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

March 10, 2016

Mr. Bruce Backus, Assistant Vice Chancellor,
Environmental Health & Safety
Washington University in St. Louis
Campus Box 8053
660 S. Euclid Avenue
St. Louis, MO 63110-1093

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002271/2016001(DNMS) AND NON-CITED VIOLATION – WASHINGTON UNIVERSITY IN ST. LOUIS

Dear Mr. Backus:

On January 25, 2016, through January 29, 2016, with continued in-office review through February 10, 2016, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your St. Louis, Missouri campus. 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. Mr. Robert Gattone of my staff conducted a final exit meeting with Sue Langhorst of your staff on February 10, 2016, to discuss the inspection findings. The in-office review included information that was unavailable during the onsite inspection, including information about the uninterrupted power supply in a Perfexion device.

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, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated 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 violation is being treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy.

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

Information regarding the NCV is provided in the publicly available Safety Inspection Record (Enclosure 1). Information regarding security inspection findings are provided in the non-publicly available Security Inspection Record (Enclosure 2).

If you contest the violation or significance of the NCV, you should provide a response within 30 days of the date of this letter, with the basis for your denial, to the NRC, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region III; and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

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 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, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

Please feel free to contact Robert Gattone of my staff if you have any questions regarding this matter. Mr. Gattone can be reached at 630-829-9823.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-02271
License No. 24-00167-11

Enclosures:
1. Safety Inspection Record (public)
2. Security Inspection Record (non-public)

cc w/encls: Sue Langhorst, Ph.D., Radiation
Safety Officer
cc w/o encl 2: State of Missouri

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1. Safety Inspection Record (public)
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cc w/encls: Sue Langhorst, Ph.D., Radiation Safety Officer
cc w/o encl 2: State of Missouri

DISTRIBUTION w/encls:
Darrell Roberts
John Giessner
Christine Lipa
Richard Skokowski
Carole Ariano
Paul Pelke
Carmen Olteanu
Jim Clay
MIB Inspectors

ADAMS Accession Number: ML16070A225

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OFFICE	RIII-DNMS		RIII-DNMS		RIII-EICS		RIII-EICS	
NAME	RGattone:ps		DO'Dowd		RSkokowski		AMcCraw	
DATE	3/8/2016		3/8/2016		3/9/2016		3/10/2016	

OFFICIAL RECORD COPY

SAFETY INSPECTION RECORD

Region: III **Inspection Report No.** 2016-001 **License No.** 24-00167-11
Docket No. 030-02271

Licensee: Washington University in St. Louis
660 S. Euclid Avenue
St. Louis, MO

Locations Inspected: Various facilities on the campus of Washington University in St. Louis in St. Louis, MO

Licensee Contact: Sue Langhorst, RSO **Telephone No**. 314-362-2988

Program Code: 02110 **Priority**: 2

Type of Inspection: ( ) Initial (X) Routine (X) Announced
( ) Special ( ) Unannounced

Last Routine Inspection Date: 11/3-7/14 **Date of This Inspection**: 1/25-29/16, with continued in-office review through 2/10/16

The in-office review included information that was unavailable during the onsite inspection, including information about the uninterrupted power supply in a Perfexion device.

Next Inspection Date: 1/25/17 ( ) Normal (X) Reduced

Justification for reducing the routine inspection interval: In accordance with RIII's initiative, the licensee will be inspected annually such that the full scope of the inspection is completed biennially.

Summary of Findings and Actions:

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
(X) Non-cited violation (NCV)
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspectors: Robert G. Gattone, Jr., Senior Health Physicist

/RA/ Date 3/8/2016
Signature

Dennis O'Dowd, Health Physicist

/RA/ Date 3/8/2016
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA/ Date 3/10/2016
Signature

Enclosure 1

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
81	11/20/14	Approved alternative training and experience for "Review of a Specific Medical Authorized User of the Perfexion Gamma Stereotactic Radiosurgery Unit"
82	12/17/14	Approved transfer of generally licensed sources contained within devices originally obtained under 10 CFR 31.5 for the purpose of decommissioning devices and the disposal of the general licensed sources
83	3/25/15	Removed J.L. Shepherd Model Mark I Series Submodel 25 irradiator
84	6/9/15	Approved new radioactive waste facility
85	7/24/15	Approved commercial radiopharmacy distribution
86	11/4/15	Approved for not doing monthly checks of the ViewRay multi-leaf collimator speed

2. INSPECTION AND ENFORCEMENT HISTORY:

On January 13, 2015, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the license's facilities in St. Louis, Missouri with continued in-office review through February 2, 2015, with a focus on nuclear medicine activities. No violations were identified.

