UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

December 30, 2020

EA-20-155

Arthur Lemay, M.S. R.Ph., Vice President
Yale-New Haven Hosptial
Radiological Physics - WWW 229
20 York Street
New Haven, CT 06510

SUBJECT: YALE-NEW HAVEN HOSPTIAL - NRC INSPECTION NO. 03001244/2020001 AND EXERCISE OF ENFORCEMENT DISCRETION AND NOTICE OF VIOLATION

Dear Mr. Lemay:

This letter refers to the inspection conducted on September 14 through September 18, 2020, at your New Haven, CT; Guilford, CT; Norwich, CT; and North Haven, CT facilities. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. A preliminary exit meeting was held with yourself and select staff on September 18, 2020. A final exit meeting was held via telephone with Neil Whiteside on December 28, 2020.

Based on the results of this inspection, the NRC has determined that five Severity Level IV violations of NRC requirements occurred. For two of the violations, the NRC is exercising discretion and not taking any enforcement action. Namely, 10 CFR 35.60 requires, in part, that licensees calibrate the instrument used to measure the activity of the dosage before it is administered to each patient or human research subject. This calibration may either be performed in accordance with nationally recognized standards or calibration instructions provided by the manufacturer. However, the NRC determined that Yale-New Haven Hospital was unable to calibrate a Rubidium-82 (Rb-82) generator unit in accordance with the regulations because there are currently neither nationally recognized standards nor specific calibration procedures for calibrating detectors in a dynamic mode (i.e., while liquids are flowing past the detector). Until such standards or procedures are developed, compliance with 10 CFR 35.60 is not possible. Additionally, 10 CFR 35.63 requires, in part, that a licensee determine the activity of each dosage administered before medical use. However, the NRC concluded that, due to the 76-second half-life of Rb-82 and direct infusion of the Rb-82 into the patient, users of this generator system are unable to measure patient dosages of Rb-82 prior to administration.

Although violations of 10 CFR 35.60 and 10 CFR 35.63 were identified, which, in accordance with the NRC Enforcement Policy would normally be categorized at Severity Level IV, Yale-New

Haven Hospital met all of the criteria in NRC Enforcement Guidance Memorandum (EGM) 13-003, “Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Doses,” dated April 18, 2013. Therefore, the NRC is exercising enforcement discretion and not pursuing any enforcement action for these violations.

The NRC’s decision is based on the criteria listed in EGM 13-003. Specifically: (1) Yale-New Haven Hospital has written test procedures to ensure that the infusion pump flow rate is consistent and accurate, and that the radiation detector meets the manufacturer’s specifications; (2) Yale-New Haven Hospital has confirmed that the required infusion rate and radiation detector tests were performed within the last twelve months and has maintained records documenting the performance and results of these tests; (3) all authorized users for medical uses under 10 CFR Part 35.200 who are using the Rb-82 generator and infusion cart, as well as the Radiation Safety Officer, have successfully completed training specific to the manufacturer and model of generator and infusion cart being used, and documentation of satisfactory completion of such training has been maintained; and (4) Yale-New Haven Hospital has recorded the activity of each dosage administered, as provided by the infusion cart. No further action or response is required on your part with regards to these issues.

The NRC identified three additional violations involving Yale-New Haven Hospital’s failure on several occasions to 1) perform surveys in accordance with 10 CFR 20.1501; 2) calibrate instrumentation used for direct measurements of unsealed byproduct material prior to administration to each patient in accordance with 10 CFR 35.60; and 3) test sealed sources for leakage in accordance with 10 CFR 35.67. The NRC evaluated these issues in accordance with the NRC Enforcement Policy and assessed the violations at Severity Level IV. The current Enforcement Policy is included on the NRC's Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. These violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC’s "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC Web site 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.

If you have any questions regarding this matter, please contact Shawn Seeley of my staff at 610-337-5102 or via electronic mail at Shawn.Seeley@nrc.gov.

Thank you for your cooperation.

