NRC FORM 591M PART 1 (07-2012) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Curators of the University - Columbia c/o Gary Ward Vice Chancellor of Operations 900 East Stadium Blvd., Suite 180 Columbia, MO REPORT NUMBER(S) 2019002	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-02278	24-00518-32	5/6-10/2019

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☐ 1. Based on the inspection findings, no violations were identified.

☑ 2. Previous violation(s) closed.

☑ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

1 Non-cited violation(s) were discussed involving the following requirement(s):

Title 10 of the Code of Federal Regulations (CFR) Section 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. Contrary to Section 20.1801, on February 25, 2019, the licensee did not secure from unauthorized removal or limit access to 144 microcuries of Phosphorus-32 located in Room 415A of the Bond Life Science Center, which is a controlled area. (See Part 2 for corrective actions to prevent a similar violation)

4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Robert Gattone & Shawn Seeley	Robert D. Gattone, Jr. and	6/3/19
BRANCH CHIEF	Aaron T. McCraw		6/6/19

NRC FORM 591M PART 2
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U.S. NUCLEAR REGULATORY COMMISSION

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(Continued)

Two workers who used Room 415A locked the door and confirmed it was locked. The authorized user (AU) determined that the door was unlocked by an unknown individual. A Radiation Safety Professional delivered a package containing licensed material for Room 415A and identified that the door was unlocked and there was nobody in the room to maintain surveillance of 0.144 millicuries of phosphorus-32 to prevent unauthorized access or removal of licensed material. There was no loss of the licensed material.

Corrective actions to prevent a similar violation included: (1) locking the door; (2) verifying the licensed material inventory; (3) providing licensed material security re-training; (4) re-keying the lab door lock and providing new keys; (5) implemented that keys not be shared with personnel outside of the group unless prior authorization is obtained by the (AU); (6) people who wish to use the room must have an authorized person to unlock the lab door and the AU is responsible for ensuring the door is closed once the visitor leaves; and (7) the door tumbler lock was modified so that the key can only be removed from the door when it was in the locked position such that it will be impossible for the door to be left closed but not unlocked.

During the onsite inspection, the inspectors verified that the licensee implemented the corrective actions to prevent a similar violation. As such, this violation is closed.

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87134	03.01- 03.07 & 03.09

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02110	2	Sue Langhorst, RSO	(573) 864-2941

☑ Main Office Inspection Next Inspection Date: 05/06/2020

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an announced, routine inspection of the licensee's radiation protection program. The licensee operated a large Type A medical/academic and research broad scope program under the authority of NRC byproduct materials License No. 24-00513-32. The license authorized, in part, the possession of any byproduct material with atomic numbers between 3 and 96, in any form, for human medical use and for research and development pursuant to 10 CFR 30.4, including animal use and select actinides, in any form, for laboratory research and development.

The majority of the medical use occurred at the University Hospital. Collectively, the licensee's nuclear medicine departments were staffed with six full-time technologists (some individuals rotate to the other sites) who performed approximately 250-350 plus diagnostic nuclear medicine procedures monthly, including PET studies. The hospital performed a full spectrum of studies and received unit doses only. The hospital administered numerous iodine-131 (I-131) dosages (mostly capsules) for whole body follow-up studies, hyperthyroid, and thyroid carcinoma treatments. One physician served as the primary authorized user (AU) for the nuclear medicine activities and there are other AUs that work under the Authorization; additional qualified physicians work under the supervision of the authorized user.

In April 2019, the radiation oncology department began administering high dose rate afterloader gynecological and breast treatments. In addition, the licensee administered palladium-103 permanent prostate seed implants. The department performed 10-15 permanent prostate implants per year.

The licensee established a Radiation Safety Committee (RSC) to review and approve all users and uses of licensed material. Each authorized user performed his research under the permit issued by the RSC, and the user must renew the permit every 3 years. The RSC provided program direction and oversight through its established policies and procedures. The RSC met on a bimonthly basis to conduct business. The licensee established a medical quorum to review the human uses of byproduct material.

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PROGRAM SCOPE

The radiation safety program was managed by a dedicated, part-time, temporary radiation safety officer (RSO), supported by two health physicists and one full time lab safety professional. The RSO reported to the Director of Environmental Health and Safety; the director reported to the Vice Chancellor for Operations. The radiation safety staff audited all areas of use and storage at frequencies based on the amount of material processed/used. Each member of the radiation safety staff served as a principle auditor or project manager for select research laboratories. Radiation safety also performed confirmatory surveys (monthly or quarterly based on the amount of material and use) of these areas to ensure compliance with the licensee's NRC license and NRC regulations.