On November 3 through 7, 2014, inspectors from the NRC conducted a routine inspection at the licensee's facilities in St. Louis, Missouri, with continued in-office review through December 22, 2014. No violations were identified.

On October 21 through 25, 2013, inspectors from the NRC conducted a routine inspection at the licensee's facilities in St. Louis, Missouri. No violations were identified.

3. INCIDENT/EVENT HISTORY:

Perfexion Treatment Incident

During this inspection, the inspectors noted that the licensee had an event involving patient intervention during a Perfexion gamma stereotactic radiosurgery treatment (treatment). On October 7, 2014, at about 37 minutes into the patient's treatment, the patient complained of a headache. In response, the licensee paused the treatment that shielded all of the sealed sources in preparation for administering pain medication to the

patient. As the Perfexion patient table was moving out of the treatment position, the patient intervened by removing his head from the stereotactic frame. The prescribed dose was 18 Gray (Gy) to 50 percent of the target volume.

As a result of the patient's intervention, 15 Gy was delivered to 50 percent of the target volume. The authorized user physician (AU) consulted the patient and the patient's wife, and a decision was made that no further radiotherapy would be given to the patient. The AU determined that the treatment dose was delivered to the intended target volume and under dosed due to patient intervention.

The licensee considered the need to notify the NRC about this event and noted 10 CFR 35.3045(b) that states, "A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician." The licensee determined that the event did not need to be reported to the NRC because the AU determined that the treatment dose was delivered to the intended target volume and under dosed due to patient intervention, and the event did not result in unintended permanent functional damage to an organ or a physiological system.

Viewray Software Issue

The Viewray written directives and the treatment information were generated using Viewray's "MRIDIAN" software (software). During a Viewray pre-treatment check, a licensee therapist identified that a written directive dated May 30, 2014, did not include the last gantry angle position. The therapist identified the issue by comparing the written directive with the treatment information and noted that the last gantry angle position was entered into the software but it did not get entered into the written directive.

Prior to the first treatment fraction, the written directive was modified to add the missing gantry angle position and the patient was treated without incident. In addition, the licensee instructed applicable staff that they must compare the gantry angle positions on the written directive with the treatment information to verify that the written directive contains all of the gantry angle positions prior to the first treatment fraction.

The licensee also contacted Viewray to report the issue. Viewray subsequently determined that the cause of the issue was that the software limited text characters to three lines for the gantry angle positions for the written directive resulting in truncating the last gantry angle position which exceeded the three line limit. In November 2014, Viewray issued MRIDIAN "Customer Release Notes – 3.6" that includes Item 2.10 which states, "Beam Angle Groups Summary page on the Plan Summary PDF displays all the beams when there are a large number of beams without cutting any off the report" as a means of communicating completion of the software fix for the text limitation issue.

Based on the inspectors' review of selected patient treatment records, the licensee's actions to prevent discrepancies of the gantry angle positions in the written directive versus the treatment information was successful. In addition, the inspectors noted that the aforementioned software fix was successful based on the inspectors' review of

selected written directives that had more than three lines of text for the gantry angle positions.

No other incidents or events were identified during this inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The Radiation Safety Officer/Radiation Safety Director reported to the Assistant Vice Chancellor for Environmental Health and Safety. The radiation safety personnel were supervised by 2 health physicists, who reported to the Associate RSO. The licensee's radiation safety staff included 13 full-time technical staff who were assigned specific duties relating to the radiation safety program to ensure compliance with NRC regulatory requirements.

