



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

June 14, 2017

EN 52121
NMED No. 160320 (Closed)

Mr. Gary Ward
Vice Chancellor of Operations
The Curators of the University of Missouri
Environmental Health and Safety
#8 RPDB
Columbia, MO 65211

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002278/2017001(DNMS)
THE CURATORS OF THE UNIVERSITY OF MISSOURI

Dear Mr. Ward:

On May 8 through 12, 2017, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Columbia, Missouri campus, with continued in-office review through May 26, 2017. 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 inspection included a review of your report of three leaking cesium-137 sources your radiation safety staff identified during the preparation for an equine brachytherapy procedure. The in-office review included a review of additional information you provided concerning a contamination incident involving licensed material in a chemistry laboratory. Ms. Deborah Piskura of my staff conducted a final exit meeting by telephone with Ms. Felicity Beckfield of your staff on May 26, 2017, to discuss the inspection findings. The enclosed inspection record provides the details of this inspection.

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. The inspection included a review of three leaking sources reported by the University and a non-reportable contamination incident, involving licensed material. The NRC has no further questions about these events. Detailed information concerning the contamination incident is in the enclosed inspection record.

No violations were identified during the inspection. Therefore, you are not required to respond to this letter unless the description herein does not reflect your corrective actions or your position. In that case, or if you choose to provide additional information, please submit the information in accordance with the methods described in Title 10 of the *Code of Federal Regulations* (CFR) Section 30.6(a)(1) and (b)(2).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and 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, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Ms. Piskura if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

/RA/

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

Docket No. 030-02278
License No. 24-00513-32

Enclosure:
IR 03002278/2017001(DNMS)

cc w/encl: Felicity J, Beckfield, M.S., CHP
Radiation Safety Officer
State of Missouri

Letter to Gary Ward from Aaron McCraw dated June 14, 2017

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THE CURATORS OF THE UNIVERSITY OF MISSOURI

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OFFICE	RIII-DNMS		RIII-DNMS		RIII		RIII	
NAME	DPiskura:ps		AMcCraw					
DATE	6/9/2017		6/14/2017					

OFFICIAL RECORD COPY

INSPECTION RECORD

Region: III

Inspection Report No. 2017001

License No. 24-00513-32

Docket No. 030-02278

Licensee: The Curators of the University of Missouri
Environmental Health and Safety
#8 RPDB
Columbia, MO 65211

Locations Inspected: Main Hospital

Selected Laboratories, Main Campus

Licensee Contact: Felicity Beckfield, M.S., CHP, RSO

Telephone No. 573-882-0853

Program Code: 02110

Priority: 2

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

Last Inspection Date: April 11-15, 2016, with continued in-office review through June 1, 2016

Date of This Inspection: May 8-12, 2017, with continued in-office review through May 26, 2017 to review bioassay results for individuals involved in a laboratory contamination incident

Next Inspection Date: May 2019 (X) Normal () Reduced

Summary of Findings and Actions:

- (X) 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
- () Violation(s), regional letter issued
- () Follow-up on previous violations

Inspector: Deborah A. Piskura, Senior Health Physicist

/RA/
Signature

Date 6/9/2017

Approved: Aaron T. McCraw, Chief, MIB

/RA/
Signature

Date 6/14/2017

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
116	12/23/2016	new RSO
115	9/8/2016	mailing address change, new Am-241 and Cs-137 sources
114(corrected copy)	7/27/2016	various corrections
114	6/20/2016	changes to possession limits for decommissioning activities

2. INSPECTION AND ENFORCEMENT HISTORY:

The last inspection conducted April 11-15, 2016, with continued in-office review through June 1, 2016, resulted in two violations of NRC requirements: (1) the failure to use a nickel-63 source in accordance with the terms and conditions of a permit issued by the radiation safety committee as required by the policies and procedures referenced in the license renewal application dated December 30, 2013, and by License Condition 31; and (2) the failure secure licensed material within a research laboratory as required by Title 10 of the *Code of Federal Regulations* (CFR) Part 20.1801. These non-repetitive, licensee-identified, and corrected violations were treated as noncited violations, consistent with Section 2.3.2.b of the Enforcement Policy. The previous routine inspection on September 8-12, 2014 (with continued in-office review through September 30, 2014), resulted in no violations of NRC requirements.

