for an IND, that has not been used yet. No IND or IDE use currently. 7 authorized users and 3 medical physicists are involved in the radiation oncology program. The licensee also has a Radiation Oncology residency and medical physics training program. Manual brachytherapy includes sirspheres (by a Radiation Oncology Physician), Ir-192 in neck cancers and 10 gynecological treatments/year using Cs-137/Ir-192 combo tandems. The strontium-90 eye applicator is still not used. [redacted]

[redacted]

The Radiation Safety Officer (RSO) is new since the last inspection and is assisted by 2 staff for training, audits, etc. Survey meters are sent out for calibrations. Since the last inspection, several new nuclear medicine physicians, 1 radiation oncology physician, and 1 medical physicist were approved by the RSC. The permits issued for the nuclear medicine physicians and the radiation oncologist contained mistakes and authorized the users for more uses than their training supported (e.g., oncologist approved for 35.600, even though training only supported 35.300 and 35.400). During the inspection, the licensee confirmed that the physicians only used licensed material for which they had training and revised the permits to more accurately reflect the users training. The licensee also removed "Teletherapy" from all radiation oncologists' authorizations. The documentation reviewed by the RSC for the new medical physicist included the physicist's statement that he had a M.S. in Physics, 1 year of medical physics training at Georgetown, and 1 year of experience at Georgetown. The topics of the medical physics training were not specifically described. In a letter dated August 29, 2007, the licensee provided a copy of his Physics diploma, vendor training certificates while in Ecuador, and generically described his medical physics training under the previous chief clinical physicist. A review of the additional information supported the licensees's approval of the physicist, however, during the exit, the licensee was reminded to clearly document all medical physics training prior to approval of an individual as an AMP.

The license includes a license condition for use of the Webster formula when calculating personnel exposures. The Interventional Radiologist involved with sirsphere treatments is the only physician necessitating this calculation to remain below the occupational dose limits.

During the exit, the licensee was reminded to update their financial assurance to address changes to the trustee. In addition, for concerns identified during the inspection, the licensee: (1) revised their return shipment policy for Tc-99m to list the current limited quantity allowance; (2) re-trained nuclear medicine staff on appropriate meter settings for survey instruments; and (3) labeled all radioactive waste and storage containers in nuclear medicine.

The inspector determined that the licensee had released 2 patients to area hotels. In a letter dated August 29, 2007, the licensee provided additional information to support the release. In response to a TAR issued on June 12, 2008, OGC indicated that release to a hotel was not prohibited by the regulations.

2 SLIV violations were identified: 49CFR173.421 - Failure to ensure that excepted packages offered for shipment contained less than the limited quantity amounts (e.g., shipping back 75 mCi of Tc-99m when the LQ was 11 mCi); 20.1904 - Failure to label radioactive waste containers with an estimate of the quantity of radioactivity. The licensee provided their corrective actions in a letter dated August 29, 2007, which included retraining of staff of the amount of licensed material that constitutes limited quantity and properly labeling all waste containers to include the quantity of radioactivity.

[redacted]

Jason D. Dunavant, CHP
Radiation Safety Officer

Georgetown University Hospital

MedStar Health

Department of Radiation Safety

August 29, 2007

08-30577-01
03035409/2007001

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

RECEIVED
REGION 1
2007 AUG 31 PM 12:46

Dear Ms. Lanzisera

Enclosed is the response to questions that were raised during the inspection on August 9-10, 2007of Georgetown University Hospital (GUH). You requested this information in the exit interview on August 10, 2007 for Nuclear Regulatory Commision (NRC) License Number 08-~~577~~-01. 30577 nmp

Additional information on the qualifications for authorized medical physicist Nicolas Recalde is included in Appendix 1. Mr. Recalde has two masters' degrees, a masters of science in physics from the University of South Carolina that was documented on the NRC Form 313A and a masters of science degree in medical physics from Paul Sabatier University in Toulose, France award in 1998. He also had medical physicst experience in Ecuador starting in 1995. Mr. Recalde has worked as a junior physicist since 1995 except for the four years he was a graduate student at the University of South Carolina (1999 to 2003). Mr Recalde's experience and training includes four years at Georgetown University Hospital 2004-2007, most of which was supervised by the previous chief clinical physicist, Azam Niroomand-Rad, PhD, DABR. In addition, Mr. Recalde has documented at least 22 days of short courses in medical physics in 1998 and 1999. While at GUH, Mr. Recalde participated in at least 100 hours of medical physics lectures that reviewed the Physics of Radiotherapy by Khan. These lectures include reviews of brachytherapy, high dose rate after-loaders, prostate implant and intravascular brachytherapy. Mr. Recalde's qualifications have been reviewed by the American Board of Radiology and he has taken Parts I and II of the Therapy Physics board exams.

Because of concerns raised during the NRC inspection that Mr. Recalde did not meet the qualifications, the Radiation Safety Committee rescinded his approval as an authorized medical physicist for NRC regulated activities. Mr. Recalde and his current employer were notified of this action. This action was taken because Mr. Recalde had

NMSS/RGNI MATERIALS-004

3800 Reservoir Road, NW, Gorman Building - Suite 2040, Room 2047, Washington, DC 20007-2113
phone: 202 444 4049 • *fax:* 202 444 0069

never acted independently as an authorized medical physicist at GUH and thus will limit any impact should the NRC determine that Mr. Recalde is not fully qualified.

In the future, GUH will use the NRC's Licensing Guidance for Using NRC Form 313A Series of Forms. Specifically, documentation will be generated to details for the year of full time training and the year of full time experience.

A review of all inpatient iodine ablation patients in the last two years was made and two patients were identified who were released to hotels after receiving iodine-131 ablation therapy. The documentation for both patients in included in Appendix 2.