The licensee has a very large, active, Type A broad scope medical program. The licensee is a privately owned and operated university with approximately 14,000 students, 3,000 faculty members, and about 700 research laboratories approved for radioactive material use. Washington University and Medical Center has approximately 270 authorized users of licensed radioactive material. The licensee has a Radiation Safety Committee that approves a variety of uses including medical diagnostic and therapeutic procedures, human research, and non-human research and development.

The license authorized the use of byproduct materials with Atomic Numbers 1-83 and transuranics (Atomic Numbers 84-103) for medical diagnosis, therapy and research in humans; and non-medical research and development (including animal studies), instrument calibration, student instruction, and in-vitro studies. In addition, the license authorized the use of: (1) two remote afterloader brachytherapy devices for physics quality assurance testing, dosimetry measurements, medical use (including research in humans) and irradiation of animals; (2) four self-shielded irradiators for the irradiation of various materials, including blood and blood products; (3) a Leksell Gamma Stereotactic Radiosurgery Unit (a.k.a. Gamma Knife Perfexion) for the treatment of humans, human research studies, and non-human research studies (including animal studies); and (4) a ViewRay device for medical use, research and development (including animal studies), prototype testing, and calibration.

The licensee has a commercial nuclear pharmacy for PET radiopharmaceuticals.

The licensee possessed, used, and stored radioactive material at two research facilities; Danforth Campus (including Tyson Research Center) and Washington University School of Medicine. In addition, the licensee used licensed material at six Washington University Medical Center facilities which include Barnes-Jewish Hospital, Heart Care Institutes, St. Louis Children's Hospital, Washington University School of Medicine, and Howard Hughes Medical Institute.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87126, 87134, 87137, TI 2800/042

Focus Areas Evaluated: All

The focus of this inspection was security, medical use, commercial radiopharmacy activities, use of a new radioactive waste facility, general licensed devices transfer and disposal, irradiator safety, and dosimetry.

The inspectors toured various facilities at the Washington University campus, including Barnes-Jewish Hospital, St. Louis Children's Hospital, Washington University School of Medicine, and the new radioactive waste facility, to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspectors observed licensee staff conduct and demonstrate implementation of various licensee procedures regarding safe use of self-shielded irradiators, remote and manual brachytherapy treatment planning and administration, ordering of radioactive material, liquid radioactive waste management and disposal, decommissioning, and closeout activities.

The inspectors observed a prostate seed implant treatment involving the administration of 83 iodine-125 radioactive seeds, three HDR remote brachytherapy therapies using iridium-192, 250 mCi of sodium iodine-131, and a cardiac imaging procedure using technetium-99m. In each case, the inspectors observed preparations prior to carrying out the procedure and post-procedure activities, including completion of surveys.

The inspectors interviewed several licensee employees and found that they were knowledgeable about radiation protection principles, licensee procedures and regulatory requirements. The inspectors observed: (1) that licensed material was secured from unauthorized access or removal; (2) that shielding was used to reduce radiation exposure; (3) that package receipt surveys were done as required; (4) licensee personnel conduct ambient dose rate and contamination surveys using calibrated survey instruments; (5) staff members assay dosages prior to administration of millicurie quantities of iodine-131, yttrium-90 microspheres, and technetium-99m; and (6) that licensee staff followed the licensee's procedure prohibiting chewing gum, eating, or drinking in the restricted areas.

The inspectors reviewed selected licensee audit records pertinent to medical use of the Perfexion device, the Viewray device, yttrium-90 microspheres, high dose rate remote afterloader devices, and 10 CFR 35.300 and 35.200 activities.

The inspectors also reviewed a selection of records related to the aforementioned aspects of the licensee's program, including annual audit records; irradiator safety checklists; written directives and treatment planning documents for high dose rate brachytherapy, manual brachytherapy, iodine-125 eye plaque brachytherapy, and yttrium-90 microspheres therapy; written directives and associated documents relative to therapeutic and diagnostic radiopharmaceuticals including administrations of sodium iodide-131 capsules, Xofigo (radium-223 dichloride), yttrium-90 (Zevalin), and samarium-153 (Quadramet); purchase orders for radioactive material; package receipt documents, including survey results; solid and liquid waste disposal records; closeout survey records of decommissioned locations of use; and Radiation Safety Committee meeting minutes and authorizations for radioactive material use and various routine records related to past use of radioactive materials for medical and research purposes.

