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

January 29, 2016

EA-15-269

Mr. Terrance Alexander, Executive Director
The Regents of the University of Michigan
Radiation Safety Service
1239 Kipke Drive
Ann Arbor, MI 48109-1010

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03001988/2015001(DNMS) AND NOTICE OF VIOLATION – THE REGENTS OF THE UNIVERSITY OF MICHIGAN

Dear Mr. Alexander:

On October 26, 2015, through October 30, 2015, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Ann Arbor, Michigan campus, with continued in-office review through January 6, 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, in part, receipt and review of information that was unavailable during the onsite inspection, including information about personal contamination events. Messrs. Robert Gattone and Ryan Craffey of my staff conducted a final exit meeting by telephone with Mr. Mark Driscoll and several other members of your staff on January 6, 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, the NRC has determined that four Severity Level IV violations of NRC requirements occurred. The violations were 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. Three violations are safety-related and one of the violations is security-related. One of the safety-related violations

Enclosures 2 and 4 contain Sensitive Unclassified Non-Safeguards Information. When separated from Enclosures 2 and 4, the transmittal letter and Enclosures 1 and 3 are decontrolled.

is cited in the enclosed Notice of Violation (Notice 1) (Enclosure 1). The security-related violation is cited in the enclosed Notice of Violation (Notice 2) (Enclosure 2). Details of the security violation are available in the enclosed, non-public Security Addendum (Enclosure 4). The NRC is citing these two violations in the enclosed Notices because the inspectors identified them. The other two safety-related violations are being treated as Non-Cited Violations (NCVs), consistent with Section 2.3.2 of the Enforcement Policy. Information regarding the NCVs is provided in the publicly available Inspection Record (Enclosure 3).

You are required to respond to this letter and should follow the instructions specified in the enclosed Notices when preparing your response. 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. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

Because the security-related violation is cited in Notice 2, your response to Notice 2 will not be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Document Access and Management System (ADAMS). Please mark the top of each page of your response "Security-Related Information – Withhold Under 10 CFR 2.390". To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information.

Please feel free to contact Mr. Gattone of my staff if you have any questions regarding this inspection. 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. 03001988
License No. 21-00215-04

Enclosures:
1. Notice of Violation (public)
2. Notice of Violation (non-public)
3. Inspection Record (public)
4. Security Addendum (non-public)

cc w/encls: Mark Driscoll, Radiation Safety Officer
bcc w/o encls 2 & 4: State of Michigan

is cited in the enclosed Notice of Violation (Notice 1) (Enclosure 1). The security-related violation is cited in the enclosed Notice of Violation (Notice 2) (Enclosure 2). Details of the security violation are available in the enclosed, non-public Security Addendum (Enclosure 4). The NRC is citing these two violations in the enclosed Notices because the inspectors identified them. The other two safety-related violations are being treated as Non-Cited Violations (NCVs), consistent with Section 2.3.2 of the Enforcement Policy. Information regarding the NCVs is provided in the publicly available Inspection Record (Enclosure 3).

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Aaron T. McCraw, Chief
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cc w/encls: Mark Driscoll, Radiation Safety Officer
bcc w/o encls 2 & 4: State of Michigan

**ADAMS Accession Number: ML16032A413**

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|---|---|---|---|---|---|---|---|---|
| NAME | RGattone:ps | | RCraffey RGattone for | | RSkokowski | | AMcCraw | |
| DATE | 1/21/2016 | | 1/21/2016 | | 1/21/2016 | | 1/29/2016 | |

**OFFICIAL RECORD COPY**

Letter to Terrance Alexander from Aaron Mccraw dated January 29, 2016

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03001988/2015001(DNMS) AND NOTICE OF VIOLATION – THE REGENTS OF THE UNIVERSITY OF MICHIGAN

DISTRIBUTION w/encl:
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NOTICE OF VIOLATION

The Regents of the University of Michigan
Ann Arbor, Indiana

License No. 21-00215-04
Docket No. 03001988
EA-15-269

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 26, 2015, through October 30, 2015, with continued in-office review through January 6, 2016, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (CFR) 20.1502 requires that licensees shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part.