3. INCIDENT/EVENT HISTORY:

This inspection included a review of the licensee's report of three leaking cesium-137 (Cs-137) sources that the radiation safety staff identified during the preparation for an equine brachytherapy procedure. On July 22, 2016, the licensee notified the NRC Operations Center of three leaking Cs-137 brachytherapy sources (Event Number 52121). During the planning and preparation of the equine implant, the radiation safety staff noted that some of the sources were stored in an aseptic solution for an extended time. The sources were used occasionally (every 2-3 years) and according to the licensee's practice were leak tested immediately prior to an implant. The licensee staff also identified Cs-137 contamination on the bench paper. The staff isolated the leaking sources and the contaminated paper from the rest of the source inventory. The licensee submitted its written report of the leaking source to the NRC in a letter dated August 18, 2016, detailing the cause of the leaking sources and the licensee's corrective actions. The report included the information required by 10 CFR 30.50(c)(2). Upon completion of the equine implant, the remaining sources were placed in storage. The licensee attributed the cause of the leakage to the age of the sources (c. 1970s) and the method of storage in the aseptic solution. The licensee transferred its veterinary Cs-137 source inventory to an authorized firm for disposal on December 6, 2016. This event is considered closed.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

This inspection was conducted as part of the Region III broad scope initiative with focus on the licensee's medical use activities. The inspection included a review of the licensee's report of three leaking Cs-137 sources used for veterinary implants and a contamination incident in one of the research laboratories.

The Curators of the University of Missouri (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+ diagnostic nuclear medicine procedures monthly. The hospital performed a full spectrum of studies and received unit doses only. The hospital administered numerous iodine-131 (I-131) dosages (capsules only) for whole body followup studies, hyperthyroid, and thyroid carcinoma treatments. One physician served as the authorized user for the nuclear medicine activities; additional qualified physicians work under the supervision of the authorized user.

The radiation oncology department was staffed with two authorized medical physicists, and one authorized user, assisted by five qualified radiation oncologists, who administered palladium-103 permanent prostate seed implants and temporary iridium-192 gynecological implants (last case 2016). The department performed 10-15 permanent prostate implants per year. The hospital maintained an inventory of Cs-137 tube brachytherapy sources (c.1980) for temporary implants. These sources had not been used for several years. In 2016, the licensee's consultant advised the licensee to transfer its Cs-137 brachytherapy sources inventory to a waste broker for disposal.

The radiation safety program was managed by a dedicated full-time radiation safety officer (RSO), supported by three health physicists and three health physics technicians. The RSO reported to the Director of Environmental Health and Safety; the director reported to the Vice Chancellor of 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. The radiation safety also performed confirmatory surveys (monthly or quarterly based on amount of material and use) of these areas to ensure compliance with its NRC license and regulations.

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 a permit issued by the RSC; the user must renew the permit every three years. The RSC provided program direction and oversight through its established policies and

procedures. The committee met on a bimonthly basis to conduct business. The licensee established a medical quorum to review the human uses of byproduct material.

The RSC reviewed the radiation safety program on an annual basis, last completed on December 8, 2016. The results of the review were provided to the Vice Chancellor in a written report. The inspector noted that the scope of the review and the followup on deficiencies identified during the audit were adequate to ensure safe operations. The licensee retained the services of a consultant who conducted an independent audit of the radiation safety program.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used:

IP 87102, "Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)"

IP 87103 "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing"

IP 87134, "Medical Broad-Scope Programs"

IP 83822, "Radiation Protection"

Focus Areas Evaluated: All

The inspector toured the actinide laboratory and the nuclear medicine and radiation oncology departments. The inspector observed licensee personnel prepare, assay, and administer several unit dosages for various testing procedures. The inspector also observed the administration of a 30-millicurie I-131 hyperthyroid treatment. The inspector reviewed the written directive for the procedure and observed the patient treatment. The inspector also interviewed the physician authorized user who attended the patient. Use of material in the actinide laboratory was inactive at this time pending a review/discussion of the contamination incident during the next scheduled RSC meeting.

The inspector noted all areas of use and storage were posted with caution signs, NRC-3 forms, and license documents in accordance with 10 CFR Parts 19 and 20. Radiation levels in unrestricted areas were found to be within Part 20 limits. The licensee maintained adequate security of its laboratories and storage areas. The inspector interviewed several medical and research personnel who demonstrated their knowledge of the licensee's radiation safety requirements.

The inspector observed the licensee personnel followed the following radiation safety practices during this inspection:

1. All licensee personnel wore their assigned dosimetry;
2. Staff performed personal surveys prior to leaving the restricted areas;
3. Staff wore gloves and lab coats and used tongs while handling radioactive material;
4. Staff used shields while preparing and dispensing radiopharmaceuticals for veterinary patients;
5. Staff confined the use of licensed material to designated areas; and
6. No evidence of eating or drinking in the restricted areas.