Sincerely,

Donna M. Janda

Digitally signed by Donna M. Janda
Date: 2020.12.30 09:56:37 -05'00'

Donna M. Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

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

Enclosure:
Notice of Violation

cc w/ enclosure
Neil Whiteside, Radiation Safety Officer
State of Connecticut

YALE-NEW HAVEN HOSPTIAL - NRC INSPECTION NO. 03001244/2020001 AND EXERCISE OF ENFORCEMENT DISCRETION AND NOTICE OF VIOLATION DATED DECEMBER 30, 2020

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NOTICE OF VIOLATION

Yale-New Haven Hospital
New Haven, Conneticut

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

During an NRC inspection conducted from September 14 through December 28, 2020, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violation(s) are listed below:

A. 10 CFR 20.1501 requires, in part, that the licensee shall make or cause to be made, surveys of areas that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels and concentrations or quantities of residual radioactivity and the potential radiological hazards of the radiation levels and residual radioactivity detected.

   Contrary to the above, since at lease September 26, 2019, the licensee failed to make or cause to be made, surveys of areas that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels and concentrations or quantities of residual radioactivity and the potential radiological hazards of the radiation levels and residual radioactivity detected. Specifically, the licensee did not make surveys to evaluate the magnitude and extent of radiation levels in multiple areas where unsealed byproduct material was routinely handled.

   This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7).

B. 10 CFR 35.67(b) states, in part, that a licensee in possession of a sealed source shall test the source for leakage at internals not to exceed 6 months.

   Contrary to the above, from January 2020 to September 2020 the licensee failed to leak test all sealed sources at the required interval. Specifically, the licensee failed to leak test one Co-57 sealed source (SN: 2132-06) with a nominal activity of 10 mCi every six months as required. The leak test was performed in January 2020 by the vendor, and then not again as of September 18, 2020; this is a period greater than six months.

   This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3).

C. 10 CFR Part 35.60(b) requires, in part, that a licensee shall calibrate the instrumentation used to measure the activity of byproduct material before it is administered to each patient in accordance with nationally recognized standards or the manufacturer's recommendations.

   Nationally recognized standards indicate that accuracy tests should be conducted on an interval not to annually or upon installation and the manufacturer recommends that accuracy tests be conducted annually or upon installation.

   Contrary to the above, the licensee did not calibrate instrumentation used to measure the activity of byproduct material before it is administered to each

patient in accordance with nationally recognized standards or the manufacturer's recommendation. Specifically, the licensee installed a dose calibrator with serial number 252002 on April 15, 2019, but did not perform an accuracy test. Furthermore, the licensee performed an accuracy test for dose calibrator with serial number 550625 on January 12, 2018, but did not repeat the accuracy test until September 14, 2020. On these two occasions the accuracy test was not performed in accordance with nationally recognized standards or the manufacturer's recommendations.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.3).

Pursuant to the provisions of 10 CFR 2.201, Yale-New Haven 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. 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 30th day of December 2020

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001244/2020001
Docket No.	03001244
License No.	06-00819-03
Licensee:	Yale-New Haven Hospital Radiological Physics - WWW 229 20 York Street New Haven, CT 06510
Location(s):	Medical Center Campus 20 & 25 York Street New Haven, CT 06510 Shoreline Medical Center 111 Goose Lane Guilford, CT 06437 Heart & Vascular Center 2 Devine Street, Suite 1 North Haven, CT 06473 Heart & Vascular Center 79 Wawecus Street Norwich, CT 06360 St. Raphael's Hospital 1450 Chapel Street New Haven, CT 06511
Inspector(s):	_*Shawn W. Seeley*_____ ___12/22/20__ Shawn Seeley date Health Physicist Medical and Licensing Assistance Branch Division of Nuclear Materials Safety ___ *Shawn W. Seeley for*_____ ___12/22/20_____ Elizabeth Tindle-Engelmann date Health Physicist Medical and Licensing Assistance Branch Division of Nuclear Materials Safety

Approved By: *Donna M. Janda* 12/30/2020

Donna M. Janda, Chief date
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Yale-New Haven Hospital
NRC Inspection Report No. 03001244/2020001

A routine announced inspection was performed at Yale-New Haven Hospital (YNHH) on September 14, 2020 with in office review through December 28, 2020. The inspection was conducted with regard to NRC radioactive materials license number 06-00819-03 and in accordance with inspection procedures 87130, 87131, 87132, 87137; and the NRC Licensing Guidance documents for "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®" and "Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™". The inspection focused on the performance of the licensee's program through interviews with licensee workers, demonstrations by workers performing licensed activities, independent measurements of radiation conditions at the licensee's facilities, and review of selected records.