Title 10 CFR 20.2106(a) requires that licensees shall maintain records of doses received by all individuals for whom monitoring was required pursuant to § 20.1502, and records of doses received during planned special exposures, accidents, and emergency conditions. These records must include, in part, the shallow-dose equivalent to the skin and the shallow-dose equivalent to the extremities.

Title 10 CFR 20.2106(c) requires that licensees shall maintain the records specified in paragraph (a) of this section on NRC Form 5, in accordance with the instructions for NRC Form 5, or in clear and legible records containing all the information required by NRC Form 5. The instructions for NRC Form 5 include for Item 13, "Enter the shallow dose equivalent recorded for the skin of the whole body". The instructions for NRC Form 5 include for Item 14, "Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose".

Contrary to the above, as of October 30, 2015, the licensee did not maintain the records specified in paragraph (a) of this section on NRC Form 5, in accordance with the instructions for NRC Form 5, or in clear and legible records containing all the information required by NRC Form 5. Specifically, on November 13, 2014, a radiation worker's finger was contaminated with licensed material. Based on measurements and calculations, the licensee determined that the shallow-dose equivalent to the extremities was 0.890 rem; however, the licensee entered 0.610 rem in Item 14 of the individual's NRC Form 5 for 2014. In addition, on December 17, 2014, a radiation worker's face and hair next to an ear was contaminated with licensed material. Based on measurements and conservative calculations, the licensee determined that the ear skin dose was 16.513 rems and the skin dose of the face was 9.652 rems; however, the licensee entered 0.430 rem in Item 13 of the individual's NRC Form 5 for 2014.

This is a Severity Level IV violation (Section 6.7.d.).

Enclosures 2 and 4 contain Sensitive Unclassified Non-Safeguards Information. When separated from Enclosures 2 and 4, the transmittal letter and Enclosures 1 and 3 are decontrolled.

Pursuant to the provisions of CFR 2.201, The Regents of the University of Michigan is hereby required to submit a written statement or explanation 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). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or its severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously 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.

Your response 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. Therefore, to the extent possible, the 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 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 of receipt.

Dated this 29th day of January, 2016.

INSPECTION RECORD

**Region**: III **Inspection Report No.** 2015-001 **License No.** 21-00215-04
**Docket No.** 030-01988
**EA-15-269**

**Licensee**: The Regents of the University of Michigan, Radiation Safety Service
1239 Kipke Drive
Ann Arbor, MI 48109-1010

**Locations Inspected**: Various facilities on the campus of the University of Michigan in Ann Arbor, MI

**Licensee Contact**: Mark Driscoll, RSO **Telephone No**. 734-647-2251

**Program Code**: 02110 **Priority**: 2

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

**Last Inspection Date**: 06/23-27/2014 **Date of This Inspection**: 10/26/2015 - 10/30/2015, with continued in-office review through 1/6/16

The in-office review included receipt and review of information that was unavailable during the onsite inspection including information about doses resulting from personal contamination events.

**Next Inspection Date**: 10/26/2016 ( ) 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.

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Enclosure 3

**Summary of Findings and Actions:**

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

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

***/RA by Aaron T. McCraw for/*** Date ***01/29/2016***
*Signature*

Ryan J. Craffey, Health Physicist

***/RA by Aaron T. McCraw for/*** Date ***01/29/2016***
*Signature*

Approved: Aaron T. McCraw, Chief, MIB

***/RA/*** Date: ***01/29/2016***
*Signature*

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

| AMENDMENT # | DATE | SUBJECT |
|---|---|---|
| 103 | 4/24/15 | Added a License Condition requiring that, if abnormal radiation levels or any malfunctions of a J. L. Shepherd and Associates, Mark I Cesium-137 irradiator are detected at any time, the licensee shall cease using the irradiator, restrict access to the area housing the irradiator, immediately notify the Radiation Safety Officer, and submit reports required under 10 CFR Parts 20, 21, or 30. |

2. INSPECTION AND ENFORCEMENT HISTORY:

On June 23, 2014, through June 27, 2014, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at the license's facilities in Ann Arbor, Belleville, and Dearborn, Michigan, with continued in-office review through August 5, 2014. As a result, the NRC cited one Severity Level IV violation of a security-related nature.

