UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

March 28, 2016

EA-15-249

Mr. Wright Alcorn
Vice President of Operations
Methodist Hospital of Gary, Inc.
8701 Broadway
Merrillville, IN 46410

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03011234/2015001(DNMS)
AND NOTICE OF VIOLATION – METHODIST HOSPITAL OF GARY, INC.

Dear Mr. Alcorn:

On October 13, 2015, through October 14, 2015, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facilities in Merrillville and Gary, Indiana, with continued in-office review through March 10, 2016. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of information that was unavailable during the onsite inspection, including security violation determination. Messrs. Aaron McCraw and Zahid Sulaiman of my staff conducted a final exit meeting by telephone with you, Mr. Matthew Rodriguez, and Ms. Laurel Valentino of your staff on March 10, 2016 to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as 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.

Based on the results of this inspection, an apparent violation of NRC requirements was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation is of a security-related nature. Details about the apparent violation are available in the Security Addendum to Inspection Report, enclosed with this letter (Enclosure 3).

Enclosure 3 contains Sensitive Unclassified Non-Safeguards Information. When separated from Enclosure 3, the transmittal letter and Enclosures 1 and 2 are decontrolled.

The circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with you at the final inspection exit meeting on March 10, 2016.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violation addressed in this inspection report within 30 days of the date of this letter; (2) request a Predecisional Enforcement Conference (PEC); or (3) request Alternative Dispute Resolution (ADR). **Please notify Aaron T. McCraw at 630-829-9650 of your intended response within 10 days of the date of this letter.**

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 03011234/2015001(DNMS); EA-15-249," and should include, for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC's website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

In addition, if you choose to provide a written response, please mark your entire response, "Security-Related Information – Withhold from Public Disclosure under Title 10 of the *Code of Federal Regulations* (CFR) 2.390." In accordance with 10 CFR 2.390(b)(ii), the NRC is waiving the affidavit requirements for your response to this letter. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. If a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however, the conference will be closed to public observation because security-related information will be discussed. The NRC normally tries to schedule a PEC within 30 days of the date of the letter.

In lieu of a PEC, you may also request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a third party neutral. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help

them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. **Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.**

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

Based on the results of this inspection, the NRC has also determined that three Severity Level IV (SL IV) violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The violations are described in detail in the enclosed inspection report (Enclosure 2). The SL IV violations are cited in the enclosed Notice of Violation (Notice) (Enclosure 1). The NRC is citing the SL IV violations in the Notice because the violations were identified by the inspector.

The NRC has concluded that information regarding the reason for the SL IV violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was or will be achieved is already adequately addressed on the docket in Enclosure 2. Therefore, you are not required to respond to these SL IV violations unless the description in Enclosure 2 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 and Enclosures 1 and 2 will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. Enclosure 3 contains security-related information and its disclosure to unauthorized individuals could present a security vulnerability; therefore, Enclosure 3 will not be made available electronically for public inspection.

Please feel free to contact Zahid Sulaiman of my staff if you have any questions regarding this inspection. Mr. Sulaiman can be reached at 630-829-9752.

Sincerely,

/RA/

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 030-11234
License No. 13-16558-01

Enclosure:
1. Notice of Violation (public)
2. IR 03011234/2015001(DNMS) (public)
3. Security Addendum to Inspection Report (non-public)

cc w/encls: Mathew G. Rodriguez, RSO
cc w/encls 1 & 2: State of Indiana

Please feel free to contact Zahid Sulaiman of my staff if you have any questions regarding this inspection. Mr. Sulaiman can be reached at 630-829-9752.

Sincerely,

/RA/

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 030-11234
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cc w/encls: Mathew G. Rodriguez, RSO
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NAME	ZSulaiman:ps		RSkokowski		AMcCraw		JGiessner	
DATE	3/22/2016		3/23/2016		3/25/2016		3/28/2016	

OFFICIAL RECORD COPY

Letter to Wright Alcorn from John Giessner dated March 28, 2016

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03011234/2015001(DNMS)
AND NOTICE OF VIOLATION – METHODIST HOSPITAL OF GARY, INC.