Performance Observations

The inspectors: (1) noted that the licensee is actively searching for a permanent RSO; (2) reviewed records showing that the two high dose rate afterloader unit (HDR) AMPs were qualified; (3) reviewed records showing that the 3 AUs for HDR were qualified, including the licensee's RSC approval; (4) noted that the HDR intercom was on full volume; however, the volume was low but audible, and the licensee planned to either replace the intercom or repair it; (5) observed the licensee's switch to prevent the HDR and the linear accelerator from simultaneous operation; (6) observed that the HDR was secured as required; (7) used an NRC, calibrated survey instrument to conduct independent exposure rate surveys at the surface of the HDR, and the result was well below the public dose limit; (8) conducted an ambient exposure rate survey at selected surfaces of the exterior walls of the HDR treatment room with the source exposed in the room, and the highest result was low background; (9) observed that selected survey instruments were calibrated as required; (10) noted that the licensee had emergency tools in the event of an HDR source stuck in the patient; (11) reviewed selected HDR written directives and there were no concerns; (12) observed an HDR breast treatment and there were no concerns; (13) observed that the AU and AMP were at the HDR console during the HDR treatment; (14) reviewed documents pertinent to HDR treatment planning, in part, anatomy images overlaid with the isodose(s), and comparing the pretreatment records showing the settings for the HDR to complete the treatment properly and comparing them with the post-treatment records showing that the settings for the HDR were correct to complete the treatment; (15) reviewed the HDR procedures required by 10 CFR 35.41; (See next page)

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PROGRAM SCOPE

(16) noted that the licensee conducted ambient exposure rate surveys of HDR patients before releasing them; (17) observed an HDR spot check; (18) reviewed selected HDR patients' records including gynecological and breast treatments and there were no concerns; (19) reviewed the HDR Acceptance Testing document, and there were no concerns; (20) reviewed information showing that the licensee released licensed material into the sanitary sewer system as required; (21) observed two radiation safety professionals each conduct an audit of a lab to assess radiation safety, including, in part, ambient exposure rate surveys and removable surveys in the lab, licensed material security, and training and refresher training and there were no concerns; (22) interviewed a veterinary nuclear medicine technologist (VNMT) and observed the VNMT demonstrate how Flourine-18 FDG was handled for diagnostic scans for dogs; (23) observed the VNMT demonstrate how to respond to a Flourine-18 FDG spill based on a scenario posed by the inspector, and there were no concerns; (24) observed that the VNMT wore whole body and extremity badges; (25) conducted an independent ambient exposure rate survey at selected surfaces in the veterinary hot lab, and the highest result was well below the public dose limit; (26) observed that licensee material was properly secured in the veterinary hot lab; (27) observed a prostate implant procedure; (28) interviewed the authorized medical physicist (AMP) and authorized user (AU) prior to and after the procedure and observed both AU and AMP demonstrate sound radiation safety practices; (29) observed and interviewed several nuclear medicine technologists in the performance of their duties; (30) observed several injections; (31) observed a package receipt survey; (32) observed an iodine-131 capsule administration; and (33) reviewed dosimetry records and all were within regulatory limits; (34) verified that the licensee implemented its corrective actions to prevent previous violations from the previous inspection regarding two examples of a violation of 10 CFR 20.1801 for failure to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas (i.e., On May 11, 2017, the licensee identified an apparent violation of 10 CFR 20.1801 when a health physics technologist (technologist) left a radioactive materials waste storage room unattended). The room contained 2.51 millicuries (mCi) of radium-223, 0.5 mCi of technetium-99m (Tc-99m), and 21 mCi of cesium-137 (Cs-137). The stored licensed material was not secured by the licensee which could have resulted in unauthorized removal or access of the licensed material. Specifically, upon leaving the room, the technologist turned the room door key right in a left locking deadbolt and nudged the door too softly to move it, leaving the door unlocked for about 30 minutes. The inspectors determined that the root cause of the apparent violation was human error.

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87134	03.01 through 03.07 & 03.01 through 03.09

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PROGRAM SCOPE

As corrective actions for the May 11, 2017, security violation, the licensee secured the room and conducted an inventory of licensed material and verified that no licensed material was missing. On May 23, 2017, the licensee replaced the door lock and installed an automatic door closer such that the door shuts automatically, locks on its own, and unlocks with use of a key.

During the onsite inspection on May 14, 2018, the inspectors observed that a University Hospital nuclear medicine hot lab door was propped open and not secured to prevent unauthorized removal or access to licensed materials that were stored in a controlled area. The hot lab was unsecured for a few minutes, and the licensee failed to maintain constant surveillance over the licensed material. Two nuclear medicine technologists were nearby; however, they were in separate rooms such that they were unable to surveil the licensed material that was in the hot lab. The hot lab contained 0.098 mCi of Cs-137, 3.15 mCi of cobalt-57 (Co-57), 0.118 mCi of barium-133, and 68.12 mCi of Tc 99m. There was no evidence of lost licensed material. The inspectors determined that the root cause of the apparent violation was individual error, in that the licensee propped the hot lab door open, thereby preventing the automatic door closer from closing, latching, and locking the hot lab door. As corrective actions for the May 14, 2018, security violation the licensee trained applicable staff about closing the hot lab door when leaving the hot lab, and the importance of not propping the hot lab door open such that the automatic door closer is able to close, latch, and lock the hot lab door. On May 15, 2018, the licensee trained all hospital nuclear medicine staff members about the apparent violation and its causes, discussed 10 CFR 20.1801 (including constant surveillance), and removed the hardware that propped the door open such that the automatic door closer was able to close, latch, and lock the hot lab door, and discussed the information with the AU. In addition, the licensee enforced the policies set forth as part of the radiation safety program, and emphasized the importance of securing radioactive material from unauthorized removal or access. As such, this violation is closed.