One patient completed the GUH iodine ablation questionnaire and indicated that she would be sharing a bathroom at a residential hotel. The decision was made to release this patient when her exposure rate at one meter of not more than 7 mR/h. This patient's exposure rate at discharge was less than 4.9 mR/h. (See Appendix 2, Annex A)

The second patient completed the questionnaire stating that he could comply with all of the guidance for early release at 14.3 mR/h. Additional instruction was provided to him due to his going to a hotel and his having a small child at home. The RSO at the time performed a dose calculation based upon his being below12 mR/h at one meter at the time of release. (See Appendix 2, Annex B). The dose assessment determined that the maximum dose to any member of the public would be 91 mrem.

An additional dose assessment was made right after the NRC Inspection in August 2007. Using equations B-3, B-4, and B-5 from NUREG 1556, volume 9, a curve fit was made using the initial dose rate and the release dose rate. Using a fast half life of 0.58 days with a fast fraction of 0.95, a slow half life of 7.3 days with a slow fraction of 0.05, an initial reading of 27 mR/h at 15:30 and a release reading of 11.7 mR/h at 09:30 the next day, it was determined that the patient would have checked into the hotel at 15:00 with an exposure rate of approximately 9 mR/h at one meter and with approximately 53 milliCuries of Iodine-131 in his body. It was determined using the model that if the patient checked out of the hotel 45 hours later (the maximum two day stay), his exposure rate would have been approximately 2 mR/h at one meter and would have had approximately 10 milliCuires still in his body.

In a worst case scenario, where the patient laid on his bed for the entire 45 hours of his hotel stay, and an individual in the next room laid on a bed within six feet, the maximum dose to the individual in the next room would have been approximately 52 mrem. Assuming one hour of maid service each day and using equation B-6 from NUREG 1556, volume 9, the worst case scenario for housekeeping would be an external dose of approximately 6 mrem and an internal dose of approximately 23 mrem.

GUH has started screening all ablation patients to ensure that if the patient indicates that they are going to a hotel that they will be held no more than 7 mR/h at one meter until clarification is received from the NRC.

Ms. Nancy Harrison at US Bank Corporate Trust Services was contacted on August 13, 2007. Ms. Harrison stated that she had the originals of the Standby Trust Agreement for GUH and that she would send one of the originals to the NRC. GUH received a copy of a memorandum from US Bank to the NRC Region I indicating that the original had been forwarded to the NRC on August 17, 2007.

A training session was held on August 13, 2007 with the Nuclear Medicine staff to review the proper operation of the Victoreen Ionization Chamber. The training included a review of the different modes of operation and how to recognize the different modes. A practical exercise using a Cs-137 check source was performed to ensure that the Nuclear Medicine staff could properly operate the survey meter.

The training also covered the procedures for properly returning unused radiopharmaceuticals to Cardinal Health's nuclear pharmacy. The training covered the use of the return form and the need to wait two days before returning any unused radioactive material. A review of the radiopharmaceutical return forms has been added to the monthly Nuclear Medicine Audit checklist.

In the Nuclear Medicine Hot Lab, all drawers containing radioactive material were marked as containing radioactive material during the inspection. The radioactive sharps containers were resituated so that they are farther away from Nuclear Medicine Staff working in the hot lab and an additional layer of lead bricks was added to the top of the sharps container shielding. A sign was posted instructing the Nuclear Medicine Staff on proper placement of the radioactive sharps containers. A lead lined container was placed under the sink for disposal of the ventilation atomizers. In addition, lead vinyl shielding was added to the existing steel wall between the waste container and the hot lab sink.

All containers of radioactive waste for decay-in-storage were labeled with an estimate of the activity of the radioactive material in addition to the isotope. In the future, all decay-in-storage containers of radioactive waste will be labeled with an estimated activity.

The Radiation Safety Committee permits were change to reflect that teletherapy is only performed using linear accelerators, and stereotactic radiosurgery is performed using a Cyberknife, and that the uses of radioactive material in nuclear medicine are qualified IAW 35.392, 35.394, and 35.396.

If you have any additional question, please contact me at 202-444-4534, facsimile at 202-444-0069, or e-mail at jdd2@gunet.georgetown.edu.

JASON D. DUNAVANT, CHP
Director, Radiation Safety

PATIENT RADIATION SURVEYS

Patient Name: [redacted] Room No: B3017

CJA Nuclide: I 131 Activity: ~~180~~ 182.32 mCi. Date/Time of Dosing: 01/24/06 @ ~~1550~~ 1450 h CJA

Dosing Personnel	Bioassay Dates / (Ok?: Y/N)
[redacted]	01/26 / Y
	01/26 / Y
	01/30 / Y
	01/26 / Y
	01/27 / Y

Dose Rate Readings in mrem/h:

A – One meter from stomach, pt standing erect
B – Maximum at 30 cm, head to waist*
C – Doorway at waist level
D – Adjacent Room No. 16
E – Adjacent Room No. 18
F – Hallway (highest value)

* If readings indicate an abnormal localization in the esophagus, throat or mouth, notify the Nuclear Medicine physician. Make survey at the time of dosing.

Date	01/24/06	01/25/06		
CJA **Time** 1450 ~~1550~~ h		0925 h		
A mR/h	20 mR	4.9		
B (initial)	250 mR			
C (initial)	10 MR			
D (initial)	I131 Tx			
E (initial)	0.47			
F	220 MR			
Surveyor	Alston, C.	Alston, C.		
Instrument	451P ET 6308	451B #6155		

Do not release the patient until the radiation level measured at one meter is not more than **7 millirem/hour or the value indicated on the attached worksheet** (cf.: Regulatory Guide 8.39).