The inspectors also reviewed selected records of management oversight including Radiation Safety Committee meeting minutes and selected physician authorized user approvals and the bases for the approvals.

Perfexion Treatments

The inspectors observed an authorized medical physicist (AMP) demonstrate how he had checked Perfexion treatment plans prior to treatment. The inspectors noted that, prior to approval of the treatment plans and export to the Perfexion console, all treatment plans have contoured tumor volumes without viewing the isodose curves for each tumor to be treated, and each shot location is verified by the AMP and the authorized user physician (AU) or neurosurgeon. The inspectors observed that prior to treatment, applicable staff compared the treatment plan with the treatment information that was exported to the Perfexion unit to verify that the Perfexion unit was set to treat in accordance with the written directive and the treatment plan.

The inspectors observed a treatment using the Perfexion unit. The staff conducted dual, independent verification of the patient's identity prior to treatment. The inspectors observed applicable staff members conduct dual, independent verification of the details of each shot prior to starting each shot. The inspectors observed applicable staff members conduct dual, independent verification of the details of each shot as soon as each shot was started. If the next shot is started and an error is identified, the staff would pause the treatment and consult the AU before proceeding with the treatment. The inspectors observed that, during treatment an illuminated "Radiation In Use" source position indicator was operable at the vault door. The patient was monitored by audio and video surveillance. The inspectors noted that a calibrated ion chamber was available at the Perfexion console during the treatment. The inspectors noted that after treatment, applicable staff conducted dual, independent verification of the treatment plan with the treatment information that was implemented by the Perfexion unit to verify that the treatment was implemented in accordance with the written directive and the treatment plan.

The inspectors reviewed selected records of Perfexion treatments, including written directives, treatment plans, post treatment printouts, and other records.

Viewray Treatments

During the onsite inspection, the Viewray device was out of commission.

The inspectors observed a physicist demonstrate how pre-treatment checks were done for gated Viewray treatments. The inspectors noted that the checks included, in part, verification of complete written directives, gantry angle positions, beam on times, patient identity by 3 different means, treatment site, and the video of the planned treatment including the regions of interest.

The inspectors observed a physicist demonstrate how gated Viewray treatments were monitored during the treatments. The inspectors noted that the Viewray operator viewed the live video of the treatment to verify, in part, that the beam(s) go off and on as planned and the multi-leaf collimators are configured as planned.

The inspectors observed a physicist demonstrate how gated Viewray treatments were checked after treatment. The inspectors noted that the checks included, in part, the gating parameters, the beam on times for each gantry angle position, and the total time of the treatment from start to finish. In addition, the Viewray system monitors itself to identify treatment issues that occur during treatments and communicates the issues to the operator.

Dosimetry

The inspectors observed that radiation oncology, nuclear medicine, and radiation safety staff members wore whole body dosimeter badges. The inspectors noted that licensee staff members wore extremity dosimeters with the TLD on the palm side of the dominant hand, as applicable.

The inspectors reviewed 2014 dosimeter badge records showing that the maximum whole body and extremity occupational doses were 1,200 millirems (mrems) and 13,610 mrems, respectively. The 2015 dosimeter badge records through December 15, 2015, showed that the maximum whole body and extremity occupational doses were 1,097 mrems and 8,328 mrems, respectively. Records of bioassays for radioiodine in 2014 showed that the highest thyroid dose was 9 mrems in 2014, and 17 mrems in 2015.

Commercial Radiopharmacy Distribution

The inspectors observed applicable staff demonstrate how commercial radiopharmacy activities had occurred (only once) on October 8, 2015. The inspectors noted that a fluorine-18 radiopharmaceutical was shipped using the Biodex Compact PET Shipping System for One Unit Dose Pig, as required. The package was marked and labeled as required, the syringe shield was as required, and a tamper evident seal was used. The licensee used a proper shipping paper that included a proper emergency phone number. Prior to shipment, the licensee obtained the applicable Agreement State's license for the recipient to verify that the recipient was authorized for the material. The licensee did not receive any radioactive waste from the customer.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspectors used NRC owned, calibrated survey instruments to measure a maximum of 1.5 milliroentgens per hour (mR/hr) at selected surfaces of the Perfexion device, 9 mR/hr at the surface of a package labeled Yellow II containing iodine-131 in a nuclear medicine hot lab, and less than 2 mR/hr at selected surfaces in a nuclear medicine hot lab.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Title 10 *of the Code of Federal Regulations* (CFR) 35.40(a) requires that a written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries (µCi), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

Title 10 CFR 35.40(b) requires that a written directive must contain the patient or human research subject's name and the following information: (1) For any administration of quantities greater than 30 µCi of sodium iodide I-131: the dosage; (2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration; (3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site; (4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site; (5) For high dose-rate remote afterloader brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or (6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders: (i) Before implantation: treatment site, the radionuclide, and dose; and (ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

Title 10 CFR 35.40(c) requires that a written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

Condition 29 of Amendment No. 86 of NRC License No. 24-00167-11 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in a list of documents, including any enclosures. One of those listed documents is a letter dated November 15, 2013, which states, in part, that written directives and modifications to those written directives will meet the requirements of 10 CFR 35.40 and the written directive requirements as stated in the NRC ViewRay System licensing guidance (guidance). The guidance dated July 24, 2013, Revision 0 states, in part, that, “For the ViewRay System use, the written directive will contain the patient or human research subject’s name; the total dose, dose per fraction, number of fractions; isocenter and gantry angle positions, and treatment site.”

The following are examples of failing to meet the above requirements:

On November 20, 2014, an authorized user revised a ViewRay treatment by changing the number of treatment fractions from 19 to 14; however, the licensee identified that the authorized user revised the applicable written directive and did not sign or date it before administration. The inspectors determined that the cause of the violation was oversight. As corrective action, the licensee initiated reviews of Viewray patient records, including written directives, to verify that they are completed and signed as required. Based on the inspectors’ review of selected patient treatment records, the licensee’s actions to prevent incomplete, revised Viewray written directives were successful.

Three written directives for therapeutic doses of yttrium-90 TheraSpheres™ microspheres treatments, were not dated before the respective administrations. On January 16, 2014, and two occurred on January 30, 2014. During a quarterly radiation safety audit by the licensee conducted on February 3, 2014, the licensee identified the aforementioned written directives for the two treatments that occurred on January 30, 2014, which had not been dated by the authorized user (AU) before the

respective administrations. The inspectors determined that the root cause of the violations was oversight, with a contributing cause being the absence of a prompt for the date on the written directive form.

Upon identification of this issue, the licensee initiated immediate corrective action by adding a prompt for the date on the written directive form for yttrium-90 treatments. Licensee staff, including the AUs involved in the procedure, were notified of the need for the written directive to be dated, as required. Licensee staff, including the AUs involved in the procedure, were notified of the need for the written directive to be dated, as required.

Based on the inspectors' review of selected patient treatment records, the licensee's actions to prevent incomplete yttrium-90 microspheres written directives were successful.

The inspectors identified the third aforementioned incomplete written directive for an yttrium-90 TheraSpheres treatment that was administered on January 16, 2014, in that it also had not been dated by the AU before the respective administration. The inspectors noted that although the licensee did not identify this incomplete written directive during the audit conducted on February 3, 2014, this written directive was signed two weeks prior to the two that it had identified as being incomplete. The licensee provided documentation that the AU had reviewed and approved the parameters contained in the written directive as part of the treatment planning process for each of the aforementioned cases. The AU reviewed and verified that the orders for yttrium-90 microspheres were correct. Although the AU did not date the directives prior to each administration, he signed each written directive prior to entering the treatment room where the yttrium-90 microspheres administration took place, and was physically present when the yttrium-90 microspheres were administered. Finally, the three cases represented 1.7% of the total cases requiring a written directive that the licensee had performed in 2014.