The previous inspection identified seven violations of 10 CFR Part 37, Subparts B & C. During this inspection, the inspectors reviewed the corrective actions associated with all the violations and concluded that corrective actions were implemented and were effective. These violations are closed.

During the inspection three severity level IV (SLIV) violations of NRC requirements were identified. The violations involved the failure to:

1) perform surveys in accordance with 10 CFR 20.1501;
2) calibrate instrumentation used for direct measurements of unsealed byproduct material prior to administration to each patient in accordance with 10 CFR 35.60; and
3) test sealed sources for leakage in accordance with 10 CFR 35.67.

REPORT DETAILS

1. Organization and Scope of the Program

a. Inspection Scope

The inspectors reviewed the organization and scope of the licensee's programs through direct observation of work activities, interviews with licensee workers, and review of selected records.

b. Observations and Findings

The licensee was a medical institution with a Type C broad scope NRC license authorized for use in medical diagnosis, therapy, and research in humans. Additionally, the licensee was authorized for Ge-68 sealed sources, Y-90 TheraSpheres, Y-90 SIR-Spheres, Sr-90 sealed sources, Mo-99/Tc-99m generators, Pd-103 sealed sources, I-125 sealed sources, Cs-131 sealed sources, Cs-137 sealed sources, I-131 in any form, Gd-153 sealed sources, Am-241 sealed sources, Ra-223 in liquid form, Ir-192 as a High Dose Rate Remote Afterloader (HDR) sealed source, and Co-60 as a Gamma Stereotactic Radiosurgery (GSR) sealed source. The licensee had seven locations of use at the time of the inspection.

The primary location of use was the Medical Center Campus. This location housed one Nuclear Medicine (NM) department with Positron Emission Tomography (PET), one Nuclear Cardiology department with PET, and one Radiation Oncology department. The NM department conducted diagnostic studies and a wide range of therapeutic treatments using unsealed byproduct material. This department received unit doses of various radionuclides from vendors including Cardinal Health, PETNET, Advanced Accelerator Applications, SirTex, and Nordion. They also had one Mo-99/Tc-99m generator. The Nuclear Cardiology department had two areas of use at this location. This department received a Mo-99/Tc-99m generator weekly and a BRACCO Sr-82/Rb-82 generator as needed. They received very few unit doses. The Radiation Oncology department conducted manual brachytherapy, HDR treatments, and GSR treatments. The licensee also conducted Y-90 microsphere procedures at this location.

Secondary locations of use included the Shoreline Medical Center, Heart & Vascular Center-Norwich, St. Raphael's Campus, Heart & Vascular Center-North Haven, Temple Medical Center, and Yale School of Medicine. Shoreline Medical Center performed sentinel node treatments and diagnostic cardiology studies using unsealed Tc-99m. Heart & Vascular-Norwich and Heart & Vascular-North Haven performed diagnostic cardiology studies using unit doses of Tc-99m. St. Raphael's Campus housed a small NM department and satellite Nuclear Cardiology department. This location performed general nuclear medicine and cardiac studies. This location primarily received unit doses from Cardinal Health. At the time of the inspection the licensee was no longer performing licensed activities at the Temple Medical Center and was preparing to remove the location from the NRC license. The Yale School of Medicine location performed blood volume studies using unsealed byproduct material. Doses at all locations were measured in a dose calibrator prior to administration.

The radiation safety program was run by one Radiation Safety Officer (RSO) who reported to the Vice President. The RSO had a staff of three full time Health Physicists, one full time Health Physics Technician, and one part time Health Physics Technician. The radiation safety staff performed sealed source leak tests, sealed source inventories, training, therapeutic administration oversight, coordination of the dosimetry program, coordination of instrument calibrations, and general program support. Additionally, the radiation safety staff performed program audits for each licensed activity annually. The audits consisted of reviewing Authorized Users (AUs), authorized uses, training, dosimetry, postings, dose measuring equipment calibrations, dosage determinations, radiation protection, radiation surveys, radioactive waste, radioactive packages, written directives, and medical events. This closed the violation of 10 CFR 20.1101(c) from NRC Inspection No. 03001244/2018001.

The RSO was assisted by an Associate Radiation Safety Officer (ARSO). The licensee underwent an RSO and leadership reorganization in 2019 and 2020. As part of the change the license hired a company to perform an external audit of the radiation safety program. The audit identified areas of possible improvement and as a result the licensee created a corrective action plan to address the programmatic weaknesses identified. The Radiation Safety Committee (RSC) met quarterly and had representation from each type of use, nursing, and management. The RSC oversaw the radiation safety program and was chaired by a Therapeutic Radiologist.

2. Material Receipt, Use, Transfer, and Control

a. Inspection Scope

The inspectors reviewed the material receipt, use, transfer, and control of the licensee's programs through interviews with workers, demonstrations by workers performing tasks regulated by NRC, and a review of selected records.

b. Direct Observations/Interviews and Record Review

The inspectors toured the Medical Center Campus, Shoreline Medical Center, Heart & Vascular Center-Norwich, St. Raphael's Campus, and Heart & Vascular Center-North Haven locations. At the inspected locations the inspectors observed package receipts, dose calibrator quality control, explanations of procedures to patients, and preparations/administrations of patient dosages. The inspectors observed the preparation and infusion of one Lu-117 dotatate therapy and one I-131 Iomab therapy. The inspectors reviewed annual program audits and RSC meeting minutes. The following records were reviewed at all locations: area surveys, area wipes, package receipts, package returns, sealed source inventories, sealed source leak tests, dosimetry, waste disposals, instrument calibrations, dose calibrator calibrations, and radiation safety training. A sample of written directives were reviewed for each type of therapeutic treatment. Additionally, patient release calculations and various written procedures were reviewed for therapy administrations. The following is a summary of the findings from the observations, interviews, and record review:

- The inspectors observed area radiation level surveys being performed and interviewed various staff regarding the timing of radiation level surveys. Through

discussion and review of survey records it was determined that radiation level surveys are performed at the end of the shift. This closed the violation of 10 CFR 35.70(a) from NRC Inspection No. 03001244/2018001. Through this review the inspectors identified inconsistencies in the licensee's radiation level survey procedures. Specifically, the licensee performed daily radiation level surveys for all patient rooms in the Nuclear Cardiology department but only in therapeutic administration locations in the NM department. Furthermore, the licensee failed to perform radiation surveys in the Nuclear Cardiology department's compounding room where they eluted a Mo-99/Tc-99m generator daily. This is a violation of 10 CFR 20.1501 as the licensee failed to make or cause to be made, surveys of areas that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels and concentrations or quantities of residual radioactivity and the potential radiological hazards of the radiation levels and residual radioactivity detected.

- During the inspection of St. Raphael's Campus, the inspectors asked the licensee to perform a sealed source inventory. The licensee discovered that a new Co-57 sealed source (SN:2132-06) with a nominal activity of 10 mCi was received by the site in March 2020. The source was leak tested by the manufacturer in January 2020, but the licensee failed to leak test the sealed source by the time of the inspection. This is a violation of 10 CFR 35.67 as the licensee failed to test the source for leakage from January 2020 to September 2020, an internal greater than the required 6 months.

- The inspectors reviewed the calibration of the licensee's various dose calibrators. The inspectors noted that the accuracy checks for dose calibrators were to be performed upon installation or annually per manufacturer's recommendation or in accordance with the nationally recognized standard IEEE N42.13. The inspectors determined that the licensee did not calibrate the dose calibrators in accordance with a nationally recognized standard or the manufacturer's recommendations. Specifically, the licensee installed a dose calibrator (SN: 252002) in the Nuclear Cardiology department in April 2019 but failed to perform the accuracy test while the dose calibrator was in use from April 2019 through May 2020. Furthermore, the licensee had a dose calibrator (SN:550625) at the Heart & Vascular Center-North Haven that had an accuracy performed on January 12, 2018 and not again until September 14, 2020. This is a violation of 10 CFR 35.60.