Patient was provided written instructions for limiting doses to others by: C.J. Alston JAS
Final radiation level at one meter from the patient was 4.9 mrem/h.
Survey Meter: 451B S/N: 6155. Calibration Date: 02/23/05
Patient Released by C.J. Alston. Date: 01/25/06

PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

Appendix B Annexa

EXHIBIT 1
NUCLEAR MEDICINE DEPARTMENT
INFORMATION CONCERNING HOSPITALIZATION FOR PATIENTS ADMINISTERED RADIOACTIVE IODINE

The Nuclear Regulatory Commission has concluded that the radioactive iodine that you receive for therapeutic purposes will cause only small radiation exposures to others if you are released from the hospital in accordance with Nuclear Regulatory Commission guidelines. Special precautions are required for women patients nursing infants or small children. Exposures occur mainly if other people remain close to you (less than 3 feet) for long periods of time (at least one hour) during the first few days after you leave the hospital. The Nuclear Medicine Department will make measurements with a radiation detector to determine that you meet Nuclear Regulatory Commission guidelines prior to leaving the hospital.

Normally, these measurements indicate that a patient may be released less than 24 hours after receiving the dose of radioactive iodine. Thus you may only need to be in the hospital for one night. Sometimes, the measurements indicate that a patient does not meet the Nuclear Regulatory Commission's guidelines assuming normal contact and activities with other people. In those circumstances, you may need to remain for a second night. By answering the following questions and agreeing to follow the guidelines, you may be able to be released earlier because of your limited contact with other people.

1. Are you a woman nursing a small child or infant?

   Yes ____ No X

   NOTE: Nursing an infant or small child after receiving radioactive iodine will transfer the radioactive iodine from the mother to the child through the milk. Radioactive iodine ingested by the child will expose the thyroid of the child to potentially harmful levels of radiation. Lifelong medication may be required to prevent serious effects both mentally and physically if the child's thyroid receives a high dose of radiation. **If you are nursing a child, inform Nuclear Medicine personnel and we must reschedule your administration at a later date after you have permanently ceased nursing this child.**

2. Can you take care of yourself except for brief visits and not be in the same room with another person for more than three hours total during each of the first two days?

   Yes X No ____

   If no, briefly explain circumstances: _____

   _____

   _____

3. Will you be able to maintain distance from other people, including:
   - Sleeping alone for at least one night (recommend 3 nights)?
   - Avoiding kissing and sexual intercourse for at least 3 days?
   - Staying at least 3 feet away from people if you will be involved with them for more than an hour a day in the first 3 days?

   Yes X No ____

   If no, briefly explain circumstances: _____

4. Will you avoid travel by airplane or mass transit for the first day?

   Yes X No ____

   If no, briefly explain circumstances: _____

5. Will you avoid prolonged travel in an automobile with others for the at least first two days?

   Yes X No ____

   If no, briefly explain circumstances: _____

6. Will you have sole use of a bathroom for at least two days?

   Yes ____ No X

   If no, briefly explain circumstances: I am living in a one-bedroom residential hotel w/ my husband. However he can stay with friends if necessary. We can do housekeeping & laundry separately, if necessary.

I have read these guidelines, understand the instructions and agree to avoid contacts in accordance with my answers to items 2 through 6. [Note: If you can not manage at home and avoid close contact, it may be necessary for you to remain in the hospital up to an additional 24 hours.]

American Foreign Service Association

Signa[redacted] Date: 1.23.06

(Patient or other person in accordance with hospital informed consent policy.)

PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

EXHIBIT 2

WORKSHEET FOR DETERMINING ACCEPTABLE DOSE RATES FOR RELEASE OF PATIENTS ADMINISTERED RADIOACTVE IODINE

I. Regulatory Limit

10 CFR 35.75 permits release of patients if the **total effective dose equivalent to any other individual from exposure to the released** individual is not likely to exceed 0.5 rem.

II. Acceptable methods

Acceptable methods are described in Regulatory Guide 8.39 "*Release Of Patients Administered Radioactive Materials.*"

III. Calculations

Calculations will be based on **Equation B-1from this guide.**

$$D(t) = \frac{34.6\ \Gamma\ Q_0\ T_p\ E\ (1 - e^{-0.693t/Tp})}{r^2}$$

where

D(t) = Accumulated dose to time t, in rem
34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44)
Γ = Exposure rate constant for a point source, R/mCi x hr at 1 cm
Q_O = Initial activity at the start of the time interval
Tp = Physical half-life in days
E = Occupancy factor that accounts for different occupancy times and distances when an individual is around a patient
r = Distance in centimeters. This value is typically 100 cm
t = exposure time in days

However the dose rate in R/hr for the effective remaining activity Q_m at time t_m (when a measurement is made) is by the definition of Γ:

$$\frac{d\ D(t)}{dt} = \frac{\Gamma\ Q_m}{r^2} \quad \text{or} \quad Q_m = \frac{d\ D(t)}{dt} \times \frac{r^2}{\Gamma}$$

and since the dose to infinity after the dose rate measurement at time t_m is:

$$D_\infty = \frac{34.6\ \Gamma\ Q_m\ T_p\ E\ (1 - 0)}{r^2}$$

$$\text{Then } D_\infty = (dD/dt)*34.6*T_p*E$$

For the purposes of this worksheet:

D = 500 millirem

T_p = 8.08 days

And the acceptable dose rate is therefore

dD/dt = 500/(34.6*8.08*E) = 1.79/E mrem/hour

E = .25 or 0.125 depending on the patient circumstances.

IV. Evaluation (Sign for the appropriate dose rate for this administration)

1. The patient has not submitted information about possible contacts with other people, we can assume without further justification the occupancy factor is 0.25. [Reference: Regulatory Guide 8.39 "*Release Of Patients Administered Radioactive Materials*" and 10 CFR 35.75]

   The measured dose rate at 1 meter must be equal to or less than 7 millirem/hour

2. If the patient has submitted information about possible contacts with other people and has answered yes to all questions 2 – 6 of the questionnaire, we can assume the occupancy factor is 0.125. [Reference: Section B.1.2, "Occupancy Factors To Consider for Patient-Specific Calculations," Regulatory Guide 8.39 "*Release Of Patients Administered Radioactive Materials*".