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PROGRAM SCOPE

Title 10 CFR 30.41(c) requires that, prior to transferring byproduct material, the licensee verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred. Title 10 of the Code of Federal Regulations (CFR) 30.41(d) specifies acceptable methods for this verification. On November 2, 2017, the licensee transferred 5.35 millicuries (mCi) of cobalt-57 (Co-57) to International Isotopes, Inc. and, prior to the transfer, the licensee did not verify by an acceptable method that International Isotopes, Inc.'s license authorized receipt of this material. In addition, on March 20, 2018, the licensee transferred 15 mCi of Co-57 to International Isotopes, Inc. and, prior to the transfer, the licensee did not verify by an acceptable method that International Isotopes, Inc.'s license authorized receipt of this material. As corrective action to prevent a similar violation, the licensee verified that all of the offsite licenses on file have the current amendment. In addition, the licensee revised a "Control Check Sheet for Packaging Radioactive Material for a Type A and Limited Quantity Shipment". Specifically, the licensee added verbiage about the need to verify that the licensee has the transferee's current license amendment to verify that the transferee is authorized to receive the radioactive material before transferring the radioactive material. In addition, the licensee updated its Standard Operating Procedures (SOPs) to add verbiage about the need to verify that the licensee has the transferee's current license amendment to verify that the transferee is authorized to receive the radioactive material before transferring the radioactive material. The licensee transported licensed material on a public highway. For example, on May 4, 2018, the licensee transported 368 microcuries of phosphorus-32, and on May 15, 2018, the licensee transported 3.9 mCi of gallium-67 on a public highway. On both dates, the driver placed the shipping paper on the floor between the front bucket seats of the vehicle with licensed material inside. Title 10 CFR 71.5(a) and 49 CFR 177.817(e) requires, in part, that the driver of a motor vehicle containing hazardous material ensure that the shipping paper is readily available to, and recognizable by, authorities in the event of an accident or inspection. Specifically, when the driver is not at the vehicle's controls, the shipping paper shall be: in a holder which is mounted to the side of the door on the driver's side of the vehicle; or on the driver's seat in the vehicle. As corrective action to prevent a similar violation, the licensee placed the shipping paper in a new pouch mounted to the inside of the door on the driver's side of the vehicle. As such, this violation is closed.

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☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

On May 15 and May 16, 2018, the inspectors visited a category II laboratory that was approved to possess and use mCi quantities of natural uranium and thorium, depleted uranium, and neptunium-237, in any form. Due to the hazards associated with studies that were being conducted in this laboratory, the handling of the nuclides was conducted within ventilated glove boxes. The inspectors noted that three trained radiation workers who were processing and handling RSC-approved radionuclides in glove boxes, were not wearing laboratory coats. The inspectors interviewed the workers who stated that laboratory coats were not used because the laboratory coat sleeves restricted their arm movement in the glove ports of the boxes.

License Condition Number 33.E of Amendment Number 120 requires, in part, that the licensee conduct its program in accordance with statements made in the letter dated December 30, 2013. In Item 10.E of the letter, entitled "Safe Use of Radionuclides and Emergency Procedures", the licensee committed to adopt the general rules published in Appendix R to NUREG-1556, Volume 11, dated April 1999. Specifically, Appendix R describes topics to be implemented for the safe use of radioisotopes, which included, "Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are used". The licensee's failure to wear laboratory coats or other protective clothing in areas where licensed materials were being used is a violation of License Condition Number 33.E. of Amendment Number 120.

At the time the violation was observed, the licensee staff in the laboratory were instructed to don laboratory coats. Immediate corrective action was taken by the end of the day on May 16, 2018, and the inspectors observed that all three workers were wearing laboratory coats. The licensee re-educated AUs and laboratory personnel on the importance of proper PPE usage, created a laboratory PPE policy for all campus laboratories, and enforced existing applicable policies. In addition, the licensee had its Industrial Hygienist perform a formal risk assessment regarding the concern about the laboratory coat sleeves restricting arm movement in the glove ports of the boxes. The licensee prepared a lab specific PPE plan for the laboratory where this violation was observed. As such, this violation is closed.

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PROGRAM SCOPE

Title 10 CFR 20.1502(a)(1) states that each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum, (a) each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by (1) adults likely to receive in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a). The licensee failed to conduct an evaluation for the need to wear dosimeter badges, or to monitor individuals with dosimeter badges is a violation of 10 CFR 20.1502(a)(1) and License Condition Number 33.E. of Amendment Number 120. The licensee implemented corrective actions to prevent a similar violation. Specifically, on the day that the violation was identified, the licensee assigned dosimeter badges to the three aforementioned radiation workers and the workers started to wear their dosimeter badges. The licensee reviewed their dosimeter badge results to inform their evaluation to determine if the workers are likely to receive in one year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a). In addition, the licensee used dosimetry results for the three staff who use radioactive material at the highest frequency for a year to inform their dose modeling for the other lab staff. As such, this violation is closed.