The following table summarizes the maximum total effective dose equivalent (TEDE) and the shallow dose equivalent (SDE) to personnel in millirem:

<u>Year</u>	<u>TEDE</u>	<u>SDE</u>
2016	738	*20,800
YTD 2/2017	64	665

*elevated extremity exposure attributed to increased PET workload for one individual (retired)

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector performed direct radiation measurements in and around the licensee's medical use and storage areas that indicated similar results as noted in the licensee's survey records. Radiation levels in the unrestricted areas outside the nuclear medicine, PET, medical waste storage, and laboratories were indistinguishable from background. All survey measurements in the restricted areas were comparable to the licensee's survey results. The inspector concluded that these radiation levels within the facility complied with Part 20 limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

No violations of NRC requirements were identified during this inspection. The inspector reviewed a non-reportable contamination incident that occurred in the actinide laboratory on May 2, 2017.

On May 2, 2017, at approximately 5:30 pm, a researcher was working with approximately 17 microcuries (μCi) of Neptunium-237 (Np-237) in a 50 milliliter (mL) solution (dissolved in an acid mixture). All work was performed in a fume hood with a face velocity of 100 feet per minute at the sash opening, with the sash raised to approximately 18 inches. As required by the experimental protocol, the individual wore two layers of latex gloves, a lab coat, and shoe covers. The individual maintained a dedicated pair of shoes in the lab. The lab personnel used a Ludlum model 177 Frisker coupled with a ZnS alpha scintillation probe to conduct daily personal surveys and contamination surveys of work surfaces. The individual started work in the morning, and had previously processed the bulk quality for the experiment. The final experiment did not obtain the desired results. The researcher attempted to salvage the original stock Np-237, by re-concentrating the aliquots from numerous experimental vials into one vessel in order to return the material to a solid state and attempt to resume the experiment. The researcher intended to boil the contents in the vessel, within a fume hood, to evaporate the aliquot off in an oil bath. The remaining material would have been dried in an oven, to return the Np-237 to its original oxidation state. The researcher would attempt the original experiment again.

As the researcher boiled the contents in the flask for approximately 30 minutes, the material boiled over and violently reacted with the oil. Approximately 10 mL, containing 11.3 μCi Np-237, of the original 50 mL flask contents escaped from the flask, contaminating the oil bath, and splashed contaminated oil in the fume hood. The researcher immediately recognized the incident, removed the flask from the oil bath, removed his outer gloves, turned on the emergency exhaust for the hood, and closed

the hood sash. His personal surveys revealed no contamination, and he notified the RSO.

The health physicist on call responded to the spill, donned the appropriate personal protective equipment, performed surveys, and removed the contaminated bench paper within the hood. The health physicist used absorbent materials to collect the contaminated oil. All surveys and wipe tests of the laboratory floors, benchtops, etc. showed no contamination over the licensee's action limit of 20 disintegrations per minute (dpm) alpha. One spot of contamination remained in the hood of approximately ~25 dpm alpha. All articles and materials used for decontamination efforts remained secured in waste boxes within the lab. Surveys of the unrestricted areas outside of the lab identified no contamination. On May 11, 2017, the licensee collected 24-hour urine samples from the health physicist and the researcher (nine days post incident). These samples were processed and analyzed by an independent service provider starting on May 15, 2017. The service provider reported the bioassay results for both individuals as "less than minimum detectable activity (MDA)" indicating no internal intake from the Np-237 contamination incident.

At this time, all work with Np-237 was suspended. The licensee attributed the root cause of this contamination incident to the use of a flask that was too small for the volume of material; the size of the flask did not allow for expansion of the contents during boiling. The lab will change its process to use a larger volume of flask. The lab will also change its process/medium for boiling from the oil bath to a sand bath; this non reactionary material should absorb the contents in case of boil over. The RSO also advised the lab to change its methods for lining the hood for ease in decontamination efforts. This incident will be discussed during the next RSC meeting.

No violations were identified during this inspection.

5. PERSONNEL CONTACTED:

#+Felicity J. Beckfield, M.S., Assistant Radiation Safety Officer
Wen Zhou Chen, Ph.D., Medical Physicist
#Ronald Dobey, CHP, Radiation Safety Officer, MURR
Teki Grahl, Health Physics Professional
Bryan Higgins, Health Physics Professional
#Eskil Hudson, Health Physics Professional
Todd Houts, Director, Environmental Health & Safety
Silvia Jurisson, Ph.D., Chair, Radiation Safety Committee
Michelle Kenett, Assistant Vice Chancellor, Office of Research
#Ashley Milligan, CNMT, Supervisor Nuclear Medicine
Alexander Myers, Graduate Student
Amolak Singh, M.D., Professor of Radiology (Authorized User, Nuclear Medicine)
Justin Walensky, Ph.D., Associate Professor & Associate Chair, Undergraduate Studies
#Gary Ward, Vice Chancellor of Operations & Chief Operating officer
Steven Westgate, M.D., Radiation Oncologist

Attended exit meeting on May 12, 2017.

+ Individual contact on May 26, 2017, for final exit teleconference