   The measured dose rate at 1 meter must be equal to or less than 14.3 mrem/hr for thyroid patients.

   Signature of person making evaluation _____

3. If the patient has submitted information about possible contacts with other people but has answered no to any of the questions 2 – 6 of the questionnaire, the Radiation Safety Officer or Deputy Radiation Safety Officer will make the determination of acceptable dose rate. [Reference: Section B.1.2, Regulatory Guide 8.39 "*Release Of Patients Administered Radioactive Materials*".

   The measured dose rate at 1 meter must be equal to or less than 7 millirem/hour

   Basis:

   _____

   _____

   _____

Signature of Radiation Safety Officer _____

John E. Glenn, PhD
Radiation Safety Officer

Georgetown University Hospital

Radiation Safety

June 7, 2006

Radiation Safety Precautions at Home and Elsewhere for Patients Who Have Received Therapeutic Amounts of Radioactivity

Note: **Please carefully read and follow the instructions in this document. If you or your health care providers have any questions or concerns regarding the radionuclide therapy you have received, please contact:**

Nuclear Medicine Attending Physician
(202) 444-3360
Telephone number

[redacted] received a therapeutic dose of **5735 MegaBecquerels (MBq) (155 millicuries (mCi))** of **Iodine-131 Sodium Iodide** at Georgetown University Hospital on June 6, 2006 at 3:30 p.m. and should observe the following radiation safety precautions as follows.

- Avoid close contact with (less than 1 meter, or 3 feet, away from) pregnant women and children until **June 9, 2006**.
- Do not hold or embrace children for more than **10 minutes** a day until **June 13, 2006**.
- From **June 13, 2006** until **June 20, 2006** you should avoid very close contact with children for longer than an hour but may spend 3 to 4 hours per day at 3 feet from children.
- After **June 21, 2006** you may resume very close contact with children for 3 hours a day.
- Do not sleep in the same bed with your sleeping partner until **June 9, 2006**.
- Beginning **June 7, 2006**, there are no restrictions on public transportation for periods up to 3 hours.

MedStar Health
3800 Reservoir Road, NW, LL 17 PHC, Washington, DC 20007-2113
phone: 202 444 4049 • *fax:* 202 444 0069 • *email:* jeg43@gunet.georgetown.edu

Appendix 2, Annex b

In addition, the following precautions should be observed until **June 9, 2006**:

1. To the extent that is reasonable, try to remain far away from individuals around you
2. You should otherwise observe good personal hygiene and may shower, bathe, shave, etc as you normally would, rinsing the shower stall, tub, or sink thoroughly after use.
3. Wipe up any spills of urine, saliva, and/or mucus with disposable paper toweling or tissues, dispose of the paper in the toilet, and flush the toilet two times.
4. While at the hotel, rinse plates, bowls, spoons, knives, forks, and cups. If disposable utensils can not be rinsed or flushed, refer to item 8.
5. Rinse the sink thoroughly after use (tooth brushing) and wipe the fixtures with disposable paper toweling, disposing of the paper toweling in the toilet, and flushing the toilet two times.
6. Store and launder your soiled/used clothing separately from those of the rest of your household, running the rinse cycle two times at the completion of machine laundering.
7. Do not share food or drinks with anyone.
8. Any disposable items that come into contact with body fluids and can not be flushed down the toilet should be placed in a plastic bag and held. The bag should be held for 3 weeks before going into the home trash or brought to the Georgetown University Hospital Radiation Safety Office for disposal. Phone: 202-444-4657. Office: Gorman 2047.

After **June 9, 2006,** contamination should not be an issue.

John E. Glenn

John E. Glenn, Ph.D.

Date: June 7, 2006

Fast HL	0.6
Slow HL	7.3
fast frac	0.95
slow Frac	0.05
Init Reading	27

Occupancy Factors	Dose at 1 meter
0.5	364
0.25	182
0.125	91

t	X(t)	Infinity Dose(.25)	Infinity Dose (0.125)	Infinity Dose (0.125) 1 foot	Infinity Dose (1 hour) 1 foot
0.00	27	1704.9	852.5	7672.1	2557
0.75	12.044	760.5	380.2	3422.2	1141
1.00	9.309	587.8	293.9	2645.2	882
2.00	3.6626	231.3	115.6	1040.7	347
3.00	1.8176	114.8	57.4	516.5	172
4.00	1.1762	74.3	37.1	334.2	111
5.00	0.9195	58.1	29.0	261.3	87
6.00	0.7889	49.8	24.9	224.2	75
7.00	0.7025	44.4	22.2	199.6	67
8.00	0.6342	40.0	20.0	180.2	60
9.00	0.5753	36.3	18.2	163.5	54
10.00	0.5227	33.0	16.5	148.5	50
11.00	0.4752	30.0	15.0	135.0	45
12.00	0.4321	27.3	13.6	122.8	41
13.00	0.393	24.8	12.4	111.7	37
14.00	0.3574	22.6	11.3	101.6	34

EXHIBIT 1
NUCLEAR MEDICINE DEPARTMENT
INFORMATION CONCERNING HOSPITALIZATION FOR PATIENTS ADMINISTERED RADIOACTIVE IODINE

The Nuclear Regulatory Commission has concluded that the radioactive iodine that you receive for therapeutic purposes will cause only small radiation exposures to others if you are released from the hospital in accordance with Nuclear Regulatory Commission guidelines. Special precautions are required for women patients nursing infants or small children. Exposures occur mainly if other people remain close to you (less than 3 feet) for long periods of time (at least one hour) during the first few days after you leave the hospital. The Nuclear Medicine Department will make measurements with a radiation detector to determine that you meet Nuclear Regulatory Commission guidelines prior to leaving the hospital.