On February 11, 2014, an NRC inspector conducted a follow up escalated enforcement inspection which resulted in closure of the 3 violations that were identified during the previous inspection. In addition, the inspector followed up on a reported leaking source event. No violations were identified.

On June 24, 2013 through June 28, 2013, NRC inspectors conducted a routine inspection that resulted in two Severity Level Ill violations, a civil penalty, and a Severity Level IV violation. The violations were security-related.

3. INCIDENT/EVENT HISTORY:

On May 1, 2015, the licensee informed an NRC inspector that on August 6, 2014, an Authorized User Physician (AU) intended to prescribe 4 millicuries (mCi) of liquid I-131 to a patient who did not have an intact thyroid gland. The AU entered 1 mCi on the written directive (WD) by mistake. When a nuclear medicine technologist (NMT) overlooked that the WD stated 1 mCi, the NMT presumed that the AU meant to prescribe 4 mCi per the normal amount per the protocol; therefore, the NMT administered 4 mCi of liquid I-131 to the patient. On September 1, 2014, an authorized nuclear pharmacist did a review of selected cases and identified that the patient received greater than 20% more dosage than what was prescribed on the WD. The licensee conducted dose assessments to determine if the dose thresholds in 10 CFR 35.3045 were exceeded and determined that the highest dose to an organ or tissue as a result of the administration was 12 rem to the urinary bladder and the whole body dose was 352 millirems. On September 8, 2014, the AU learned about the issue and made a record that he/she intended to enter 4 mCi on the WD.

The inspector informed the RSO about the potential violation of 10 CFR 35.63(d) because it involved using a dosage when the dosage differed from the prescribed dosage by more than 20 percent. In addition, the inspector discussed with the RSO the benefit of informing applicable staff that, if they see a prescribed dose that they think is odd or incorrect, they should not presume that they know what the physician wants to give the patient and subsequently administer material per their presumption, contrary to the written directive. Rather, if they see a prescribed dose that they think is odd or incorrect, they should stop and inquire with the AU to verify what the AU is prescribing and administer what the AU prescribes.

The inspectors followed up on the event during the inspection by interviewing selected licensee staff and reviewing selected records. See Part II, Section 4 of this record for more information.

**PART II - INSPECTION DOCUMENTATION**

1. ORGANIZATION AND SCOPE OF PROGRAM:

The licensee is authorized under the U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-00215-04 to conduct medical broad scope activities that includes use of licensed material by individuals designated by the licensee's Radiation Policy Committee (RPC). The licensee maintained a student population of approximately 42,000 at the main campus in Ann Arbor, Michigan. The license also authorizes licensed activities to be conducted at facilities in Dearborn, Flint, Belleville, and Pellston, Michigan. The licensee's RPC had designated approximately 350 individuals as Authorized Users, and about 1,500 people worked as Supervised Users. The licensee utilized licensed materials for medical applications and research and development.

The licensee's Radiation Safety Service (RSS), led by the RSO was located within its Occupational Safety & Environmental Health (OSEH) department. The OSEH department was overseen by an Executive Director, who reported to the Associate Vice President for Facilities and Operations. Approximately 13 staff members worked in the RSS. The RSS staff conducted instrument calibrations, conducted leak tests, and reviewed authorized user applications. The RSS technicians were involved with package delivery and receipt, laboratory reviews, confirmatory surveys, laboratory close-out, and assistance to research and development staff regarding radiation safety matters.

Medical use was conducted at the University of Michigan Hospital, Cardiovascular Center, C.S. Mott Children's Hospital, and Von Voigtlander Women's Hospital. At the University of Michigan Hospital, the licensee used licensed materials under the authorities of Title 10 of the *Code of Federal Regulations* (CFR) 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000. Radiopharmaceutical therapies included iodine-131 metaiodobenzylguanidine (MIBG) human research cancer treatments at the University of Michigan Hospital. Manual brachytherapy activities included iridium-192 ribbons for cervical and lip cancer treatments at the University of Michigan Hospital, iodine-125 seeds for ocular melanoma treatments, and yttrium-90 TheraSpheres® for neuroblastoma treatments at the Cardiovascular Center. The University of Michigan

Hospital also contained a blood bank that utilized a self-shielded irradiator for irradiating biological materials.

