YALE-NEW HAVEN HOSPITAL
RADIATION SAFETY OFFICE

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March 3, 2006

MS16
Q-5

License No.: 06-00819-03
Docket No.: 03001244
Control No.: 137205

Elizabeth Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: Reply to the Letter Dated February 3, 2006 from the NRC, Requesting Additional Information Concerning the Renewal of YNHH's Byproduct Materials License No.: 06-00819-03

Dear Ms. Ullrich:

Yale-New Haven Hospital (YNHH) offers the following responses to each item identified in your letter concerning the renewal of our license, dated February 3, 2006.

1. We listed 20 York Street, New Haven, CT as the primary location of use because this is the main mailing address and entrance to the Hospital. However, YNHH is a large academic medical center. The main medical center campus is bounded on the North and East by South Frontage Road, on the South by College Street and Congress Avenue and on the West by Ward Street, Davenport and Howard Avenues. Please refer to the attached map (Exhibit 1). In addition, YNHH owns and operates a remote YNHH Shoreline Medical Center at 111 Goose Lane, in Guilford, CT (Exhibit 2). Maps of the primary use facilities have already been provided in our application dated November 30, 2005, in attachments 9.1.1 through 9.1.12.

   In Item 9.5.1 of our license application, dated November 30, 2005, we requested that the NRC specifically authorize those four addresses for receipt of radioactive packages. This was done in order to provide the highest security for the delivery of any radioactive packages. Our policy is to require all labeled radioactive packages to be delivered either directly to a Nuclear Medicine Hot Lab or to the Radiation Safety Office. These are all medical use facilities, either for human use nuclear medicine or for human use in the practice of therapeutic radiology. The specific

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delivery of radioactive packages to these addresses is done to ensure that these packages are kept secure at all times and to aid in compliance with the requirements of 10 CFR 20.1906, including section (c) of that part, the 3 hour monitoring requirement. The addresses provided in 9.5.1 are the addresses given to radioactive source providers for direct delivery purposes.

The addresses, 40 Temple Street, 60 Temple Street and 229 George Street, listed in Amendment 51 of our license, were originally there to support the NeuroSPECT Research Facility and a satellite diagnostic nuclear medicine clinic. The research facility is now independently operated under their own NRC licensing authority as Molecular Neuroimaging, LLC, under NRC license No.: 06-30624-01. The satellite facility is now located at the YNHH Shoreline Medical Center site. These addresses are no longer part of our operational use area.

2. YNHH either has or may use the following forms of sealed sources:

   a. Cesium-137 sealed sources in needles and applicator cells for topical, interstitial and intracavitary treatment of cancer, manufactured by 3M Corp., that were authorized for medical use prior to October 24, 2002, as described in the "Sealed Source and Device Registry: Supplement for 10 CFR 35 Uses", linked to the NRC's Medical Uses Licensee Toolkit.

   b. Iridium-192 as seeds encased in nylon ribbon for interstitial, intracavitary, or topical treatment of cancer, that were authorized for medical use prior to October 24, 2002, as described in the "Sealed Source and Device Registry: Supplement for 10 CFR 35 Uses", linked to the NRC's Medical Uses Licensee Toolkit.

   c. Strontium-90 as a sealed source in a Tracerlab, Model RA-2 applicator for treatment of superficial eye conditions, that was authorized for medical use prior to October 24, 2002, as described in the "Sealed Source and Device Registry: Supplement for 10 CFR 35 Uses", linked to the NRC's Medical Uses Licensee Toolkit.

   d. Strontium-90 as a sealed source in a Baldwin Industrial Controls, Dartford, England, No. B.I.S. 183, for use as an ion chamber constancy reference source that was authorized before October 24, 2002.

   e. Iodine-125 as a sealed source in seeds for interstitial, intracavitary or topical treatment of cancers, that were authorized for medical use prior to October 24, 2002, as described in the "Sealed Source and Device Registry: Supplement for 10 CFR 35 Uses", linked to the NRC's Medical Uses Licensee Toolkit.

   f. Palladium-103 as a sealed source in seeds for interstitial, intracavitary or topical treatment of cancers, that were authorized for medical use prior to

October 24, 2002, as described in the "Sealed Source and Device Registry: Supplement for 10 CFR 35 Uses", linked to the NRC's Medical Uses Licensee Toolkit.

g. Americium-241 as sealed sources for medical research & development and intracavitary treatment of cancers, that were manufactured for YNHH by Amersham, Monsanto and Gulf Nuclear Corps., under its Type A medical use, broad scope license before October 24, 2002, as described in the "Sealed Source and Device Registry: Supplement for 10 CFR 35 Uses", linked to the NRC's Medical Uses Licensee Toolkit.

h. Americium-241 as sealed sources for diagnostic medical research & development, that were manufactured by Amersham, before October 24, 2002, as described in the "Sealed Source and Device Registry: Supplement for 10 CFR 35 Uses", linked to the NRC's Medical Uses Licensee Toolkit.

i. Gadolinium-153 as sealed sources for diagnostic use in bone mineral analysis or as a transmission source in SPECT imaging devices, that were authorized for medical use prior to October 24, 2002, as described in the "Sealed Source and Device Registry: Supplement for 10 CFR 35 Uses", linked to the NRC's Medical Uses Licensee Toolkit.

j. Radium-226 as sealed sources for research & development and for intracavitary or topical treatment of cancers that were in medical use prior to October 24, 2002.

k. Germanium-68 as sealed sources for diagnostic use as a transmission source in PET/CT scanners.

l. Cesium-131 as a sealed source in seeds for interstitial, intracavitary or topical treatment of cancers as manufactured by Isoray Medical, Inc.

m. Yittrium-90 microspheres, manufactured by either MDS Nordion (Theraspheres) or Sirtex Medical (Sirspheres), for Selective Internal Radiation Therapy (SIRT).

n. Iodine-125 in the GliaSite liquid brachytherapy source and radiation therapy system.

o. Iridium-192 in the Cordis Checkmate (TM), Strontium-90 in the Novoste Beta-Cath (TM) and Phosphorous-32 in the Guidant Galileo systems designed for use in intravascular brachytherapy.

p. Iridium-192 as a sealed source for use in photon emitting remote afterloading sources, for use in the Varian GammaMed plus, High Dose Rate (HDR) brachytherapy system.

3. The GammaMed 12i device and all applicable Iridium-192 sources have been returned to the manufacturer's licensed representative. YNHH no longer possesses this device, the depleted uranium shielding material contained within it or any associated sources have been replaced by the GammaMed plus system, listed as items 6.O and 7.O on the amended No. 51, version of our license.

4. The depleted uranium shielding materials that was contained within the treatment head of a Varian 4S accelerator head, has been transferred for disposal to a licensed disposal contractor, Duratek.

5. YNHH (and its predecessors) have historically been the teaching hospital (since 1826) associated with the Yale University School of Medical (YUSM). These two separate corporate institutions have long operated in a cooperative manner to serve the needs of both academic medical research and human health care. Both institutions are separately licensed by the NRC. Within the institutions, licensed operations are generally separated; where laboratory based research, including animals, is conducted under the Yale University license and human research and medical use under the YNHH license.

   Occasionally, a research program involving a laboratory or animal model may need to use the licensed facilities of YNHH. YNHH has historically maintained the authority to allow research use of its facilities for laboratory or animal models. This would only be authorized when the proposed use has been reviewed and endorsed by the Yale University Animal Care Committee, both the University and Hospital Radiation Safety Committees and any other involved institutional authorities. In these circumstances, care and control of Yale University research materials and animal models will be transferred to the University license after administration of the imaging or treatment source. The housing facilities, training, and instructions to researchers and animal caregivers will be provided by Yale University and subject to their institutional research and animal care requirements, as listed in their license and commitments.

6. a. YNHH conducts research involving human subjects and byproduct materials and has implemented the Federal Policy for the Protection of Human Subjects on all human use protocols. All human use protocols are subject to approval by the Human Investigation Committee (HIC), which is Yale University's Institutional Review Board (IRB), under which YNHH participates as a research affiliate and YNHH has signed a Federal-Wide Assurance (FWA). When human use of byproduct materials or other radiation sources are involved, the YNHH Radioactive Drug Research Committee (RDRC), which is

an arm of the YNHH Radiation Safety Committee (RSC), must review and approve the protocol before it is authorized by the HIC.

b. Prior to performing research on human subjects, the YUSM-HIC and the YNHH-RDRC/RSC will review and approve all protocols. They will require that informed consent is obtained before conducting research on any human subject.

7. a. The management structure of the YNHH Radiation Safety Program consists of the President and Chief Executive Officer (CEO) who has delegated administrative responsibility and oversight of the Radiation Safety Program to the Director of Oncology Services. The Radiation Safety Office is integrated into the Department of Radiological Physics. The Radiation Safety Officer (RSO) reports to both the Director of Radiological Physics and the Director of Oncology Services. In cases where a conflict of interest may exist with the Director of Radiological Physics, the RSO may report directly to the Director of Oncology Services or in extreme cases, directly to the President/CEO. The Radiation Safety Office currently is staffed by a Medical Health Physicist/RSO, a Medical Health Physicist/Asst. RSO and a Radiation Safety Technician.

The Radiation Safety Committee (RSC) is considered a medical board and reports to the Chief Medical Director of the Hospital and minutes of the RSC are presented for review by the Hospital's Medical Board and Board of Trustees.

In addition, the RSO is a member of the YNHH Safety Committee and reports to and advises the committee on any radiation safety related issues. This committee also reports to senior management levels of the Hospital Administration.

b. 1) The YNHH RSC ensures that licensed radioactive materials and other radiation sources are used safely. This includes reviews as necessary of training programs, equipment, staffing, facilities, supplies and procedures. The RSC ensures that all radiation sources are used in compliance with all local, state and federal regulations and any institutional license commitments. The RSC establishes investigational levels for individual occupational radiation exposures and ensures that the uses of radiation sources are consistent with the ALARA philosophy and program. The RSC is also involved with identifying program problems and solutions.

2) The YNHH RSC membership includes at least one authorized user for each type of use allowed by the license, the RSO, a representative of the nursing service and a member of management who is neither an authorized user or the RSO. The committee also includes a chairman,

who is appointed by the medical board, who is either a senior medical physicist or authorized user. In addition, the committee membership is supplemented by other persons who have expertise in radiation management and evaluation of research protocols. Examples of such individuals currently on the committee, include a therapeutic medical physicist, a consultant diagnostic medical physicist, the chief nuclear medicine technologist, the Asst. RSO, a health physicist/Asst. RSO from the Yale University licensed program and a radiopharmacist. In addition, the RSC currently has adjunct members from the YNHH Security & Protective Services program and a member from the affiliated licensed program at the West Haven, CT, Veterans Administration, Nuclear Medicine program.

The RSC meets routinely on a quarterly basis. To establish a quorum, one-half of the voting members of the committee, along with the chairman, the management representative and the RSO, must be present. Management may appoint alternate members to participate in meetings in case of unavoidable absences by principle members of the committee.

3) The RSC will approve non-human medical users (e.g. – Lab Medicine in-vitro users) when they demonstrate that they have appropriate training and experience in the use of licensed materials and have demonstrated to the Committee that they have developed the appropriate policies, procedures, equipment and facilities needed to ensure safe use of radioactive materials.

4) The RSC will approve Authorized Users (AU) for medical use, Authorized Nuclear Pharmacists (ANP) and Authorized Medical Physicists (AMP) when they demonstrate to the committee that they have completed the requirements contained in 10 CFR 35, for each type of use they wish to become authorized for.

c. The RSC will approve existing AUs, for emerging technologies by requiring the AU to provide documentation to the committee as required by our existing research protocol. The RSC will also require the submission of a written attestation from a person (or persons) knowledgeable about the radiation safety aspects of the new medical use and/or associated equipment, if applicable.

d. 1) A statement of the job descriptions of all RSO personnel is attached as Exhibit 3.

2) A copy of management's written delegation of authority is attached as Exhibit 4.

e. 1) YNHH wishes to retain the authority to change programs and procedures and will limit them to the following areas: training; audit program; radiation monitoring instruments; material receipt and accountability; safe use of radionuclides and emergency procedures and radiation surveys. The Hospital also wishes to have the authority to relocate operational facilities, within existing licensed spaces, as needed, with the exception of therapeutic facilities where exposed radiation source levels can exceed 0.01Gy/hr at 1 meter (1 rad/hr @ 1m), e.g. High Dose Rate (HDR) afterloading facilities, or any other facilities fixed by license conditions.

2) Any proposed revisions will be documented, reviewed, and approved by the RSC, in accordance with established procedures prior to implementation.

3) Any revised programs will be in accordance with regulatory requirements, will not change license conditions, and will not decrease the effectiveness of the Radiation Safety Program.

4) All staff affected by revised procedure will be trained prior to their implementation.

5) Our audit program will evaluate the effectiveness of the change and its implementation.

8. YNHH's training program description is attached as Exhibit 5. The RSO will supervise the training program and has developed a number of general and specialized training programs, each developed for the many varied groups of workers employed by the Hospital. Each training program is designed to provide the operational and safety training required by each group of workers. Examples of workers trained include, but are not limited to, authorized users, residents & fellows, nurses, technologists, housekeeping, security, engineering, food service workers, etc. The RSO may delegate training responsibilities to individuals that he/she has determined are competent to provide the level of training needed. Training may be provided by a variety of methods, including but not limited to, formal lectures, computer based training, instructional videos, written instructions, policy and procedure reviews, demonstration & observation and via informal discussions and communications.

9. YNHH will limit its operations to medical use of radioactive materials for diagnostic, therapeutic or laboratory medicine based applications. Any operational facilities will meet the normal standards required of a nuclear medicine, therapeutic radiology or laboratory medicine facility. All primary facilities have already been described in our earlier application dated November 30, 2005, in attachments 9.1.1 through 9.1.12. The classification and survey procedures for any existing or new medical or medical research facilities will be consistent with the guidance contained

within Appendix R, of NUREG-1556, Vol. 9, Rev. 1. Any pure research operations will be conducted under the authority and in the facilities of the YUSM and under their license and associated conditions.

10. a. YNHH will conduct annual audits of the radiation safety program that will review all aspects of the radiation safety program. The audit will be conducted by the Chairman of the RSC, the management representative, the RSO and other applicable individuals. The audit will review the program performance by reviewing survey records, leak tests, training programs, inventories, calibrations, dosimetry, bioassays, waste disposal, etc, including the results of any investigations or incidents. The results of the audit will be reported to the RSC and included in the minutes. The minutes will be available for review by upper management and the medical board of the Hospital.

    b. The RSO will perform an ALARA review quarterly and report his findings to the RSC. In addition, an annual ALARA summary will be prepared and reported to the RSC.

11. a. As part of the RSC approval process, the RSO is required to review the equipment and facilities for any proposed use. The RSO will advise the RSC during the protocol review process, if any additional radiation survey or monitoring equipment is required for safe use. The RSC will then make any necessary instrumentation, conditional before approval of the proposed use.

    b. YNHH will implement instrument calibration procedures that are compatible with the model procedure in Appendix O of NUREG-1556, Volume 11. The lower limit of detection will be determined for instruments used in quantitative sampling and analysis. In addition, YNHH may accept the calibrations of instrument calibration services that are specifically authorized by the NRC or Agreement States to perform this service.

12. The RSC and the RSO have authorized the Chief Nuclear Medicine Technologist or their designee, to order all research and clinically needed radiopharmaceuticals. The RSC and RSO have also authorized the Chief Dosimetrist or their designee, to order all clinically needed brachytherapy sources. They will notify the RSO immediately of any unusual orders that require special measures or if orders are requested by unauthorized users. The Department of Laboratory Medicine is authorized to order exempt quantity radioimmunoassay kits (generally licensed materials in 10 CFR 31.11) on an as needed basis. Each designee is required to keep ordering, receipt, inventory and administration records for RSO review. All other orders for licensed materials will be performed by the RSO.

    All packages containing levels of radioactivity greater than exempt quantities (White I, Yellow II, and Yellow III) must be received either in one of the approved nuclear medicine facilities or directly by the RSO. Records will be kept of all

receipts in these areas that specify the isotope, activity received and other applicable information. These records will be reviewed by the RSO to insure all orders are appropriate and in compliance with applicable licensed limits.

The RSO conducts a physical inventory of all sealed sources on a quarterly basis and leak tests all sealed sources that are in use, on a semi-annual basis. Sources considered to be in storage, will be inspected and leak tested before being returned to use.

All off-hour deliveries will be delivered to one of the approved nuclear medicine or RSO facilities. Routine off-hours delivery personnel have been issued keys to allow entry to the designated hot lab. Security personnel have been instructed to unlock the designated hot lab for off-hour, non-routine deliveries. The doors to the designated hot labs are always kept locked and each requires a key for all entries.

13. YNHH has attached copies of our general rules for safe use of medical radioisotopes as Exhibit 6.

14. In order to evaluate external and internal radiological hazards, YNHH will implement a survey program that is compatible with the model procedure for area surveys contained in Appendix R of NUREG-1556, Vol. 9, Rev. 1.

15. YNHH will release facilities for unrestricted use by using the following criteria:

    a. All radioactive materials and contaminated equipment will be removed from the facility and transferred to another restricted area, licensee or licensed waste disposal site.

    b. A radiation survey of all surfaces in the area where licensed materials were used or stored, using a suitable detection instrument on its lowest scale, will be performed. This will include a survey of any vents or drains that may have been inaccessible during use. Any dose rates observed that are above background, will be documented at contact and at 1 meter.

    c. Total and removable contamination levels will be determined for each area where elevated radiation levels were detected. A wipe frequency of at least one wipe, comprising of at least 100 cm^2 per 100 m^2, will be performed. Any areas with removable contamination levels above 200 dpm/100 cm^2 will be decontaminated. Any areas of fixed contamination, will be removed and disposed as described in section 15.a. above, if the integrated dose at 1 meter exceeds 25 mrem per year. This calculation will assume an occupancy factor of 8 hours per day, 5 days per week, 50 weeks per year (2,000 hrs/yr).

16. YNHH will implement the leak test procedures attached as Exhibit 7. In addition, YNHH may use leak-testing services that are specifically authorized by the NRC or Agreement States to perform this service.

17. YNHH will implement the radioactive waste management procedures attached as Exhibit 8. For radioactive wastes that cannot be held for decay-in-storage, disposed to the sanitary sewerage system or returned to the manufacturer, the Hospital may use the waste processing and compaction facilities of Yale University under a cooperative agreement that has been historically authorized by the NRC, and as documented in previous licensing cycles. This process is only used when waste volumes, which cannot be disposed by alternative methods, become large enough to fill a 7.5 cu. ft. compacted shipping container. The last shipment using this method of disposal was performed in December of 1995. The Hospital will maintain its responsibility for the wastes and the costs associated with their ultimate disposal. The University will only be responsible for the processing of the waste (compaction) and delivery to the currently contracted waste vendor.

This completes the Hospital's response to each item identified in your letter. If you have any further questions, please feel free to contact the Radiation Safety Officer at the address or phone number above.

Sincerely,

Michael J. Bohan
Radiation Safety Officer/Health Physicist

Arthur P. Lemay, M.S., R.Ph.
Exec. Director, Oncology Services

Enclosure: Exhibits 1 through 8

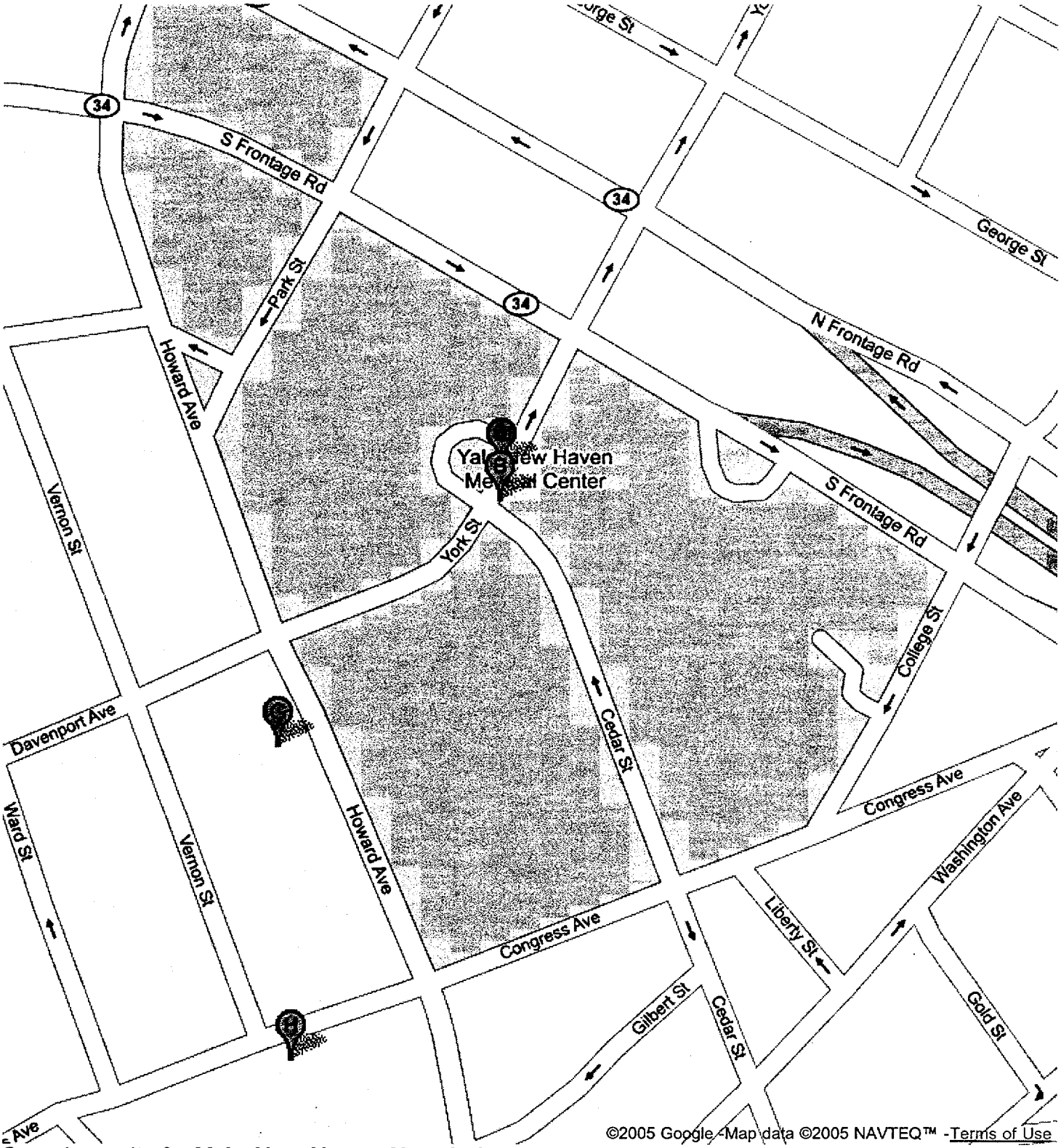
cc: State of Connecticut - Dept. of Environmental Protection, Rad. Control Unit
Marna P. Borgstrom, President, Chief Executive Officer

Exhibit 1

Google Local

NRC License No.: 06-00819-03
Docket No.: 03001244
Control No.: 137205

To see all the details that are visible on the screen,use the "Print" link next to the map.



Search results for **Yale-New Haven Hospital** near **New Haven, CT**

A. **Yale New Haven Hospital**
20 York St, New Haven, CT
(203) 688-2604

B. **Yale-New Haven Hospital** Phys
20 York St, New Haven, CT
(203) 688-4242

Exhibit 2

NRC License No.: 06-00819-03
Docket No.: 03001244
Control No.: 137205

Google Local

To see all the details that are visible on the screen,use the "Print" link next to the map.

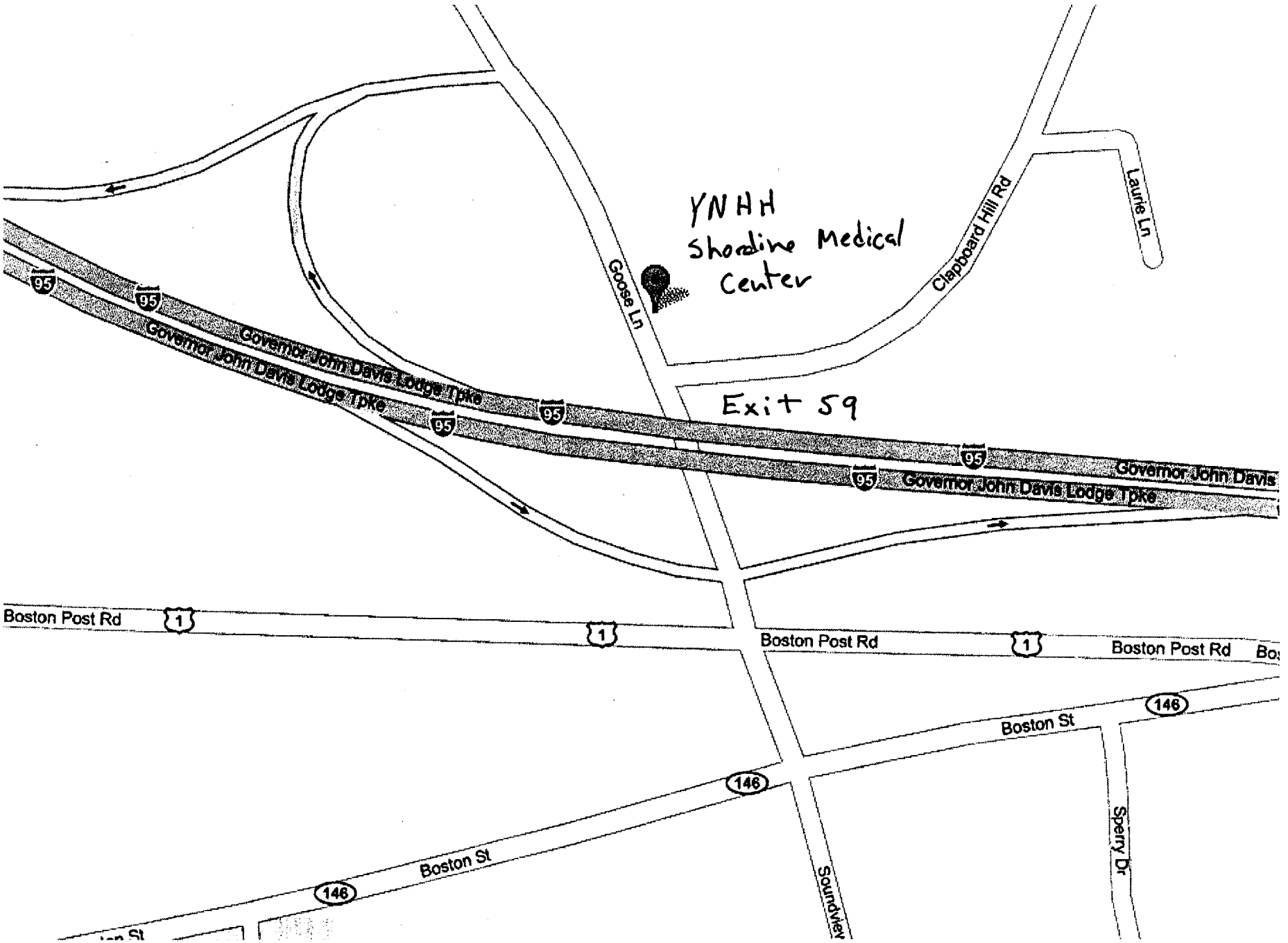


Exhibit 3

YALE-NEW HAVEN HOSPITAL
RADIATION SAFETY OFFICE

August 12, 2005

Job Descriptions for Radiation Safety Office Personnel

1. Radiation Safety Officer/Senior Health Physicist

General Description of Responsibilities and Duties

The Radiation Safety Officer (RSO) is responsible for ensuring that ionizing radiation sources are used safely and in accordance with all federal, state and local regulations, to the benefit of patient care and the community. In a medical environment, the RSO must possess a number of skills to effectively accomplish this task. First, he/she must recognize that people come first and they should be treated with dignity and respect and encourage them to achieve to their full potential. Relationships with hospital personnel, patients and visitors are built on a foundation of honesty, integrity and trust. Excellence is achieved through teamwork, leadership, creativity and a strong work ethic. The RSO must respect the diversity of people and thought. In addition, the RSO must achieve efficiency through the wise use of the Hospital's human, physical and financial resources. He/she must be committed to intellectual achievement, to ensure that the most modern and enlightened methods are actively explored and used to accomplish the missions of the Hospital in patient care, teaching, research and community service.

In order to accomplish this task, the RSO must be knowledgeable and proficient in a number of scientific and technical disciplines including physics, biology, chemistry, mathematics, anatomy, engineering, architecture, psychology, education, public relations, emergency response and numerous others. As a professional, the RSO must be committed to using his/her skills to complete required tasks, even though it may necessitate being on-call 24/7, after hours or weekend duty.

Examples of Work Performed

Supervises and directs the work of the Asst. RSO and Radiation Safety Technician

Maintains current licenses and registrations as required by various federal and state authorities

Maintains a current inventory of radioactive materials possessed by the Hospital and periodically confirms the presence of all sources

Ensures that radiation sources are secured from unauthorized use or accessible to unapproved personnel

Tests for leakage and contamination of sealed sources

20 York Street
New Haven, CT 06504

Monitors personnel exposures and investigates questionable results

Performs and analyses bioassay data to quantify internal doses from radioactive materials

Performs special measurements to assist medical staff in patient care needs

Consults and advises medical physics personnel on the health physics and safety aspects of their duties

Specifies and calibrates equipment used to detect and measure radiation and quantify radioactivity levels

Administers the Hospital's Radiation Protection Program and reports to the Radiation Safety Committee, the Hospital Safety Committee and Hospital Administration

Performs or directs the performance of radiation protection surveys to ensure radiation levels are maintained within accepted standards

Conducts and supervises the training of all personnel who work with radiation sources

Assists medical staff in research uses of radiation and during the introduction of new clinical treatment modalities involving radiation sources to ensure their safe and effective implementation

Designs or reviews the design of all shielded radiation facilities to insure that they meet requirements, inspects the shielding to ensure it is installed correctly and tests the shielding before approving the facility for operational use.

Inspects or directs the inspection of all radioactive packages shipped to the hospital to ensure the correct materials have been received safely and properly added to the inventory

Prepares or directs the preparation of radioactive packages shipped from the Hospital and ensures that radioactive wastes are disposed properly

Approves the ordering of all licensed materials to ensure that licensed limits are not exceeded

Counsels patients and their family members who are concerned about radiation uses in medicine to ensure that they are informed to their satisfaction before giving their consent

Educates patients who have received therapeutic radioactive treatments and their family members about radiation precautions to follow upon their release from the Hospital

Calculates doses from various medical procedures to provide data to clinicians needed for medical decision-making, especially in special cases involving pregnancy or pediatric procedures

Counsels declared pregnant workers and ensures that their assigned duties are modified as needed to limit exposure to the embryo/fetus

Prepares and directs the radiation safety response to incidents involving radiation sources, including Emergency Services responses to offsite radiological events

Provide assistance and advice to affiliated and community healthcare institutions on medical radiological issues consistent with the Hospital's mission statement

Performs other duties as may become apparent or necessary

Required Knowledge and Abilities

Knowledge of radiation safety regulations and industry standards and recommendations

Ability to communicate effectively both orally and in writing

Ability to exercise discretion and judgment to maintain a safe workplace environment and avoid excessive use of regulatory powers granted to the RSO

Ability to use resources effectively to plan and organize work efforts

Administrative ability to organize and maintain required records

Ability to use computers for data/record keeping, analysis, computational, communication and educational purposes

2. Assistant Radiation Safety Officer/Health Physicist

General Description of Responsibilities and Duties

The Assistant Radiation Safety Officer (ARSO) is responsible for assisting the RSO in ensuring that ionizing radiation sources are used safely and in accordance with all federal, state and local regulations, to the benefit of patient care and the community. In a medical environment, the ARSO must possess a number of skills to effectively accomplish this task. First, he/she must recognize that people come first and they should be treated with dignity and respect and encourage them to achieve to their full potential. Relationships

with hospital personnel, patients and visitors are built on a foundation of honesty, integrity and trust. Excellence is achieved through teamwork, leadership, creativity and a strong work ethic. The ARSO must respect the diversity of people and thought. In addition, the ARSO must achieve efficiency through the wise use of the Hospital's human, physical and financial resources. He/she must be committed to intellectual achievement, to ensure that the most modern and enlightened methods are actively explored and used to accomplish the missions of the Hospital in patient care, teaching, research and community service.

In order to accomplish this task, the ARSO must be knowledgeable and proficient in a number of scientific and technical disciplines including physics, biology, chemistry, mathematics, anatomy, engineering, architecture, psychology, education, public relations, emergency response and numerous others. As a professional, the ARSO must be committed to using his/her skills to complete required tasks, even though it may necessitate being on-call 24/7, after hours or weekend duty.