Normally, these measurements indicate that a patient may be released less than 24 hours after receiving the dose of radioactive iodine. Thus you may only need to be in the hospital for one night. Sometimes, the measurements indicate that a patient does not meet the Nuclear Regulatory Commission's guidelines assuming normal contact and activities with other people. In those circumstances, you may need to remain for a second night. By answering the following questions and agreeing to follow the guidelines, you may be able to be released earlier because of your limited contact with other people.

1. Are you a woman nursing a small child or infant?

   Yes ____ No X

   NOTE: Nursing an infant or small child after receiving radioactive iodine will transfer the radioactive iodine from the mother to the child through the milk. Radioactive iodine ingested by the child will expose the thyroid of the child to potentially harmful levels of radiation. Lifelong medication may be required to prevent serious effects both mentally and physically if the child's thyroid receives a high dose of radiation. **If you are nursing a child, inform Nuclear Medicine personnel and we must reschedule your administration at a later date after you have permanently ceased nursing this child.**

2. Can you take care of yourself except for brief visits and not be in the same room with another person for more than three hours total during each of the first two days?

   Yes ✓ No ____

   If no, briefly explain circumstances: _____

   _____

   _____

3. Will you be able to maintain distance from other people, including:
   - Sleeping alone for at least one night (recommend 3 nights)?
   - Avoiding kissing and sexual intercourse for at least 3 days?
   - Staying at least 3 feet away from people if you will be involved with them for more than an hour a day in the first 3 days?

   Yes ✓ No ____

   If no, briefly explain circumstances: _____

4. Will you avoid travel by airplane or mass transit for the first day?

   Yes ✓ No ____

   If no, briefly explain circumstances: _____

5. Will you avoid prolonged travel in an automobile with others for the at least first two days?

   Yes ✓ No ____

   If no, briefly explain circumstances: _____

6. Will you have sole use of a bathroom for at least two days?

   Yes ✓ No ____

   If no, briefly explain circumstances: _____

I have read these guidelines, understand the instructions and agree to avoid contacts in accordance with my answers to items 2 through 6. [Note: If you can not manage at home and avoid close contact, it may be necessary for you to remain in the hospital up to an additional 24 hours.]

Signature: [redacted] Date: 6/6/06

(Patient or other person in accordance with hospital informed consent policy.)

PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

ATTACHMENT 4
CASE 2
PATIENT RELEASE TO HOTEL

	Initial		Announced	X	Unannounced	X	Routine		Special

NRC FORM 591M PART 3
(10-2003) 10 CFR 2 201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
University of Virginia **Charlottesville, VA 22904-4322** REPORT NOS 2007-002	**U.S. Nuclear Regulatory Commission** **Region I, 475 Allendale Road** **King of Prussia, Pennsylvania 19406-1415**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-03296	45-00034-26	6-11 to 15-07; 8-29-08

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS	8. INSPECTOR
87134, 87122	03.01-03.07	P. Lanzisera

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2110, 3510, etc	2	Ralph Allen, RSO	434-982-4911

[x] Main Office Inspection — Next Inspection Date: 6/09

[x] Field Office Albemarle County, VA (Incinerator & Waste), North Fork

[ ] Temporary Job Site

PROGRAM SCOPE

Broad Scope medical facility performing primarily research activities using microcurie quantities of carbon-14, tritium, phosphorus-32, sulfur-35, chromium-51, and iodine-125. In addition, unit dosages of technetium-99m and xenon-133 are primarily used in nuclear medicine to conduct approximately 100 diagnostic studies/week by 6 technologists. 100's of iodine-131 therapies, 12 yttrium-90 monoclonal therapies/year (sirsphere and therasphere), 1 Bexxar treatment/year were performed. Zevalin has not been used for several years and gliasite is not used. The inspector determined that the licensee had released 2 patients to an area hotel and the licensee provided additional information in a letter dated June 28, 2007 to support the release. In response to a TAR issued on June 12, 2008, OGC indicated that release to a hotel was not prohibited by the regulations. In addition, the inspector noted that the licensee sometimes releases patients with greater than 200 millicuries, without adding the internal dose component. In a letter dated June 28, 2007, the licensee provided a copy of notes taken during the last NRC inspection which indicated that internal dose did not need to be added. Since the last full inspection, 10 patients treated with greater than 200 millicuries have been treated (203 - 261 mCi) with a calculated maximum external dose contribution of between 334 and 430 millirem. Including the internal dose would increase about half of these values above the 500 millirem release limit. The licensee reviewed the release calculations and revised the calculations to include patient specific data to re-calculate the external and internal dose contribution. The revised values, as documented in their letter dated June 28, 2007, ranged from 175 millirem to 498 millirem. **The next inspector should review release calculations to ensure internal dose contributions are considered.**

The Radiation Safety Officer has 10 staff to assist with radiation safety operations [redacted] The RSC is actively involved in the licensed program and has undertaken many initiatives recently, including re-training technologists to have a second person review written directives to ensure they are complete. The licensee has an RDRC, but it has not been active. 1 research protocol in humans is on-going with I-125 in vycral mesh for lung treatments. [redacted] and a new provost, Dr. Arthur Garson, starts effective 7-1-2007.

[redacted]

[redacted] All spot-checks were performed in accordance with the regulations, with the exception of the linearity out to largest range. The licensee performed this test during the inspection to show the device was linear. Manual brachytherapy treatments for the year included 11 eye plaques and 30 Cs-137 vaginal implants. Alaron Corp. took possession of the strontium-90 eye applicator sources 2/9/07, with records maintained by the licensee. 4 AMPs and 2 AUs are involved in program.