Radioactive materials for research and development were located at approximately 1200 laboratories within a few dozen buildings. Research and development activities were trending down and primarily involved biological research with millicurie quantities of carbon-14, hydrogen-3, iodine-125, phosphorus-32, and sulfur-35. Occasional iodine-125 iodinations were done with 5 to 10 millicuries. The licensee used phosphorus-32 and phosphorus-33 for tooth development studies at the Eisenhower Place facility. The licensee also maintained and operated three self-shielded cesium-137 irradiators for research and development.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87126, 87134

Focus Areas Evaluated: All

The inspectors toured various facilities on the campus of the University of Michigan to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspectors observed the conduct, as well as demonstrations by staff of the implementation of various licensee procedures, including those for the safe use of self-shielded irradiators, manual brachytherapy treatment planning and administration process, safe use of neutron generators focusing specifically on handling of activation products, ordering of radioactive material, liquid radioactive waste management and disposal, as well as decommissioning and closeout activities. The inspectors interviewed numerous university employees in conjunction with these demonstrations and found that involved staff were knowledgeable of radiation protection principles, licensee procedures and regulatory requirements.

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, manual brachytherapy written directives and treatment planning documentation, purchase orders for radioactive material, package receipt documentation including survey results, liquid waste disposal accountability records, closeout surveys of decommissioned locations of use, as well as several Radiation Policy Committee meeting minutes and authorizations for radioactive material use and various routine records related to past use of radioactive materials for research purposes at the Eisenhower Place facility.

The inspectors reviewed 2014 dosimeter badge records showing that the maximum whole body and extremity occupational doses were 1390 millirems and 19230 millirems, respectively. The 2015 dosimeter badge records through August 17, 2015, showed that the maximum whole body and extremity occupational doses were 1500 millirems and 13720 millirems, respectively. Records of bioassays for radioiodine and hydrogen-3 in 2014 showed that the highest thyroid dose was 1 millirem and the hydrogen-3 whole body dose was below the minimum detectable activity.

The inspectors observed: (1) fluorine-18 labeled fluorodeoxyglucose production; (2) a Senior Research Lab Specialist demonstrate how he would respond to a radioactive spill

based on a scenario provided by the inspectors; (3) licensee staff members don dosimeter badges when using licensed material; (4) that selected licensee survey instruments were calibrated as required; (5) the preparation, administration, and post-administration activities associated with a yttrium-90 Theraspheres treatment; (6) records associated with previous yttrium-90 Theraspheres treatments; (7) administration of 19 millicuries of liquid iodine-131, and post administration activities including providing ALARA instructions to the patient; (8) records associated with previous iodine-131 hyperthyroidism treatments; (9) records associated with previous iodine-131 whole body scans; (10) records associated with previous samarium-153 Quadramet treatments; (11) administration of a ventilation/perfusion lung scan; (12) records of the licensee's Subcommittee on the Human Uses of Radioisotopes' bases for approval of a physician authorized user who did Y-90 Theraspheres treatments; and (13) records associated with personal contamination events that occurred on November 13, 2014, and December 17, 2014.

The inspectors reviewed the licensee's records showing that the public dose from carbon-11, fluorine-18, and nitrogen-13 air effluents was 0.2 millirem in 2014, and the dose to the public as a result of all licensed material air emissions was well below 10 millirems in 2014.

The inspectors noted that licensed material was last used at the Eisenhower Place facility in about February 2014. The principal activities included dental research and development involving about 100 microcuries of phosphorus-32, phosphorus-33, and hydrogen-3.

The inspectors noted that the licensee previously used 35 microcuries of iodine-125 for nephrology research and development at the Domino's Farms location.