Examples of Work Performed

Assists the RSO in the management of the Hospital's radiation protection program and is prepared to assume the duties of the RSO when needed during vacations or illness

Assists in the maintenance of the current inventory of radioactive materials possessed by the Hospital and periodically confirms the presence of all sources

Helps ensure that radiation sources are secured from unauthorized use or accessible to unapproved personnel

Tests for leakage and contamination of sealed sources

Helps monitor personnel exposures and in the investigation of questionable results

Performs and analyses bioassay data to quantify internal doses from radioactive materials

Performs special measurements to assist medical staff in patient care needs

Consults and advises medical physics personnel on the health physics and safety aspects of their duties

Calibrates equipment used to detect and measure radiation and quantify radioactivity levels

Assists in the administration of the Hospital's Radiation Protection Program and reports to the Radiation Safety Officer

Performs radiation protection surveys to ensure radiation levels are maintained within accepted standards

Conducts training of personnel who work with radiation sources

Assists medical staff in research uses of radiation and during the introduction of new clinical treatment modalities involving radiation sources to ensure their safe and effective implementation

Assists the RSO in the review and testing of new shielded facilities to insure that they meet requirements and are approved before operational use.

Inspects radioactive packages shipped to the hospital to ensure the correct materials have been received safely and properly added to the inventory

Prepares radioactive packages shipped from the Hospital and ensures that radioactive wastes are disposed properly

Counsels patients and their family members who are concerned about radiation uses in medicine to ensure that they are informed to their satisfaction before giving their consent

Educates patients who have received therapeutic radioactive treatments and their family members about radiation precautions to follow upon their release from the Hospital

Calculates doses from various medical procedures to provide data to clinicians needed for medical decision-making, especially in special cases involving pregnancy or pediatric procedures, if they are qualified to do so

Counsels declared pregnant workers and ensures that their assigned duties are modified as needed to limit exposure to the embryo/fetus

Assists in the radiation safety response to incidents involving radiation sources, including Emergency Services responses to offsite radiological events

Provide assistance and advice to affiliated and community healthcare institutions on medical radiological issues consistent with the Hospital's mission statement

Performs other duties as may become apparent or necessary

<u>Required Knowledge and Abilities</u>

Knowledge of radiation safety regulations and industry standards and recommendations

Ability to communicate effectively both orally and in writing

Ability to exercise discretion and judgment to maintain a safe workplace environment

Ability to use resources effectively to plan and organize work efforts

Administrative ability to organize and maintain required records

Ability to use computers for data/record keeping, analysis, computational, communication and educational purposes

3. Radiation Safety Technician

General Description of Responsibilities and Duties

The Radiation Safety Technician (RST) is responsible for assisting the RSO in ensuring that ionizing radiation sources are used safely and in accordance with all federal, state and local regulations, to the benefit of patient care and the community. In a medical environment, the RST must possess a number of skills to effectively accomplish this task. First, he/she must recognize that people come first and they should be treated with dignity and respect and encourage them to achieve to their full potential. Relationships with hospital personnel, patients and visitors are built on a foundation of honesty, integrity and trust. Excellence is achieved through teamwork, leadership, creativity and a strong work ethic. The RST must respect the diversity of people and thought. In addition, the RST must achieve efficiency through the wise use of the Hospital's physical and financial resources. He/she must be committed to intellectual achievement, to ensure that the most modern and enlightened methods are actively explored and used to accomplish the missions of the Hospital in patient care, teaching, research and community service.

In order to accomplish this task, the RST must be knowledgeable and proficient in a number of technical disciplines required in the field of health physics.

Examples of Work Performed

Maintains the day to day operation of the personnel dosimetry program by receiving, distributing, collecting and returning of all film and ring badges

Assists the RSO in the performance of various routine duties required of the Hospital's radiation protection program

Assists in the maintenance of the current inventory of radioactive materials possessed by the Hospital and periodically confirms the presence of all sources

Helps ensure that radiation sources are secured from unauthorized use or accessible to unapproved personnel

Tests for leakage and contamination of sealed sources

Helps monitor personnel exposures and in the investigation of questionable results

Performs bioassays to quantify internal doses from radioactive materials

Performs special measurements to assist medical staff and RSO in patient care needs

Calibrates equipment used to detect and measure radiation and quantify radioactivity levels

Reports to the Radiation Safety Officer and assists in the provision of health physics services to the Hospital

Performs radiation protection surveys to ensure radiation levels are maintained within accepted standards

Reinforces the training of personnel who work with radiation sources and reports compliance issues to the RSO

Assists medical staff in research uses of radiation and during the introduction of new clinical treatment modalities involving radiation sources to ensure their safe and effective implementation

Assists the RSO in the review and testing of new shielded facilities to insure that they meet requirements and are approved before operational use.

Inspects radioactive packages shipped to the hospital to ensure the correct materials have been received safely and properly added to the inventory

Prepares radioactive packages shipped from the Hospital and ensures that radioactive wastes are disposed properly

Counsels patients and their family members who are concerned about radiation uses in medicine to ensure that they are informed to their satisfaction before giving their consent

Educates patients who have received therapeutic radioactive treatments and their family members about radiation precautions to follow upon their release from the Hospital

Assists in the radiation safety response to incidents involving radiation sources, including Emergency Services responses to offsite radiological events

Performs other duties as may become apparent or necessary

Required Knowledge and Abilities

Knowledge of radiation safety regulations and industry standards and recommendations

Ability to communicate effectively both orally and in writing

Ability to exercise discretion and judgment to maintain a safe workplace environment

Ability to use resources effectively to plan and organize work efforts

Administrative ability to organize and maintain required records

Ability to use computers for data/record keeping, analysis, computational, communication and educational purposes

Exhibit 4

YALE-NEW HAVEN HOSPITAL
ONCOLOGY SERVICES

Delegation of Authority to the Radiation Safety Officer

YALE-NEW HAVEN HOSPITAL

MEMORANDUM

TO: Michael J. Bohan
YNHH Medical Health Physicist/RSO

FROM: Arthur Lemay, R.Ph.
Director of Oncology Services

DATE: March 8, 2006

SUBJECT: Delegation of Authority for Radiation Safety

As the responsible manager at Yale-New Haven Hospital (YNHH) for Therapeutic Radiology and Radiation Therapy, I have been delegated the responsibility for oversight of the Radiation Safety Program for the Hospital.

You are the appointed Radiation Safety Officer for YNHH and are responsible for ensuring the safe use of radiation throughout the facility. As the Radiation Safety Officer, you are responsible for monitoring the Radiation Safety Program, identifying radiation safety problems, initiating, recommending, or providing corrective action, verifying the implementation of corrective action, and ensuring compliance with current regulations. In addition to these substantial responsibilities for which you have been appropriately delegated authority to fulfill, you are also responsible for assisting the Radiation Safety Committee in the performance of its duties and serve as this committee's corresponding secretary.

Should you have any questions or concerns regarding this responsibility, please do not hesitate to contact me.