- YNHH has one BRACCO Sr-82/Rb-82 generator in the Nuclear Cardiology department. Due to the inherent design of the generator the licensee is unable to comply with 10 CFR 35.60 and 10 CFR 35.63 while using this equipment. Specifically, 10 CFR 35.60 which requires, in part, that licensees calibrate the instrument used to measure the activity of the dosage before it is administered to each patient or human research subject. This calibration may either be performed in accordance with nationally recognized standards or calibration instructions provided by the manufacturer. Contrary to the above, YNHH was unable to calibrate the generator in accordance with the regulations because there are currently neither nationally recognized standards nor specific calibration procedures for calibrating detectors in a dynamic mode (i.e. while liquids are flowing past the detector). Until such standards or procedures are developed, compliance with 10 CFR 35.60 is not possible. Secondly, 10 CFR 35.63 which

requires, in part, that a licensee determine the activity of each dosage administered before each medical use. Due to the short half-life of Rb-82 and direct infusion of the Rb-82 into the patient, users of this generator system are unable to measure patient dosages of Rb-82 prior to administration. Although violations of 10 CFR 35.60 and 35.63 were identified which, in accordance with the NRC Enforcement Policy, would normally be categorized a SLIV, YNHH met all of the criteria listed in NRC Enforcement Guidance Memorandum (EGM) 13-003, "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Doses," dated April 18, 2013. Specifically: (1) YNHH has written test procedures to ensure that the infusion pump flow rate is consistent and accurate, and that the radiation detector meets the manufacturer's specifications; (2) YNHH has confirmed that the required infusion rate and radiation detector tests were performed within the last twelve months, and has maintained records documenting the performance and results of these tests; (3) all AU for medical uses under 10 CFR 35.200 who are using the Rb-82 generator and infusion cart, as well as the RSO, have successfully completed training specific to the manufacturer and model of generator and infusion cart being used, and documentation of satisfactory completion of such training has been maintained; and (4) YNHH has recorded the activity of each dosage administered, as provided by the infusion cart. Therefore, the NRC is exercised enforcement discretion and did not pursue any enforcement action for these violations.

The inspectors reviewed other areas of the program including the HDR and GSR. The primary use of the HDR was for gynecological treatments. The inspectors observed an HDR daily spot check and one patient treatment. The AU, Authorized Medical Physicist (AMP), and radiation therapist were present during the patient treatment. Radiation surveys were performed following the treatment but prior to the patient leaving the treatment vault. HDR records for daily spot checks, full calibrations, written directives, ion chamber and electrometer calibration, maintenance records, and survey records were reviewed. The GSR was an Icon model and had the ability to perform treatments with a head frame or with a mask. The inspectors observed annual GSR drill training, annual security training, the placement of a head frame, daily quality control, and two patient treatments. The inspectors reviewed daily spot checks, full calibrations, written directives, maintenance, and survey records, with no issues identified. Annual emergency training for both HDR and GSR were conducted in accordance with the applicable NRC regulation, documented, and on-file. This closed the violation of 10 CFR 35.610(d) from NRC Inspection No. 03001244/2018001.

The inspectors also reviewed the licensee's compliance with 10 CFR Part 37 requirements as follows:

- Subpart B—Background Investigations and Access Control: The inspectors determined that the licensee allowed only individuals certified as trustworthy and reliable (T&R) unescorted access into the security zone. The inspectors reviewed the files of the individuals that were approved since the last inspection and no concerns were noted. The inspectors reviewed the licensee's written procedures for implementing the access authorization program. The Reviewing Official (RO) informed the inspectors that no individual since the last inspection had been denied unescorted access (UA) nor had any employee had their UA unfavorably

terminated. Records documenting the basis for T&R determinations were secured as were the license's security plan and procedures. Electronic versions of the plan/procedures were password protected. The inspectors determined that the licensee conducted an annual review of the elements of the access authorization program required by 10 CFR 37.33.

- Subpart C—Physical Protection Requirements During Use: The inspectors found that the category 2 quantities of material were adequately secured within the licensee-established security zone. The inspectors verified that the means of detecting unauthorized entry functioned as intended, and the appropriate response was received, through functional tests of the alarm system. The inspectors also interviewed staff to verify that they were knowledgeable in the proper procedures to follow in the event of a suspicious person or an unauthorized attempt to gain access. During a review of the licensee's physical security program, the inspectors identified that the licensee had developed a written security program and provided training to individuals implementing the security program

- Subpart D—Physical Protection in Transit: Not applicable.

The previous inspection identified seven violations of 10 CFR Part 37, Subparts B & C. During this inspection, the inspectors reviewed the corrective actions associated with all the violations and concluded that corrective actions were implemented and were effective. These violations are closed.

Independent Radiation Measurements

Independent radiation surveys were conducted at all the inspected facilities. Survey locations included the hot labs, the camera rooms, the injection areas, the HDR vault, and the gamma knife treatment room; the survey results were consistent with the licensee's postings, the licensee's results, and applicable regulatory limits.