The licensee had not received its first shipment of SirSpheres as of the onsite inspection; however, Theraspheres were still used.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a model 44-9 pancake probe and a Thermo Fischer Scientific RadEye G Gamma Survey Meter (both calibrated on January 5, 2015), the inspectors conducted independent surveys at various locations of use. The inspectors found no readings which would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

The inspectors used an NRC owned, calibrated Canberra UltraRadiac survey instrument to measure 0.04 milliroentgen per hour at selected surfaces near the shielded processing cassette that contained fluorine-18 labeled fluorodeoxyglucose (FDG), 8.6 milliroentgens per hour at the FDG dispensing station, and 0.5 milliroentgen per hour at the yttrium-90 unit dose shield prior to administration.

The inspectors also observed demonstrations by licensee staff of survey meter use during the receipt of radioactive material as well as during the use of self-shielded irradiators and neutron generators.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

1. Title 10 CFR 35.40(a) states that a written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

   Contrary to the above, three written directives for therapeutic dose of radiation from byproduct material, specifically iodine-125 eye plaque brachytherapy treatments, were not signed and dated by an authorized user (AU) before the respective administrations. Two of the treatments occurred on August 3, 2015, and the third occurred on August 24, 2015. This non-repetitive, licensee-identified and corrected violation is being treated as a Non-Cited Violation, consistent with Section VI.A.8 of the NRC Enforcement Policy.

   During a periodic internal review of written directives for I-125 eye plaque treatments, the licensee identified the aforementioned three written directives which had not been signed and dated by an authorized user (AU) before the respective administrations.

   The licensee stated that the three written directives had not been signed by the authorized user prior to each treatment because the user had been out of the office at the time that the medical physics staff had prepared those written directives. The licensee proceeded with the planning and administration of each treatment, as the staff intended to have the AU sign the form immediately before the treatment. However, on the day of the treatments, the AU did not sign in the written directive section of the form; instead, he signed – with time and date – in the treatment verification section within minutes of each treatment beginning.

   Although the AU did not sign the directives prior to each administration, he was present during the administrations, as documented by his signature in the treatment verification section of the form which was his confirmation that the eye plaque had been placed in accordance with the treatment plan. In addition, although the specific volume parameters of each ocular melanoma were unique, the licensee always prescribed 85 Gray to these tumors, using pre-made plaques implanted for 100±1 hours. Furthermore, the parameters contained in the written directive had already been reviewed and approved by the AU as part of the treatment planning process. Specifically, each written directive had been prepared by medical physics staff using parameters from an ophthalmologist's order which was reviewed, approved and forwarded to the physics staff by the authorized user himself. Finally, the three treatments represented less than half of one percent of all administrations requiring a written directive that the licensee had performed in 2015 to date.

   The inspectors determined that the root cause of this violation was oversight by the licensee's staff at the initiation of the treatments. As corrective action, the licensee created a new checklist for eye plaque administrations which included a time-out specifically to verify the presence of an authorized user's signature on the written directive prior to administration. The licensee also enlisted additional staff to ensure that treatment documentation was reviewed and audited in a more timely fashion.

The licensee stated that since August 24, 2015, when the last of the three unsigned written directives had been used, all subsequent written directives for eye plaques had been reviewed and found to be properly signed by an AU prior to administration. The inspectors reviewed documentation for five of the eleven treatments, and confirmed that each of those reviewed had been signed by an AU prior to administration.

2. Title 10 CFR 35.63(d) requires that unless otherwise directed by the AU, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent. Contrary to the above, on August 6, 2014, a NMT administered a dosage than differed from the prescribed dosage by greater than 20 percent. Specifically, the NMT administered 4 mCi of liquid 1-131 to a patient, when the WD signed by an AU specified 1mCi. While the AU had intended to enter 4mCi of 1-131 on the WD, he had mistakenly entered 1 mCi. On September 1, 2014, an authorized nuclear pharmacist did a review of selected studies and identified that the patient received greater than 20 percent more dosage than what was prescribed on the WD. On September 8, 2014, the AU learned about the issue and made a record that he/she intended to enter 4 mCi on the WD. The licensee conducted dose assessments to determine if the dose thresholds in 10 CFR 35.3045 were exceeded. The licensee determined that the highest dose to an organ or tissue as a result of the administration was 12 rem to the urinary bladder and the whole body dose was 352 millirems; therefore, the event did not constitute a medical event as defined in 10 CFR 35.2. This non-repetitive, licensee-identified and corrected violation is being treated as a Non-Cited Violation, consistent with Section VI.A.8 of the NRC Enforcement Policy.

   The root cause of the violation was oversight. As corrective action, the licensee required dosage preparers to initial the appropriate record as verification of the prescribed dosage versus the measured dosage prior to dosage administration. In addition, the licensee trained applicable staff regarding the new requirement. The inspectors reviewed several applicable records showing that the corrective actions were implemented and there were no other similar events.

3. Title 10 CFR 20.1502 requires that licensees shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part.

   Title 10 CFR 20.2106(a) requires that licensees shall maintain records of doses received by all individuals for whom monitoring was required pursuant to § 20.1502, and records of doses received during planned special exposures, accidents, and emergency conditions. These records must include, in part, the shallow-dose equivalent to the skin and the shallow-dose equivalent to the extremities.

   Title 10 CFR 20.2106(c) requires that licensees shall maintain the records specified in paragraph (a) of this section on NRC Form 5, in accordance with the instructions for NRC Form 5, or in clear and legible records containing all the information required by NRC Form 5. The instructions for NRC Form 5 include for Item 13, “Enter the shallow dose equivalent recorded for the skin of the whole body”. The

instructions for NRC Form 5 include for Item 14, “Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose”.

Contrary to the above, as of October 30, 2015, the licensee did not maintain the records specified in paragraph (a) of this section on NRC Form 5, in accordance with the instructions for NRC Form 5, or in clear and legible records containing all the information required by NRC Form 5. Specifically, on November 13, 2014, a radiation worker’s finger was contaminated with licensed material. Based on measurements and calculations, the licensee determined that the shallow-dose equivalent to the extremities was 0.890 rem; however, the licensee entered 0.610 rem in Item 14 of the individual’s NRC Form 5 for 2014. In addition, on December 17, 2014, a radiation worker’s face and hair next to an ear was contaminated with licensed material. Based on measurements and conservative calculations, the licensee determined that the ear skin dose was 16.513 rems and the skin dose of the face was 9.652 rems; however, the licensee entered 0.430 rem in Item 13 of the individual’s NRC Form 5 for 2014.

The root cause of the violation was oversight. Specifically, when contamination events occurred, the licensee surveyed the affected areas over time and calculated the resulting dose. The calculated doses from events were reviewed to verify that they were less than 30 percent of the regulatory dose limits. In addition, the licensee independently assessed the dosimetry badge results to verify that the doses were less than 30 percent of the regulatory dose limits; however, the licensee did not assess its calculated doses received during contamination events with the applicable dosimeter badge doses as a means to determine the accurate doses to enter into NRC Form 5. The aforementioned example involving the licensee entering 0.610 rem in Item 14 of the individual’s NRC Form 5 for 2014 was because the individual’s extremity dosimeter showed 0.610 rem and the extremity dosimeter was not worn near the area that was contaminated. In addition, the aforementioned example involving the licensee entering 0.430 rem in Item 13 of the individual’s NRC Form 5 for 2014 was because the individual’s whole body dosimeter showed 0.430 rem, and the whole body dosimeter was not worn near the areas that were contaminated.

As corrective action, the licensee committed to correct the NRC Form 5s accordingly. In addition, the licensee planned to develop a new procedure and/or a checklist to ensure that Form 5s are accurate. The licensee also obtained Varskin software to generate more accurate doses resulting from contamination events and it purchased a Ludlum Model 44-1 probe with about a 10 square centimeters face to better assess skin doses resulting from contamination events.

Regarding the contamination event that occurred on December 17, 2014, an NRC Certified Health Physicist determined that since the hair was contaminated and the ear skin near it was not contaminated, there was no good means to get an accurate dose to the skin next to the contaminated hair. After the onsite inspection, the licensee used Varskin to determine that the individual’s face received 8.3 rems. An NRC Certified Health Physicist independently used Varskin to determine that the individual’s face received 8.2 rems. The licensee committed to revise the individual’s NRC Form 5 accordingly.

5. PERSONNEL CONTACTED:

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