Arthur Lemay, R.Ph.
Director, Oncology Services
YNHH Administration

Exhibit 5

YALE-NEW HAVEN HOSPITAL
RADIATION SAFETY OFFICE

Radiation Safety Training Program

YNHH personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, licensed materials
2. During annual refresher training courses
3. Whenever there is a significant change in duties, regulations, or the terms of the license
4. Upon request of management or workers
5. Whenever the Radiation Safety Officer identifies a training need

Instruction for individuals in attendance will include the following subjects as applicable to their assigned duties:

1. Applicable regulations and license conditions
2. Areas where radioactive materials are used or stored
3. Potential hazards associated with radioactive material in each area where the employees will work
4. Appropriate radiation safety procedures
5. The Hospital's in-house work rules
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
7. Appropriate response to emergencies or unsafe conditions
8. Worker's right to be informed of occupational radiation exposures, bioassay results and declared pregnancy policy
9. Locations where the Hospital has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19
10. Question and answer period

Exhibit 6

YALE-NEW HAVEN HOSPITAL
RADIATION SAFETY OFFICE

Rules for the Safe Use of Radioactive Materials

1. Laboratory coats or other protective clothing will be worn by occupationally exposed personnel at all times in areas where radiopharmaceuticals are used.

2. Disposable gloves will be worn at all times by individuals handling unsealed radioactive materials.

3. Hands will be routinely monitored during each workday for contamination by survey with a radiation detector or gamma camera. Contamination will be washed off immediately. Hands should also be washed as soon as practical after removal of gloves and before leaving for breaks and at the end of each day.

4. Vial shields will be used during the routine preparation of multi-dose vials. Syringe shields will be used during the administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated. In these exceptional cases, other protective methods such as remote dose delivery may be substituted when practical.

5. Eating, drinking, smoking, and application of cosmetics are prohibited in any area where radioactive materials are stored or used.

6. Foods (other than those used for clinical studies), drinks, and personal effects will not be stored in areas where radioactive materials are stored or used.

7. Personnel monitoring devices will be worn at all times while in areas where radioactive materials are used or stored. These devices will be worn as prescribed by the Radiation Safety Officer. The monitored individual will store the devices in an area of low background whenever they are off duty.

8. Ring badges will be worn during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals or brachytherapy sources; and when holding patients during procedures.

9. Radioactive wastes will be disposed only in designated, labeled, and properly shielded receptacles.

10. Pipetting by mouth is strictly prohibited.

11. Radiopharmaceutical storage, preparation, and administration areas will be wipe tested on a weekly basis. Contaminated areas will be cleaned or secured for decay.

12. Radiopharmaceutical storage, preparation, and injection areas will be surveyed with a GM survey meter on a daily basis. Contaminated areas will be cleaned or secured for decay.

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13. Radioactive materials will be kept in clearly labeled shielded containers. Multi-dose diagnostic vials and therapy vials should be labeled with the isotope, compound name, date, and time of calibration. A logbook will be kept to record this information along with the total prepared activity, specific activity in mCi/ml at a specified time, total prepared volume, total remaining volume, the prescribed patient dose, and other appropriate information. Syringes and other unit doses will be labeled with the radiopharmaceutical name or abbreviation, type of study, and the patient's name.

14. Flood sources, syringes, waste, and other radioactive materials will be stored in appropriately shielded containers and kept in a secure place whenever they are not under the direct supervision of approved personnel.

15. Remote handling techniques will be used whenever practicable.

A. Minor Spill Procedures

Note: Minor spills are defined as spills of diagnostic doses or less of any material unless radioiodines (I-123, I-125, or I-131), in the form of sodium iodide, are involved.

1. Isolate the area immediately and inform persons in the area that a spill has occurred.

2. Cover the spill with absorbent materials to prevent the spread of contamination.

3. Gather the materials needed for the clean up effort so they will be easily available, such as disposable gloves, plastic bags, paper towels, decontamination agents (Radiacwash, etc), and other items as necessary.

4. Wear gloves during the decontamination procedure, changing them as needed. Clean into the spill to prevent spread of contamination. Carefully place contaminated items into a plastic bag for transfer to radioactive waste storage. Wash hands after removal of gloves.

5. Survey the area with a GM survey meter. Check the area around the spill to ensure that the spill was contained in the area. Also, survey the hands, clothes, and shoes of involved personnel for contamination. Perform a wipe test of the area.

6. After decontamination, if the radiation survey exceeds 2 mR/hr at 1 inch from the spill site or the wipe test indicates greater than 2,000 dpm/100 sq cm, notify the Radiation Safety Officer (RSO) or his designee. If the survey does not exceed

these limits fill out the radioactive contamination and spill report and file it for RSO review.

7. If RSO notification is necessary, the RSO will complete the contamination and spill report and determine if further decontamination steps are necessary or will isolate the area for decay, if appropriate.

B. Major Spill Procedures

Note: Major spills are defined as spills of multiple dose stock vials, therapeutic doses, rupture of brachytherapy sources or if radioiodines (I-123, I-125, or I-131), in the form of sodium iodide, are involved.

1. Isolate the area immediately, vacate the room, and inform persons in the area that a spill has occurred. Immediately survey involved individuals, to prevent them from tracking contamination away from the area. Contaminated individuals should limit their movements until they are decontaminated.

2. Cover the spill with absorbent materials to prevent the spread of contamination. Shield the source if it can be done without spreading contamination or causing significantly increased exposure.

3. Notify the RSO immediately and secure the area until the RSO or his/her designee arrives.

4. Decontaminate personnel by removing contaminated clothing and gently washing contaminated skin with soap and lukewarm water. If contamination persists, cover the area with plastic to induce perspiration. Then wash the area again to remove any contaminants released through this process.

5. The RSO will supervise the spill cleanup or source recovery and will prepare a radioactive contamination spill report.

YALE-NEW HAVEN HOSPITAL
RADIATION SAFETY OFFICE

Procedure for Leak-Testing Sealed Sources

LEAK TEST PROCEDURE

1. All sealed sources in active use will be routinely leak tested on a semi-annual basis. Additional leak tests may be performed at the discretion of the RSO, whenever the integrity of a source may have been compromised. A list of all sources to be tested will be made. The list will include all sealed sources that are in active use. Sources that are in storage will not be routinely leak tested, but they will be visually inspected and leak tested before being returned to active use. The list will identify the source isotope and its original activity. The list will correlate to the quarterly inventory that identifies each source and its current calibrated activity.