On June 3, 2014, a written directive for an administration of a quantity greater than 30 µCi of sodium iodide I-131 did not contain the dosage, as required. Specifically, a written directive was incomplete in that it did not indicate the dosage of sodium iodide I-131 to be administered for an imaging procedure in the Nuclear Medicine Department of the Washington University Medical Center South Campus.

During a quarterly radiation safety audit conducted on July 18, 2014, the licensee identified the aforementioned written directive for the imaging procedure that did not contain the dosage to be administered. The licensee noted that the assayed activity and administered activity were recorded on the written directive and were in agreement. The inspectors determined that the root cause of the violation was oversight. As corrective action, upon identification of this issue, the licensee initiated immediate action by notifying the chief Nuclear Medicine Technologist upon discovery of the incomplete written directive on July 18, 2014. The omission was brought to the attention of the AU and the chief nuclear medicine technologist, who were reminded to review the completeness of all written directives prior to administration. The AU corrected the written directive, and initialed and dated the correction, on July 22, 2014. Information regarding this issue was shared with the primary AU for that department, as well as all of the nuclear medicine department staff who were reminded to ensure that all written

directives are complete prior to administration. The department's primary AU was notified officially in writing by the licensee of this finding.

During the inspection, the licensee provided to the inspectors documentation supporting that: (1) the written directive was clearly marked as an adult imaging study that called for a 5.0 millicuries (mCi) dosage of I-131 in accordance with standard departmental dosage for imaging procedures with I-131; (2) the Authorized User (AU) had reviewed and verified the order for the intended dosage of 5 mCi prior to submitting the order for the dosage; (3) the AU confirmed the activity of the dosage prior to administration to the patient; and (4) the AU was physically present during the administration of the dosage, as is standard departmental procedures for administrations requiring a written directive. Through interviews with the licensee staff and review of the documentation provided, including the written procedure for whole body I-131 scintigraphy (dated August 15, 2011), and the Nuclear Medicine Radiation Safety Review/Quarterly Inspection (dated August 13, 2014), the inspectors verified the accuracy of the information provided, as well as the licensee's corrective action. Based on the inspectors' review of selected patient records, this was an isolated occurrence, and the licensee's actions to prevent incomplete I-131 written directives were successful. Finally, there were 658 I-131 procedures in 2014; this one incident represents 0.2% of the total procedures performed in 2014.

This non-repetitive, licensee-identified and corrected violation of 10 CFR 35.40 is being treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the NRC Enforcement Policy.

5. PERSONNEL CONTACTED:

Michael Altman, Ph.D., Medical Physicist
Bruce Backus, Assistant Vice Chancellor, EH&S
Caroline Bradfield, Radiation Therapist
Jeffrey Bradley, M.D., Authorized User
Anapuma Chundury, M.D., Medical Resident
Briana Davis, Health Physicist II
Jeanette Davis, Public Safety Communicator
Casey Delf, Programmer/Analyst II
Daniel Doenges, Health Physicist I
Jacqueline Esthappan Zoberi, Ph.D., Medical Physicist
Eric Filliput, Registered Nurse
Jose Garcia-Ramirez, M.S., Medical Physicist
Jim Gebken, Human Resource Specialist
Olga Green, Medical Physicist
Perry Grigsby, M.D., Authorized User
Sue Langhorst, RSO
Dave Luechtefeld, Health Physicist I
Jeff Michalski, M.D., Authorized User, Vice Chair and Director of Clinical Programs
Reiko Oyama, Authorized Nuclear Pharmacist
Ellen Oza, Radiation Therapist
Clifford Robinson, M.D., Physician Authorized User
Al Schall, Public Systems

PERSONNEL CONTACTED:

Kevin Sharkey, Clinical Physics Coordinator
W. John Smith, Associate RSO
Delynn Silvestros, CNMT, Nuclear Medicine Technologist in Charge
Dan Szatkowski, Health Physicist
Sridhar Yaddanapudi, Authorized Medical Physicist
Jackie Zoberi, Medical Physicist