The licensee followed up on several events since the last full inspection. Two of these resulted in special inspections by the NRC and are described in separate reports. To address the event described in the 2007-001 inspection report regarding a manual brachytherapy event, the licensee revised their implant procedures and documentation to confirm that all components of the treatment and written directive are confirmed prior to the treatment. NMED Report 060433 involving the licensee's code team response to a brachytherapy patient was reviewed during this inspection. The licensee reported that some code team members received more than 100 millirem (i.e., 100-200 millirem) while responding to the code; some of who were not radiation workers. The inspector determined that the licensee trains all code team members on potential hazards, including radiogical, during hospital orientation courses, and that the nurse responsible for the patient informed the responders to the hazards. No violations occurred. This issue is closed. One skin contamination event of note occurred since the last inspection. The clothing and skin contamination involved 10 microcuries of P-32, and due to the quick response time by the radiation safety staff, only resulted in a skin dose of about 2 rads.

Waste: No liquid waste is disposed of in the laboratories. Sewer releases are less than 1% of the regulatory limits. The licensee tests sludge/compost semi-annually from the Moores Creek Sewer Plant, with no unusual results noted. Air effluent for incineration is not monitored, however the releases of H-3 and C-14 are estimated by activity incinerated/(flow rate x incinerator on-time). With a flow rate of 1120 CFM and on-time of 40 hours, the total releases in 2006 for H-3 and C-14 were approximately 25% of the limits. Since the licensee used a continuous incinerator on time, their results indicated less than 1% of the limits. The licensee also does not collect ash samples to analyze prior to ash disposal and relies on a 1994 gross beta ash sample to calculate ash disposal limits. The licensee uses their incinerator for radioactive waste only, and has not disposed of ash since 2004. For the 2006 incinerations, assuming 10% of the radioactivity stays in the ash, the ash does not appear to meet the disposal criteria listed in the license (e.g., 1.77 E- 2 uCi/ml H-3 versus 1E-3 and 1.8 E-3 uCi/ml C-14 versus 3E-5). The licensee assumes that no radioactivity remains in the ash and when asked to justify this assumption responded in a June 28, 2007, letter that incineration would be discontinued and all remaining ash would be analyzed and disposed of appropriately. **The next inspector should review this disposal and discuss incinerator decommissioning with the licensee**. The license also collects a water sample from the local pond and vegetation/soil samples annually from the Incinerator area, with no unexpected readings noted. The waste storage facility is still not equipped with a fire suppression/monitoring system as discussed in a 2003 inspection, however, the licensee does not store flammables in the building. The licensee agreed to review this issue and **the next inspector should discuss any changes**. Mixed waste is held for decay if possible, and if not, is shipped to Permafix or NSSI for disposal. Several sealed sources were disposed of since the last inspection and the licensee maintains records of these disposals.

2 SLIV violations were identified: 49CFR173 - Failure to block/brace packages during transport by radiation safety staff; 20.1801/20.1802 - Failure to secure from unauthorized removal [redacted] during the inspection for 5 minutes [redacted] The licensee provided their corrective actions in a letter dated June 28, 2007, which included revised procedures/methods for blocking/bracing and re-training of lab personnel on securing licensed material.

[redacted]

UNIVERSITY of VIRGINIA
ENVIRONMENTAL HEALTH and SAFETY
Special Materials Handling Facility

June 28, 2007

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

03003296

Dear Ms. Lanzisera,

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

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

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

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

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

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

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

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

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

Sincerely,

Ralph Allen

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

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

Appendix 4

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

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

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

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

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

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

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

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

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

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

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

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

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

4b

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

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

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

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

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

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

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

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

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

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

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

Appendix 4d

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

20 June 2007

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

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

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

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

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

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

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

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

Thank you.

Catherine S. Perham
Assistant Radiation Safety Officer
University of Virginia

References:

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

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

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

Patient Release Calculation
I-131 for Thyroid Cancer

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

Radiation Safety Representative

Patient Release Calculation
I-131 for Thyroid Cancer

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

Radiation Safety Representative

UNIVERSITY OF VIRGINIA HEALTH SYSTEM

PLACE LABEL HERE.

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

0700001

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

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

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

Radiopharmaceutical and Dose Prescribed

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

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

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

_____

_____

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

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

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

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

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

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

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

☐ **Patient provided with written instructions**

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

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

Activity Administered _____

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

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

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

Patient Release Criteria Determination

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

Patient Signature: _____ **Date:** _____

For NM Staff Use Only

Additional description of circumstances: _____

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

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

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

Questionnaire administered by (sign & print): _____

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

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

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

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

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

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

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

UNIVERSITY OF VIRGINIA HEALTH SYSTEM

PLACE LABEL HERE.

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

0100000

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

A. CONSENT FOR PROCEDURE

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

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

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

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

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

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

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

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

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

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

B. CONSENT FOR ANESTHESIA OR SEDATION ☐ Not required

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

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

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

---

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

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

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

C. PATIENT OR PARENT/LEGAL REPRESENTATIVE CERTIFICATION:

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

SIGNATURE OF PATIENT _____ DATE _____

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

SIGNATURE OF RESPONSIBLE PARTY _____ DATE _____

RELATIONSHIP TO PATIENT OR LEGAL AUTHORIZATION _____

D. PHYSICIAN ATTESTATION

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

SIGNATURE OF PHYSICIAN OR DESIGNEE OBTAINING CONSENT _____ DATE _____

E. INTERPRETER ATTESTATION (when applicable)

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

SIGNATURE OF INTERPRETER _____ DATE _____

Other precautions to reduce the spread of radioactive iodine.

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

Important Telephone Numbers

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

Additional Instructions: _____

_____

_____

_____

_____

_____

_____

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

Name: _____ Date: _____ Time: _____

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

Name: _____ Date: _____

Circle one: Patient/Family/Caregiver Signature

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

Calculation

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

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

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

Calculation

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

first component | 2nd component | 3rd component

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

Calculation

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

first component 2nd component 3rd component

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

UNIVERSITY OF VIRGINIA HEALTH SYSTEM

1600000

PLACE LABEL HERE.