2. An audible survey meter will be used to monitor the exposure rate during the sampling process.

3. Sources may be tested individually or in batches. Sources tested by the batch method will be of same isotope and grouped according to the manufacturer's shipment records or nominal activity. A separate sample for each source or batch of sources will be prepared. A suitable sampling device such as a cotton swab, injection prep pad, filter paper, detergent solution, activated charcoal or tissue paper will be employed to collect leakage from the sources. Each wipe or its counting vial will clearly identify the tested batch of sources. Samples will be taken as follows:

   a. For small sealed sources, a wipe of the entire accessible surface area will be taken. Particular attention will be made to seams and joints, excluding the port of beta applicators. Some sources may be tested by immersion in a detergent solution. After an appropriate soaking period, the source will be removed from the solution and the solution will be counted to determine the level of removable activity.

   b. For larger sealed sources and devices (GammaCell 3000 Elan, GammaMed plus, PET/CT), wipes will be taken as close as practicable to the radiation port or on the external shielding surfaces where contamination would be most likely to accumulate

4. The samples will be analyzed as follows:

   a. All samples will be analyzed by an instrument that is sufficiently sensitive to detect 0.005 microcurie.

   b. The detection efficiency of the device used to assay the wipe samples will be checked with a NIST traceable calibration source that has the same isotope as the sealed source, whose activity is certified by the supplier. If a calibration source is not available, a calibrated "mock" source may be used. Calculations will be made to compensate the "mock" source activity to the actual assayed isotope. Calculations

will be made to demonstrate that the Minimum Detectable Activity (MDA) of the instrument is sufficiently sensitive to detect less than 0.005 microcurie.

c. The wipe sample will be assayed in the same geometry relative to the detector, as was the certified check source.

d. The counts per minute of each sample will be recorded. The calculated activity in microcuries for each wipe sample will also be recorded.

e. Each individual source in a wipe test batch will be retested if the original test results in greater than 0.005 microcuries of removable contamination.

f. Wipe sample activities of 0.005 microcurie or greater, will cause the RSO to be notified. The source will be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the NRC will be notified.

g. The wipe test results and calculations will be signed and dated by the RSO or his designee.

Exhibit 8

YALE-NEW HAVEN HOSPITAL
RADIATION SAFETY OFFICE

Procedure for Radiation Waste Management

RAD WASTE MANAGEMENT PROCEDURE

General Guidelines:

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal into ordinary "non-radioactive" waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Workers will be trained so that non-radioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.

3. All procedures will be monitored to ensure that radioactive waste is not created unnecessarily. All new procedures will be reviewed to ensure that waste is handled in a manner consistent with established procedures.

4. Waste management procedures will be optimized to minimize the radiological, chemical and biological hazards of the materials and contain the costs of disposal.

5. Waste management procedures and training will be provided to workers who generate or otherwise participate in the waste disposal program.

6. Housekeeping staff will be trained to avoid the possibility of unauthorized disposal and minimize exposure of these individuals to radioactive materials or to radiation.

Disposal by Decay-in-Storage (DIS)

Decay-in-Storage will be the primary method of disposal used at YNHH.

1. Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.

2. Short-lived waste will be segregated from long-lived waste.

3. Waste will be stored in suitable well-marked containers that are stored in such a manner to minimize exposures.

4. Liquid and solid wastes will be stored separately.

5. When the container is full, it will be sealed and identified with a label affixed or attached to it.

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6. The identification label will include the date when the container was sealed, the longest lived radioisotope in the container and additional information as necessary to properly identify and manage the waste stream.

7. Prior to disposal as ordinary trash, each container will be surveyed with an appropriate operational radiation detection meter. The survey will be performed in a low background area with all shielding removed from around the container. All surfaces of the container will be monitored.

8. If the survey is indistinguishable from background, the contents will be disposed as ordinary trash or medical waste, if applicable. If the survey indicates residual radioactivity, the container will be returned to DIS area and the RSO will be notified.

9. If the survey indicates no residual radioactivity, a record of the date when the container was sealed, the disposal date, instrument used, survey rate, background rate and the initials of the individual performing surveys and disposing of the waste will be made.

10. All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. Syringes/needles placed into sealed waste containers for decay do not need the labels removed, provided that the following is done:
    a. Waste barrels are sealed prior to delivery to the waste disposal firm and delivered directly from the licensee's facility.
    b. External labels will be removed from the waste barrels/containers.
    c. The waste is ultimately incinerated or destroyed in such a manner that all labels will be defaced by the process.
    d. The waste disposal firm will be cautioned not to open the container prior to incineration.

Disposal of Liquids Into The Sanitary Sewerage System

1. The sewer system is a public system and is not connected to a private sanitary sewer, septic system or leach field.
2. Liquid waste being discharged must be soluble (or biological material that is readily dispersible) in water.
3. The amount of each radioisotope discharged is recorded and will not exceed the monthly and annual discharge limits prescribed in 10 CFR 20.2003(a)(4) and, Appendix B, Table 3.
4. If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3 will not exceed unity.

5. The total quantity of licensed material released into the sanitary sewerage system in any calendar year will not exceed 185 GBq (5 Ci) of H-3 (tritium), 37 GBq (1 Ci) of C-14, and 37 Gbq (1 Ci) of all other radioisotopes combined.
6. The date, radioisotope(s), estimated activity of each radioisotope, location where the material is discharged, and the initials of the individual discharging the waste will be recorded.
7. Liquid waste will only be discharged via designated sinks or toilets.
8. Liquid wastes will be slowly discharged to minimize splashing with water running, to be sure that the material moves out of the sink and into the sewer system.
9. A survey of the sink and surrounding work surfaces will be performed to confirm that no residual material or contamination remains in the sink or on work surfaces. Decontamination will be performed, as appropriate.

Procedure for Returning Generators to the Manufacturer

Used Mo/Tc-99m generators will be returned to the manufacturer. All shipments will comply with all applicable NRC, 10 CFR Part 71, regulations and also comply with DOT regulations.

The following actions will be performed when returning generators:

1. A copy of the records needed to demonstrate that the package qualifies as a DOT Specification 7A container will be kept on file.
2. The package will be assembled in accordance with the manufacturer's instructions.
3. Dose rate and removable contamination measurements will be performed and recorded.
4. The package will be labeled and the shipping papers will be completed in accordance with the manufacturer's instructions and DOT regulations.
5. Records of receipts and transfers will be retained in accordance with 10 CFR 30.51.

Procedure for Return of Licensed Material to Authorized Recipients

1. Prior to shipping licensed materials, a copy of the recipient's license to possess the materials to be shipped will be obtained, in accordance with 10 CFR 30.41(a)(5).
2. A copy of the records needed to demonstrate that the package qualifies as a DOT Specification 7A container will be kept on file.
3. The package will be assembled in accordance with the manufacturer's instructions and DOT regulations.
4. Dose rate and removable contamination measurements will be performed and recorded.
5. The package will be labeled and the shipping papers will be completed in accordance with the manufacturer's instructions and DOT regulations.
6. Records of receipts and transfers will be retained in accordance with 10 CFR 30.51.