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NOTICE OF VIOLATION

Methodist Hospital of Gary, Inc.
Merrillville, Indiana

License No. 13-16558-01
Docket No. 030-11234
EA-15-249

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 13-14, 2015, with continued in-office review through March 10, 2016, three violations of NRC safety requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. Title 10 of the *Code of Federal Regulations* (CFR) Section 35.40(b)(3) states, in part, that the written directives for gamma stereotactic radiosurgery (GSR) must contain the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site.

   Contrary to the above, as of October 14, 2015, a GSR written directive, dated June 25, 2013, did not contain the treatment site.

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

B. Title 10 CFR 35.40(b)(5) states, in part, that written directives for high dose-rate (HDR) remote afterloading brachytherapy must contain the radionuclide, treatment site, doses per fraction, number of fractions, and total dose.

   Contrary to the above, as of October 14, 2015, three HDR written directives, dated April 24, 2015, April 28, 2015, and May 5, 2015, did not contain the radionuclide.

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

C. Title 10 CFR 30.34(c) states, in part, that each licensee shall confine its possession and use of the byproduct material to the locations and purposes authorized in the license.

   Condition 10 A. of NRC License No. 13-16558-01, Amendment No. 66, dated April 30, 2015, requires, in part, that the licensed materials listed in Subitems 6.A through 6.E., and 6.G through 6.L. may be used or stored at Methodist Hospital – Southlake Campus, 8701 Broadway, Merrillville, Indiana.

   Contrary to the above, as of October 14, 2015, the licensee stored licensed materials that was not authorized by the license to use or store at the Southlake Campus. Specifically, the licensee stored licensed material, a strontium-90 eye applicator, listed on the license as Subitem 6.F., at the Southlake Campus.

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

Enclosure 3 contains Sensitive Unclassified Non-Safeguards Information. When separated from Enclosure 3, the transmittal letter and Enclosures 1 and 2 are decontrolled.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report (IR) No. 03011234/2015001 (DNMS). 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, IR 03011234/2015001 (DNMS)" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

Your response, if you choose to provide one, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 28TH day of March, 2016.

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-11234
License No.	13-16558-01
Report No.	03011234/2015001 (DNMS)
EA No.	EA-15-249
Licensee:	Methodist Hospital of Gary, Inc.
Facilities Inspected:	8701 Broadway Merrillville, Indiana 600 Grant Street Gary, Indiana
Inspection Dates:	October 13-14, 2015, with continued in-office review through March 10, 2016
Exit Meeting Date:	March 10, 2016
Inspector:	Zahid Sulaiman, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure 3 contains Sensitive Unclassified Non-Safeguards Information. When separated from Enclosure 3, the transmittal letter and Enclosures 1 and 2 are decontrolled.

Enclosure 2

EXECUTIVE SUMMARY

Methodist Hospital of Gary, Inc.
NRC Inspection Report 03011234/2015001 (DNMS)

During a routine inspection, on October 13 and 14, 2015, with continued in-office review through March 10, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) identified an apparent violation that pertained to security issues. The apparent violation and the licensee's proposed corrective actions to restore compliance are documented in the non-public Security Addendum to the Inspection Report. The inspector also identified three safety violations involving the licensee's failure to: (1) document the treatment site on the written directive for one gamma stereotactic radiosurgery (GSR) treatment, as required by Title 10 of the *Code of Federal Regulations* (CFR) 35.40(b)(3); (2) document the radionuclide on written directives for three high dose-rate remote afterloader brachytherapy (HDR) treatments, as required by 10 CFR 35.40(b)(5); and (3) limit its possession and use to the locations listed on the license, as required by 10 CFR 30.34(c) and License Condition 10 of NRC License No. 13-16558-01.

As corrective action for the violations of 10 CFR 35.40(b)(3) and (b)(5), the Radiation Safety Officer (RSO) trained the authorized users and staff to completely fill out all the information required in written directives and ensuring they are complete and accurate. As further corrective action for the violation of 10 CFR 35.40(b)(5), the RSO developed a new written directive form for HDR treatments that will always include the radionuclide (i.e., iridium-192).