Instrument type:	Model # 2401-P NRC S/N: 344918	calibration expiration date: December 6, 2020
Instrument type:	Model # 2401-P NRC S/N: 188605	calibration expiration date: September 2020

c. Conclusions

During this inspection, three SLIV violations of NRC requirements were identified. The following are the violations:

D. 10 CFR 20.1501 requires, in part, that the licensee shall make or cause to be made, surveys of areas that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels and concentrations or quantities of residual radioactivity and the potential radiological hazards of the radiation levels and residual radioactivity detected.

Contrary to the above, since at least September 26, 2019, the licensee failed to make or cause to be made, surveys of areas that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels and concentrations or quantities of residual radioactivity and the potential radiological hazards of the radiation levels and residual radioactivity detected. Specifically, the licensee did not make surveys to evaluate the magnitude and extent of radiation levels in the multiple areas where unsealed byproduct material was routinely handled.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7).

E. 10 CFR 35.67(b) states, in part, that a licensee in possession of a sealed source shall test the source for leakage at internals not to exceed 6 months.

Contrary to the above, from January 2020 to September 2020, the licensee failed to leak test all sealed sources at the required interval. Specifically, the licensee failed to leak test one Co-57 sealed source (SN: 2132-06) with a nominal activity of 10 mCi every six months as required. The leak test was performed in January 2020 by the vendor, and then not again as of September 18, 2020; this is a period greater than six months.

This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3).

F. 10 CFR Part 35.60(b) requires, in part, that a licensee shall calibrate the instrumentation used to measure the activity of byproduct material before it is administered to each patient in accordance with nationally recognized standards or the manufacturer's recommendations.

Nationally recognized standards indicate that accuracy tests should be conducted on an interval not to annually or upon installation and the manufacturer recommends that accuracy tests be conducted annually or upon installation.

Contrary to the above, the licensee did not calibrate instrumentation used to measure the activity of byproduct material before it is administered to each patient in accordance with nationally recognized standards or the manufacturer's recommendation. Specifically, the licensee installed a dose calibrator with serial number 252002 on April 15, 2019 but did not perform an accuracy test. Furthermore, the licensee performed an accuracy test for dose calibrator with serial number 550625 on January 12, 2018 but did not repeat the accuracy test until September 14, 2020. On these two occasions the accuracy test we not performed in accordance with nationally recognized standards or the manufacturer's recommendations.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.3).

3. Exit Meeting

On September 18, 2020, the inspectors conducted an onsite preliminary exit meeting with YNHH. The inspection findings and apparent violations were discussed. The

licensee acknowledged the inspection findings. On December 28, 2020, a final exit meeting was conducted with the RSO via telephone.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Individual(s) present at entrance meeting
+Individual(s) present for onsite exit meeting

#+ David Depukat, Manager, Regulatory Office
#+ William Hinchcliffe, Associate RSO
Jenna Kostka, Regulatory
#+ Arthur Lemay, Vice President
#+ Nicole Nardecchia, Radiology Quality and Safety
#+ Ravi Nath, RSC Chairman
+ Marcie Scalia, Manager HVR Cath/EP Labs
+ Dawn Tomaszewski, Manager IR Labs
#+ Brian Wang, Radiation Oncology Medical Physics Director
#+ Neil Whiteside, YNHH RSO

INSPECTION PROCEDURES USED

IP 87130, Nuclear Medicine Programs, Written Directive Not Required
IP 87131, Nuclear Medicine Programs, Written Directive Required
IP 87132, Brachytherapy Programs
IP 87137, 10 CFR Part 37 Materials Security Programs

LIST OF ACRONYMS USED

AMP: Authorized Medical Physicist
ARSO: Associate Radiation Safety Officer
AU: Authorized User
CFR: Code of Federal Regulations
EGM: Enforcement Guidance Memorandum
GSR: Gamma Stereotactic Radiosurgery
HDR: High Dose Rate Remote Afterloader
NM: Nuclear Medicine
NMT: Nuclear Medicine Technologist
NRC: Nuclear Regulatory Commission
PET: Position Emission Tomography
RSC: Radiation Safety Committee
RSO: Radiation Safety Officer
SLIV: Severity Level IV
YNHH: Yale-New Haven Hospital