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

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

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

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

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

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

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

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

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

per Dwight no one includes

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

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

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

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

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

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

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

Appendix 9

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

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

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

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

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

References:

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

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

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

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

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

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

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

REGION I TECHNICAL ASSISTANCE REQUEST

Date: 11-28-07	Package Accession Nos. ML071680002 ML072140256

ADAMS Send to: Janet R. Schlueter, Director
Division of Materials Safety and State Agreements, FSME
(cc: Kathaleen Kerr)

From: Brian Holian, Director
Division of Nuclear Materials Safety

Original signed by: ***/RA by S Weerakkody Actg For/***

Licensees: University of Virginia and Medstar Georgetown Medical Center, Inc.

License Nos. 45-00034-26 08-30577-01	Docket Nos. 030-03296 030-35409	Inspection Nos. 07-02 07-01

Letters Dated: 6-28-07 and 8-29-07	ADAMS Accession Nos. ML071840886 ML072540084

Enforcement Action being held in abeyance:	x	Yes		No

Problem or Issue:

Release of patients receiving 35.300 doses to hotel instead of to home.

Action Requested:

Determine whether releases to a hotel were permissible under 10 CFR 35.75, and if so, describe additional instructions that should be provided to released patients.

Recommended Action and Alternatives	x	Accept	x	Reject

Accept the licensees' releases conducted to date, based on the dose assessments provided by the licensees indicating low exposure potentials and detailed training provided to patients. In addition, the regulation restricts releases based on a dose and does not prohibit releases to hotels.

Reject the licensees' requests to be permitted to continue to release patients to hotels. Publish decision in an Information Notice or the FSME Newsletter indicating that additional data is being collected to determine if these types of releases are appropriate in the future.

TARs addressing similar issues (subject, date and location):

None

Background Documents (Include date and ADAMS Accession Number):

As stated above. In addition, the newspaper article at
http://www.usatoday.com/news/health/2007-11-18-thyroid-cover_N.htm
implies that these types of releases are not uncommon.

Remarks:

Recently inspections at two medical broad scope licensees (UVA and Georgetown) identified that the licensees were releasing thyroid therapy patients treated with I-131 to local hotels. The rationale provided varied, however, some reasons provided were: (i) patient traveled from long distance; (ii) patient did not want to expose their family; and (iii) patient was living in a hotel. In all cases, the licensee performed patient specific calculations using the methodology in NUREG-1556, Volume 9 to support the release. Since the NUREG-1556, Volume 9 methodology was based on NUREG-1492, which analyzed the exposure consequence from releasing a patient to their home, it is unclear if releases to a hotel should be allowed. Specifically, (i) can the licensee use an occupancy factor of 0.125, if they provide additional instruction to the patient on minimizing their exposure to hotel staff (e.g., do not allow cleaning of bathroom during stay, use personal bed linens, etc.); (ii) can the analysis for exposure to family members be related to exposure of hotel staff; and (iii) does release to a hotel instead of to a residence require an amendment to the licensee's license.

Reviewer: Penny Lanzisera	Reviewer Code: P6
Needed By (date): February 28, 2008	

DOCUMENT NAME: C:\FileNet\ML073330708.wpd
To receive a copy of this document, indicate in the box: "**C**" = Copy w/o attach/encl "**E**" = Copy w/ attach/encl "**N**" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	PLanzisera pjh for		PHenderson pjh		BHolian sdw1 for			
DATE	11/26/07		11/26/07		11/28/07 for			

ML073330708

June 12, 2008

MEMORANDUM TO: John Kinneman, Director
Division of Nuclear Materials Safety, Region I

FROM: Cynthia Flannery, Acting Branch Chief ***/RA/***
Medical Safety and Events Assessment Branch
Division of Materials Safety and State Agreements

SUBJECT: RESPONSE TO TECHNICAL ASSISTANCE REQUEST, DATED NOVEMBER 28, 2007, UNIVERSITY OF VIRGINIA, LICENSE NO. 45-00034-26, AND MEDSTAR GEORGETOWN MEDICAL CENTER, LICENSE NO. 08-30577-01

Issue:

In a technical assistance request (TAR) dated November 28, 2007, (ML071680002 and ML072140256), Region I requested assistance in determining whether patient release to a hotel was permissible under 10 CFR 35.75. The Region also requested information on additional instructions to be provided to patients released to hotels. This TAR is requested due to Region I inspections of the University of Virginia (UVA) and Medstar Georgetown Medical Center, Inc. (Georgetown). The inspections determined that the licensees knowingly released Iodine-131 (I-131) therapy patients to hotels after they received treatment.

Action Approved:

The licensees acted in accordance with existing NRC regulations and guidance at the time that the patients were released. In the future, NUREG-1556, Vol. 9, Appendix U will be revised or interim guidance will be developed that will incorporate guidance for release of radiotherapy patients to hotels.

Background:

In June and August of 2007, NRC's Region I Office performed separate inspections at UVA and Georgetown. During the inspections it was determined that each licensee knowingly released I-131 therapy patients, in accordance with the dose limits of 10 CFR 35.75, who planned to stay at a hotel. The inspection at UVA discovered that two patients, who were sisters, were treated on the same day for cancer using I-131. Both patients agreed to sleep alone, avoid mass transit, avoid sharing a bathroom, and minimize contact with others. Based on these agreements, the licensee used an occupancy factor of 0.125 to support release from the hospital, and calculated a maximum public dose of 223 millirems and 308 millirems from each sister, respectively.

CONTACT: Duane White, FSME/MSSA
(301)415-6272

The licensee also indicated that the sister receiving the higher dosage of I-131 stayed at the hospital for the first four hours after dosing, awaiting dosing and release of her sister. Therefore, the licensee concluded that the maximum dose to a member of the public from this sister would have been further reduced. The patients (sisters) indicated to the hospital staff that they planned to stay at a hotel after they were released from the hospital, due to the patients' concerns with being able to keep their children off their laps. UVA gave the sisters their standard written instructions regarding what they should do upon leaving the hospital. However, the instructions given were not specific to staying at a hotel. According to a UVA nurse, the sisters appeared to already have obtained additional instructions pertinent to reducing exposure to members of the public (e.g., notifying the hotel to remove linens so they could bring their own to use and remove, asking the hotel not to clean their room, and having food brought in by one of the husbands). These instructions led them to consider staying at a hotel. UVA did not know the source of the additional instructions the sisters received, but thought the instructions, if followed, would keep exposures to hotel staff or other guests far below the 500 millirem (mrem) release criteria limit specified in 10 CFR 35.75.

During the Georgetown inspection, Region I discovered that Georgetown was aware of certain I-131 therapy patients that stayed at hotels after being released from its hospital. Georgetown asked each iodine ablation patient to fill out a questionnaire to determine when the patient might be released from the hospital and the environment to which the patient would be released. One of the patients indicated in her questionnaire that she lived in a residential hotel with her husband and would be sharing the bathroom with him. Georgetown decided to release this patient to the residential hotel because her exposure rate at one meter was less than 7 mR/hr (4.9 mR/hr @ 1 meter), which is the dose rate for I-131 at which a patient can be released in accordance with 10 CFR 35.75 as described in NRC Regulatory Guide 8.39 "Release Of Patients Administered Radioactive Materials." (Note that Georgetown referenced Regulatory Guide 8.39, but this Regulatory Guide was superseded by NUREG-1556, Vol. 9 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses"). In the questionnaire, the second patient indicated that he was staying at a hotel, since he had a small child at home. For the stay at the hotel, he indicated that he would not be sharing the bed or bathroom with anyone else; therefore the dose assessment determined that the maximum dose to any member of the public would be 91 mrem. Therefore, this patient was released to a hotel. Georgetown provided each patient with written instructions for limiting doses to others and additional instructions, specific to staying at a hotel, were provided to the second patient. Georgetown did not provide additional instructions to the first patient because the patient resided at the hotel and her exposure rate at one meter was less than 7 mR/hr.

Discussion:

In addition to these two licensees, NRC learned that releasing patients from a hospital to go to a hotel or other temporary accommodation is not an uncommon practice. For example, in 2007, several newspaper articles were published regarding concerns with releasing radioiodine therapy patients from hospitals after treatment. One specific article indicated that patients released, after radioiodine therapy, were staying at hotels or other temporary accommodations in order to minimize the risk of exposing their families (especially small children) to radiation.

The newspaper articles also mentioned that one of the concerns with radiotherapy patients being released from a hospital is that members of the public may be exposed to radiation depending on the patients' activities (e.g., staying at a hotel, using public transportation).

10 CFR 35.75 provides that a licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (0.5 rem) (i.e.,500 mrem). The regulation does not limit the location to which the individual must be released. In 1997, NRC amended its regulations concerning the criteria for release of patients administered radioactive material to base the criteria for patient release upon potential dose to other individuals exposed to the patient. Neither the Supplementary Information accompanying the proposed rule, 59 FR 30724 (June 15, 1994) or the final rule, 62 FR 4120 (January 29, 1997) address the release of patients to hotels. However, the Supplementary Information indicates that dose to all individuals was considered during the development of this rule. The information provided in the Supplementary Information indicates that the dose-based limit of 500 mrem was considered an acceptable dose limit for any member of the public and that the dose to an individual in real circumstances probably would not approach 500 mrem.

In summary, the regulations do not prohibit the release of a patient to a hotel if the patient meets the criteria for release specified in 10 CFR 35.75 that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (500 mrem). The dose-based limit of 500 mrem is considered to be an acceptable limit to any member of the public. Guidance regarding additional instructions to be provided to patients released to hotels is expected to be developed.

The newspaper articles also mentioned that one of the concerns with radiotherapy patients being released from a hospital is that members of the public may be exposed to radiation depending on the patients' activities (e.g., staying at a hotel, using public transportation).

10 CFR 35.75 provides that a licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (0.5 rem) (i.e.,500 mrem). The regulation does not limit the location to which the individual must be released. In 1997, NRC amended its regulations concerning the criteria for release of patients administered radioactive material to base the criteria for patient release upon potential dose to other individuals exposed to the patient. Neither the Supplementary Information accompanying the proposed rule, 59 FR 30724 (June 15, 1994) or the final rule, 62 FR 4120 (January 29, 1997) address the release of patients to hotels. However, the Supplementary Information indicates that dose to all individuals was considered during the development of this rule. The information provided in the Supplementary Information indicates that the dose-based limit of 500 mrem was considered an acceptable dose limit for any member of the public and that the dose to an individual in real circumstances probably would not approach 500 mrem.

In summary, the regulations do not prohibit the release of a patient to a hotel if the patient meets the criteria for release specified in 10 CFR 35.75 that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (500 mrem). The dose-based limit of 500 mrem is considered to be an acceptable limit to any member of the public. Guidance regarding additional instructions to be provided to patients released to hotels is expected to be developed.

DISTRIBUTION:
DMSSA r/f RidsRgn1MailCenter
RidsRgn3MailCenter RidsRgn4MailCenter

ML081200856

OFFICE	DMSSA/MSEAB	DMSSA/MSEAB	OGC	DMSSA/MSEAB	DMSSA
NAME	DWhite:smh	RZelac	BJones	CFlannery	RLewis
DATE	04/04/08	04/22/08	04/23/08	04/28/08	06/12/08

OFFICIAL RECORD COPY