As corrective action for the violation of 10 CFR 30.34(c) and License Condition 10, on October 16, 2015, the licensee requested an amendment to the license to permit the possession and use of Sr-90 at its Southlake Campus, The NRC issued the amendment authorizing the possession and use of Sr-90 at the Southlake Campus on October 23, 2015.

REPORT DETAILS

1 Program Overview and Inspection History

Methodist Hospital of Gary, Inc. (licensee) is authorized under NRC Materials License No. 13-16558-01 to possess and use licensed material for uptake, dilution, and excretion studies; diagnostic imaging; radiopharmaceutical therapy; manual brachytherapy; sealed sources for diagnosis; in-vitro studies; high dose rate remote afterloading brachytherapy (HDR); gamma stereotactic radiosurgery (GSR); and GliaSite® radiation therapy as permitted by 10 CFR 35.100, 200, 300, 400, 500, 600 and 1000. The license authorizes two locations of use, one in Merrillville, Indiana (Southlake Campus) and the other in Gary, Indiana (Northlake Campus). At the Merrillville facility, the licensee conducted about 25 nuclear medicine diagnostic studies per day. The staff conducted the full spectrum of diagnostic studies. The licensee used iodine-131 to treat hyperthyroidism and thyroid cancer. The licensee also conducted about 12 HDR fractions per year and about 30 GSR treatments per year at the Merrillville facility. The HDR treatments included gynecological treatments and breast treatments. The licensee had not conducted manual brachytherapy or GliaSite® radiation therapy since the last NRC inspection. At the Gary facility, the licensee primarily conducted uptake studies, diagnostic imaging, and iodine-131 hyperthyroid treatments.

The NRC last conducted a routine inspection of the licensee on April 1 through 5 and 8, 2013. As a result of the inspection, the NRC cited the licensee for a Severity Level III (SL III) security violation and five SL IV safety violations. The SL III violation was closed during an escalated enforcement followup inspection on September 17, 2013. The status of the two SLIV safety violations is discussed in the respective sections of this report.

2 GSR

2.1 Inspection Scope

On October 13, 2015, through October 14, 2015, the inspector observed a GSR patient treatment, interviewed staff, and reviewed the elements of the licensee's safety and security programs including: security of the GSR unit, calibration measurement, and period spot check of GSR unit.

2.2 Observations and Findings

The inspector observed one GSR patient treatment. The inspector observed the initial preparation of the patient; the licensee's performance of a check to ensure the patient, treatment plan, and treatment parameters were correct and as intended; and the actual administration of the dose. The inspector interviewed staff involved in the treatment and determined they were knowledgeable of operating and emergency procedures. The inspector did not identify any issues with this treatment.

As a result of the previous routine inspection, the NRC cited the licensee for violations of 10 CFR 35.645(a)(1) and 10 CFR 35.645(d)(6) for the licensee's failure to include all required checks during monthly and periodic spot checks of the GSR unit. During the current inspection, the RSO demonstrated the monthly and periodic spot checks, and

the inspector verified that the checks included all items required by the regulations. The inspector determined that the licensee took appropriate corrective actions. The NRC considers these two violations from the previous routine inspection closed.

The inspector reviewed a sample of written directives and found one written directive, dated June 25, 2013, that did not contain the treatment site. The treatment site was left blank. Title 10 CFR 35.40(b)(3) requires that the written directives for gamma stereotactic radiosurgery must contain treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site. The licensee's failure to fully complete the written directive is a violation of 10 CFR 35.40(b)(3).

The inspector determined that the cause of the violation was an isolated oversight on the part of the licensee to ensure that this one GSR written directive contained all required information. As corrective action to prevent recurrence, the RSO trained licensee personnel to completely fill out all the information required in written directives and double check the written directive, ensuring they are complete and accurate.

2.3 Conclusions

The inspector identified a violation of 10 CFR 35.40(b)(3), which requires that the written directives for GSR must contain treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site. The licensee implemented corrective actions to prevent similar violations. The inspector closed two previously cited violations involving the licensee's GSR program.

