UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

December 22, 2016

Docket No. 03001244 License No. 06-00819-03

Arthur P. LeMay, R.Ph.
Executive Director, Smilow Cancer
Hospital Network
Yale-New Haven Hospital
Radiological Physics
20 York Street - WWW 229
New Haven, CT 06510

SUBJECT: NRC INSPECTION REPORT NO. 03001244/2016001, YALE-NEW HAVEN HOSPITAL, AND NOTICE OF VIOLATION

Dear Mr. LeMay:

On May 23-26, 2016, Penny Lanzisera and Farrah Gaskins of this office conducted a safety inspection at the above address of activities authorized by your 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 inspectors, interviews with personnel, and a selective examination of representative records. The inspection also included a review of a microsphere treatment by an NRC medical consultant. Additional information provided in the electronic mail correspondence dated June 24, 2016, from your Radiation Safety Officer (RSO), Mr. Michael Bohan, was also examined as part of the inspection. The findings of the inspection were discussed with you and other members of your organization at the conclusion of the on-site inspection and with you and Mr. Bohan upon completion of the NRC consultant's review of the microsphere treatment. During the final exit meeting conducted on December 2, 2016, the medical consultant's conclusions and future RSO and Radiation Safety Committee (RSC) involvement in reviewing post treatment imaging for therapy treatments was reviewed. The enclosed report presents the results of this inspection.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation involved the failure to obtain and review clinical casework prior to the RSC approving an authorized user for uses described in 10 CFR 35.300.

The violation is cited in the enclosed Notice of Violation (Notice), because the violation was identified by the NRC.

During our on site inspection exit meeting on May 26, 2016, you indicated that the required information would be collected and reviewed by the RSC along with a review of the regulatory and license requirements for approving authorized users. On June 24, 2016, Mr. Bohan forwarded the collected information and indicated that you have taken corrective and preventative actions to address the violation, including collecting the information and reviewing

the approval process with RSC members, and that YNHH is committed to radiation safety and to compliance with NRC regulations and licensed conditions.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed in our records and in your electronic mail correspondence dated June 24, 2016. Therefore, you are not required to respond to this letter unless the description of your corrective actions in this letter and your June 24, 2016, correspondence does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Penny Lanzisera at (610) 337-5169 if you have any questions regarding this matter.

Sincerely,

/RA/

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03001244/2016001

cc w/Enclosures:
Michael J. Bohan, Radiation Safety Officer
State of Connecticut

the approval process with RSC members, and that YNHH is committed to radiation safety and to compliance with NRC regulations and licensed conditions.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed in our records and in your electronic mail correspondence dated June 24, 2016. Therefore, you are not required to respond to this letter unless the description of your corrective actions in this letter and your June 24, 2016, correspondence does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Penny Lanzisera at (610) 337-5169 if you have any questions regarding this matter.

Sincerely,

/RA/

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03001244/2016001

cc w/Enclosures:
Michael J. Bohan, Radiation Safety Officer
State of Connecticut

DISTRIBUTION: ML16362A375
BBickett, RI
DOCUMENT NAME: G:\WordDocs\Current\Insp Letter\L06-00819-03.2016001.doc
SUNSI Review Complete: PLanzisera
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		DNMS/RI			
NAME	Lanzisera/pl		Gaskins/fcg		Dwyer/jpd			
DATE	12/22/16		12/22/16		12/22/16			

NOTICE OF VIOLATION

Yale-New Haven Hospital
New Haven, CT

Docket No. 03001244
License No. 06-00819-03

During an NRC inspection conducted on May 23-26, 2016, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Condition 11.B. of License No. 06-00819-03 requires, in part, that individuals designated in writing by the licensee's Radiation Safety Committee to work as authorized users, as defined in 10 CFR 35.2, shall meet the training and experience requirements in 10 CFR Part 35.
>
> 10 CFR 35.300(b)(2) requires, in part, that a physician who is an authorized user meet the requirements specified in 10 CFR 35.390. 10 CFR 35.390(b)(1)(ii)(G) requires, in part, that work experience include administering dosages of radioactive drugs to patients involving a minimum of three cases in each category for which the individual is requesting authorized user status.
>
> Contrary to the above, on July 29, 2015, an individual was authorized for all uses in 10 CFR 35.390 without having obtained the necessary work experience involving a minimum of three cases in each category in 10 CFR 35.390(b)(1)(ii)(G). Specifically, the Radiation Safety Committee authorized a physician to be an authorized user for the use of all unsealed sources for therapeutic use under 10 CFR 35.300 without obtaining the proper training and experience documentation to support clinical casework completion.
>
> This is a Severity Level IV violation (Enforcement Policy Section 6.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it 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).