3 HDR

3.1 Inspection Scope

The inspector reviewed the licensee's HDR program by reviewing selected HDR treatment records, interviewed selected licensee staff, and observed a demonstration of the periodic spot check of the HDR unit.

3.2 Observations and Findings

The licensee was not conducting any HDR activities at the time of the inspection; therefore, the inspector could not observe any patient treatments. The inspector interviewed licensee staff and determined that the staff were knowledgeable of operating and emergency procedures.

As a result of the previous routine inspection, the NRC cited the licensee for a violation of 10 CFR 35.643(d)(6) for the licensee's failure to include a check of timer accuracy during periodic spot checks of the HDR unit. The inspector observed the RSO demonstrate the periodic spot check of the HDR unit, which included timer accuracy. The inspector determined that the licensee took appropriate corrective actions. The NRC considers this violation from the previous routine inspection closed.

The inspector discussed with the RSO full calibrations, source exchanges, and security of the HDR unit and console with no issues identified. The inspector noted that the

licensee's HDR unit is used in a linear accelerator vault and verified that the licensee had a means to prevent the simultaneous operation of both units.

During the review of HDR treatment records, the inspector noted that three HDR written directives did not contain the radionuclide (i.e., iridium-192). Specifically, those written directives dated April 24, 2015, April 28, 2015, and May 5, 2015. The licensee's HDR written directives included the date and signature of a physician authorized user, the patient name, the treatment site, the dose per fraction, the number of fractions, and the total dose; however, the written directive did not include the radionuclide (i.e., iridium-192). Title 10 CFR 35.40(b)(5) states, in part that, the written directive for HDR must include the radionuclide, treatment site, dose per fraction, number of fractions, and total dose. The licensee's failure to include the radionuclide on HDR written directives is a violation of 10 CFR 35.40(b)(5).

As a result of the last routine inspection, the NRC cited the licensee for a violation of the same requirement for failure to include the radionuclide on HDR written directives. As a corrective action to the previously cited violation, the licensee implemented a new written directive form with a space for the user to fill in the radionuclide. Given that the current inspection revealed additional examples where the licensee failed to include the radionuclide on HDR written directives, the inspector determined that the licensee's previous corrective actions were not effective.

The inspector determined that the cause of the current violation was a lack of attention to detail in completing the spaces on the form. As corrective action, on October 14, 2015, the licensee revised its HDR written directive form to include "iridium-192", which is the only radionuclide the licensee uses for HDR treatments, on the form to prevent recurrence.

The NRC considers the previously violation of 10 CFR 35.40(b)(5) closed because the licensee had completed its corrective actions for the previously cited violation; however, because the licensee's corrective actions were ineffective in preventing recurrence, the NRC is citing a new violation of the same requirement.

3.3 Conclusions

The inspector identified a violation of 10 CFR 35.40(b)(5) states, in part, that written directives for high dose-rate (HDR) remote afterloading brachytherapy must contain the radionuclide, treatment site, doses per fraction, number of fractions, and total dose. The licensee implemented corrective actions to prevent similar violations in the future. The previous violation of the same requirement was closed.

4 Nuclear Medicine

4.1 Inspection Scope

The inspector reviewed nuclear medicine dosage administrations at both locations of use by interviewing selected staff, observing dosage preparation, observing dosage administrations, and reviewing selected patient dosage administration records.

4.2 Observations and Findings

The inspector followed up on the licensee's corrective actions to a previously cited violation of 10 CFR 35.63(d) for the licensee's administrations of dosages that differed from the prescribed dosages by more than 20 percent without an authorized user's direction. The inspector reviewed a sample of the licensee's dosage administration records and did not identify an additional examples where the administered dosage differed from the prescribed dosage by more than 20 percent. The inspector interviewed licensee staff in the nuclear medicine departments and found the staff knowledgeable of the appropriate ranges for dosages. The NRC considers this previously cited violation closed.

4.3 Conclusions

There were no issues or findings identified in this program area. The inspector closed the previously cited violation of 10 CFR 35.63(d).