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 of receipt.

Dated This 22nd day of December 2016

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001244/2016001
Docket No.	03001244
License No.	06-00819-03
Licensee:	Yale-New Haven Hospital
Location:	20 York Street, New Haven Connecticut
Inspection Dates:	May 23-26, 2016; exit meeting December 2, 2016
Date Followup Information Received:	June 24 and November 28, 2016

Inspectors:

/RA/ ***12/22/16***

Penny Lanzisera — date
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

/RA/ ***12/22/16***

Farrah C. Gaskins — date
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Approved By:

/RA/ ***12/22/16***

James P. Dwyer, Chief — date
Medical Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Yale-New Haven Hospital
NRC Inspection Report No. 03001244/2016001

A routine, unannounced inspection was conducted at Yale-New Haven Hospital (YNHH) in New Haven, Connecticut on May 23-26, 2016. Additional information, contained in correspondence from YNHH on June 24, 2016, was also reviewed. The inspection was performed in accordance with NRC Inspection Procedures 87133 and 87134 and reviewed activities associated with the use of licensed materials within the following departments at YNHH: Nuclear Medicine, Radiation Oncology, and Research. Research is limited to medical research in humans. The inspectors conducted interviews with YNHH personnel, observed day-to-day operations, toured YNHH's facilities, and reviewed documents and procedures.

The inspectors also reviewed a microsphere treatment that was conducted on January 8, 2014, where activity was noted in the bowel. The review of the treatment was performed in accordance with NRC Management Directive 8.10. A medical consultant was retained by the NRC to review the treatment. The medical consultant completed their review on November 28, 2016, and concluded that "deposition of a small percent of the radioactive microsphere in the area fed by the gastroduodenal artery (i.e. distal stomach and proximal duodenum)" had occurred and is "unavoidable" in all microsphere treatments. The medical consultant concurred with YNHH's patient follow-up to attempt to prevent an adverse effect and agreed with YNHH's conclusion that the small percentage of activity involved did not meet the medical event reporting criteria.

Based on the results of this inspection, one apparent violation of NRC requirements was identified. Specifically, the YNHH Radiation Safety Committee (RSC) approved a physician to be an authorized user (AU) for therapeutic use of unsealed licensed material under 10 CFR 35.300 on July 29, 2015, without the proper training and experience, as required by Condition 11.B of License No. 06-00819-03. This AU was board certified by the American Board of Nuclear Medicine; however, the AU's clinical casework was not documented prior to the approval by the RSC.

In addition, from Inspection Number 2014-001, one violation remains open. During the last inspection, the inspector determined that the licensee did not periodically (at least annually) review the radiation protection content and implementation in accordance with 10 CFR 20.1101(c). During this inspection, it was noted that the licensee had completed an audit in the Nuclear Medicine (NM) department and had plans for audits in: (i) cardiology (on-site) within a few months; (ii) cardiology off-site within a year; (iii) radiation oncology by the end of the year; and (iv) St. Raphael's by February 2017. This violation remains open since corrective actions have not been fully completed.

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

A routine, unannounced inspection was conducted at Yale-New Haven Hospital (YNHH) in New Haven, Connecticut on May 23-26, 2016. Additional information, contained in correspondence from YNHH on June 24, 2016, was also reviewed. The inspection was performed in accordance with NRC Inspection Procedures 87133 and 87134 and the following focus areas were reviewed: (i) security and control of licensed material; (ii) shielding of licensed material; (iii) comprehensive safety measures; (iv) radiation dosimetry program; (v) radiation instrumentation and surveys; (vi) radiation safety training and practices; and (vii) management oversight. The inspectors conducted interviews with YNHH personnel, observed day-to-day operations and equipment testing, toured the facilities, and reviewed documents and procedures.

The inspectors assessed YNHH's performance associated with the use of licensed materials within the following departments: Nuclear Medicine, Radiation Oncology, and Research. The inspection also included a review of the licensee's management of the radiation safety program, including oversight of activities by the Radiation Safety Office, the Human Use Sub-Committee, the Radiation Safety Committee (RSC), and senior management.

The inspectors also reviewed a microsphere treatment that was conducted on January 8, 2014, where activity was noted in the bowel. The review of the treatment was performed in accordance with NRC Management Directive 8.10 and is described below. A medical consultant was retained by the NRC to review the treatment. The medical consultant completed their review on November 28, 2016; with the results described below.

b. Observations and Findings

Licensed Material Program Organization and Scope

YNHH's broad scope medical license authorizes YNHH to conduct medical activities authorized by 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 (including high dose-rate remote afterloader and gamma stereotactic radiosurgery use), microsphere therapy treatments, and medical research. These activities are performed at six locations of use. Most operations take place at 20 York Street (the main medical center campus) including nuclear medicine, brachytherapy, gamma stereotactic radiosurgery (GSR), high dose-rate remote aferloader use (HDR), iodine therapies, and Ra-223 Xofigo. Nuclear cardiology procedures are performed in North Haven, Norwich, and Guilford, Connecticut. Operations at Temple Medical Center are limited to sentinel node procedures performed with technetium-99m. The St. Raphael's Campus performs diagnostic nuclear medicine (including PET imaging and cardiology). Most of the radiopharmaceutical therapy treatments are performed at the main campus, however, the St. Raphael's Campus has also performed these procedures in the past. This inspection was limited to the operations taking place at the main medical center campus, at the two Guilford, Connecticut locations, and at the North Haven, Connecticut location.

The inspectors reviewed the following records - RSC meeting minutes, new user approvals, medical research approvals, written directives, patient release calculations,

survey records, dosimetry reports, survey meter calibration records, sealed source inventory and leak test records, daily HDR spot checks, full calibration records for HDR, daily, weekly, and monthly GSR spot checks, maintenance records for HDR and GSR, and training records. The inspectors observed the following therapy treatments – microsphere, iodine-131 carcinoma, and GSR.

From review of the survey instrument records, it was noted that most survey instruments are sent off-site for calibration; however YNHH has a cesium-137 calibrator for ion chamber calibrations. From review of inventory records and an audit of the sealed source storage areas, it was noted that YNHH possesses thirty-three Am-241 sources that they are planning to dispose of through the Department of Energy.

Nuclear Medicine (NM), including Nuclear Cardiology (NC)

NM conducts approximately 700 general and therapeutic procedures and 200 PET/CT procedures per month, with a staff of 10 full-time nuclear medicine technologists (NMTs), two part-time NMTs, and five authorized users (AUs). Their facilities include five imaging cameras, two PET/CT units (shared with Nuclear Cardiology), and three quiet rooms. Most radiopharmaceuticals are received from Cardinal Health and GE Healthcare, with a Mo-99/Tc-99m generator received for unplanned procedures. All dosages are assayed in a dose calibrator prior to administration. Therapeutic nuclear medicine procedures include the oral administration of sodium iodide I-131, Ra-223 Xofigo, Y-90 SIR-Spheres, and Y-90 TheraSphere. SIR-Spheres administrations are performed by 4 interventional radiologist AUs and TheraSphere AUs are in the process of being trained for clinical use. Three TheraSphere treatments have been performed so far with the manufacturer's proctor present. It was noted that the TheraSphere proctor documents proctored cases, but does not document if the AU is approvable. This issue was discussed with the proctor following the on-site inspection. There are rooms available on the 14th floor of the main medical center for inpatient therapies. Nursing staff receive appropriate training and are monitored for occupational exposure. Written directives, release criteria, and release instructions were reviewed and no items of concern were identified. I-125 Gliasite, Y-90 Zevalin, and Sm-153 Quadramet are no longer used and YNHH will remove their uses from their license at license renewal. The licensee is considering the use of germanium/gallium generators and also use of up to one curie of Iodine-131 in patient treatments for acute myolytic leukemia. These uses will be approved through the YNHH RSC and an amendment to the NRC license will be made, if warranted, prior to commencing medical treatments.

NC is staffed by eight full-time NMTs, two part-time NMTs, and 11 AUs who perform approximately 15 cardiac and three PET studies per day. The AUs also rotate to the satellite locations in Guilford, Norwich, and North Haven. In addition to the main department, NC has a satellite facility in the chest pain room of the Emergency Department, with its own camera. The main area has five cameras, two treadmills, and a hot lab. The department receives a Mo-99/Tc-99m generator every Monday for kit preparation; no unit doses are used in NC. One NMT is assigned to the hot lab to prepare kits.

Radiation Oncology (RO)

The RO Department is responsible for temporary brachytherapy (Cs-137 gynecological implants, I-125/Pd-103 prostate implants, and I-125 eye plaques), HDR, and GSR procedures under the supervision of 22 AUs and 15 authorized medical physicists

(AMPs). Brachytherapy sources are delivered to Radiation Safety for package receipt and calibration prior to administration. Eye plaques are made by IsoAid using YNHH's plaques with a known composition and form. IsoAid also sends an extra seed for activity confirmation. Twenty-four Cs-137 sources are currently stored in the cesium hot lab. The Guidant and Best Vascular devices/sources previously used for intravascular brachytherapy were disposed and YNHH will submit documentation to remove them from the license with their license renewal. Radioactive Seed localizations are not performed at YNHH.

There is an active HDR program, with 90-95% gynecological treatments and a smaller number of breast, lung, and other interstitial procedures. Approximately 20 patients/ month are treated with the HDR. For GSR, 6-8 patients are treated each week. 70% of GSR patients are treated for bone metastases, with the rest being treated for functional concerns, vascular lesions, benign tumors, and primary malignancies. Treatment planning is done by the AU, the AMP, and the neurosurgeon. A review of calibrations performed of the HDR confirmed that the length of source transfer tubes and applicators is performed in accordance with 10 CFR 35.633(b), which closes out a prior violation. Annual training on emergency procedures and radiation safety procedures is completed by all HDR and GSR personnel.

For manual brachytherapy, YNHH adopted St. Raphael's process for treatment acceptance criteria and maintains records. For HDR, YNHH performs volumetric verification. As of the on-site inspection, YNHH did not maintain records of their acceptance criteria for volumetric verifications performed, but indicated that they would commence documenting their rationale to support this methodology. In addition, YNHH prepares an electronic written directive using EPIC and the Mosaic Treatment Planning System. Security systems are in place for the system (e.g., password protection); however, the next inspector should review the system in detail to ensure that written directives are properly protected to ensure the authorized user's request is not changed.

Research

No non-human research is performed. Human use research is approved by YNHH's RSC and Institutional Review Board. Currently there are approximately 100 active research protocols, primarily with x-ray use, but a few with F-18, C-11, and Ra-223 Xofigo; the later for a dose escalation study. All PET research studies are also approved by the Yale University Radioactive Drug Research Committee.

Management Oversight

YNHH is a large broad scope medical licensee. The radiation safety staff consists of the Radiation Safety Officer (RSO), 2 assistant RSO's, a technician, and 1 part time secretary. The RSO reports to the Executive Director, who reports to the hospital Chief Executive Officer. The RSO is very engaged in the radiation safety program and is an active member on the RSC. The RSC meets regularly and approves new users and uses. The inspectors confirmed that a representative from nursing has begun attending RSC meetings and several nurses have been named to the RSC. This closes out the prior violation on RSC representation.

The RSC has granted approval to 12 new AUs (five from the prior Norwich license - 06-30793-01) and two new AMPs since the last inspection. An absentee vote is collected if an RSC meeting is not scheduled within the next month. There are currently 42 AUs

and

15 AMPs on staff. All new users had appropriately documented board certificates (if applicable), classroom and laboratory training, work experience, and preceptor attestations; with the exception of one AU. This AU was approved for uses under 10 CFR 35.100, 35.200, and 35.300 on July 29, 2015. A review of the collected training documentation, indicated that the licensee obtained a copy of his board certification under the American Board of Nuclear Medicine. However, the AU's clinical casework was not documented to complete his authorization for therapeutic uses. This is a violation of License Condition 11.B. to ensure that the training and experience requirements of 10 CFR Part 35, including casework, are completed prior to designating an individual as an AU. A revised training form, with the clinical casework documented, along with a preceptor attestation, were completed on June 24, 2016, and provided to the NRC.

Additionally, during the last inspection, the inspector determined that the licensee did not periodically (at least annually) review the radiation protection content and implementation in accordance with 10 CFR 20.1101(c). During this inspection, it was noted that the licensee had completed an audit in the Nuclear Medicine (NM) department and had
plans for audits in: (i) cardiology (on-site) within a few months; (ii) cardiology off-site within a year; (iii) radiation oncology by the end of the year; and (iv) St. Raphael's by February 2017. Therefore, this violation remains open since corrective actions have not been fully completed.

Medical Consultant Review of Microsphere Case

On January 8, 2014, a patient was prescribed to receive 1.25 GBq of SirSpheres to the left lobe of the liver for palliative therapy to the liver tumors contained within. The dosage was delivered with no concerns noted. A NM SPECT/CT scan is routinely performed on the day of therapy, to view the distribution of microspheres. Following the administration, a NM SPECT/CT was performed on the patient, and indicated minimal small bowel uptake. The patient was informed of the small uptake and exhibited no symptoms. However, as a precaution, the attending radiologist prescribed anti-ulcer medications, anti-inflammatory steroids, a sucralfate to line the stomach from damage to the gastric lining, and a proton pump inhibitor, to inhibit gastric acid production. The patient voluntarily discontinued the proton pump inhibitor; however, in April 2014, the patient returned to YNHH with pain and was placed on another one. The patient expired on April 20, 2014. No autopsy was performed.

During the on-site inspection, YNHH staff discussed the treatment with inspectors. A medical consultant was retained by the NRC to review the treatment. The medical consultant completed their review on November 28, 2016, and concluded that "deposition of a small percent of the radioactive microsphere in the area fed by the gastroduodenal artery (i.e. distal stomach and proximal duodenum)" had occurred and is "unavoidable" in all microsphere treatments. From a review of the literature, the medical consultant confirmed that the occurrence is "unavoidable" and seen in approximately 11% of treated patients with development of clinically significant gastric or duodenal ulceration at one, three, and four months post administration. The medical consultant concurred with YNHH's patient follow-up to attempt to prevent an adverse effect and agreed with YNHH's conclusion that the small percentage of activity involved did not meet the medical event reporting criteria. During the final exit meeting, the medical consultant's conclusions and future RSO/RSC involvement in reviewing post treatment imaging for therapy treatments was reviewed.

c. Conclusions

As noted previously, the prior violation of 10 CFR 20.1101 (annual audit) remains open and the violations of 10 CFR 35.24 (nurse representative at RSC) and 35.633 (length of source transfer tubes/applicators) are closed.

During this inspection, one additional violation of License Condition 11.B. was identified involving the approval of a Nuclear Medicine Authorized User on July 29, 2015, by the RSC without documentation for his clinical casework. On June 24, 2016, the documentation for the casework was completed for the AU and signed by the preceptor. As a corrective action, the paperwork and the process for approving AUs was reviewed thru the RSC.

II. Exit Meeting

At the conclusion of the on-site inspection on May 26, 2016, the preliminary inspection findings were discussed with YNHH's senior management. YNHH acknowledged the inspectors' findings and immediately initiated corrective actions. An exit meeting was held by telephone on December 2, 2016, with Mr. Arthur LeMay, Executive Director for the Smilow Cancer Hospital Network, and other members of his staff, to discuss the results of the inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee
*+Arthur LeMay, R.Ph, Executive Director, Smilow Cancer Hospital Network
*+Michael Bohan, Radiation Safety Officer
*+Ravinder Nath, Ph.D., RSC Chair

Various technologists, authorized users, authorized medical physicists, radiation safety, and support staff

*Attended briefing conducted on May 26, 2016
+Attended telephonic exit meeting conducted on December 2, 2016