5 Other Areas Inspected

5.1 Inspection Scope

The inspector reviewed other areas of the licensee's radiation protection program by interviewing selected staff, observing licensed activities, observing demonstrations of how licensed activities had been or would be conducted based on scenarios posed by the inspector, and reviewing selected records. Areas reviewed included, in part, storage of licensed materials, occupational dose monitoring, independent radiation surveys, emergency procedures, radiation safety committee meeting minutes, and annual radiation safety program audits.

5.2 Observations and Findings

a. Storage of Licensed Materials

During an observation of licensed materials in storage at the Southlake Campus, the inspector identified a strontium-90 (Sr-90) eye applicator. Title 10 CFR 30.34(c) requires licensees to confine their possession and use of byproduct material to the locations and purposes authorized in the license. While the possession and use of a strontium-90 eye applicator was authorized on the license, it was not authorized for possession and use, which includes storage, at the Southlake campus. License Condition 10 A. of NRC License No. 13-16558-01, Amendment No. 66 requires, in part, that the licensed materials listed in Subitems 6.A through 6.E., and 6.G through 6.L. may be used or stored at Methodist Hospital – Southlake Campus, 8701 Broadway, Merrillville, Indiana. The Sr-90 eye applicator was authorized under Subitem 6.F., which was not authorized at the Southlake Campus. The Sr-90 was only authorized to be stored at Northlake Campus at 600 Grant Street in Gary, Indiana. The licensee's possession of a Sr-90 eye applicator at the Southlake Campus is a violation of 10 CFR 30.34(c) and License Condition 10 A.

The inspector determined that the root cause of the violation was an oversight on the part of the licensee during the license renewal process. During the licensee's

preparation of its renewal application, the licensee was in transition between RSOs and an interim, temporary RSO was handling the renewal request and inadvertently left the request for authorization for the Sr-90 eye applicator at the Southlake Campus off the application. The inspector noted that the previous license amendment, numbered 65, authorized the licensee to use and store Sr-90 in Subitem 6.F at both locations. However, as a result of the omission during the license renewal process, the authorization was removed from the license that was in effect at the time of the inspection (Amendment No. 66).

As corrective action, the licensee submitted a license amendment request to the NRC on October 16, 2015. The NRC issued the amended license, authorizing the possession and use of Sr-90 at the Southlake Campus, on October 23, 2015.

b. Occupational Dose Monitoring

The inspector observed that selected licensee staff members at both locations of use donned personnel dosimeters as required. The inspector noted that monitored nuclear medicine staff members at Northlake Campus received annual maximum doses of 336 millirem (mrem) to the whole body and 337 mrem to the extremities between 2013 and May 2015. In addition the inspector noted that monitored radiation oncology department staff members received annual maximum doses of 22 mrem to the whole body and 57 mrem to the extremities between 2013 and 2014.

c. Independent Radiation Surveys

The inspector conducted independent ambient exposure rate surveys of selected areas at both locations of use using an NRC-owned Ludlum Model 2403 survey meter. The inspector measurements were consistent with the licensee's survey results and within regulatory limits.

d. Radiation Safety Committee Minutes and Annual Radiation Safety Program Audits

The inspector reviewed the radiation safety committee minutes and the annual radiation safety program audits by an outside consultant every quarter, with no issues noted.

5.3 Conclusions

a. The inspector identified a violation of 10 CFR 30.34(c) and Condition 10 A. of NRC License No. 13-16558-01, Amendment No. 66, for the licensee's failure to confine its possession and use of byproduct material to the locations and purposes on the license. The licensee implemented corrective actions to restore compliance.

6 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on October 13 and October 14, 2015. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. A final telephonic exit meeting was conducted on March 10, 2016. The licensee acknowledged the findings presented.

SUPPLEMENTAL INFORMATION

LIST OF PERSONNEL CONTACTED

#* Wright Alcorn, Vice President of Operations
James Concato, Director of Oncology
#* Laurel Valentino, RN, Director of Neuroscience
#* Mathew Rodriguez, Radiation Safety Officer

Attended preliminary exit meeting on October 14, 2015
* Participated in the final telephonic exit meeting on March 10, 2016.

INSPECTION PROCEDURES USED

87131: Nuclear Medicine Programs, Written Directive Required
87132: Brachytherapy Programs
87133: Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs