UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

January 21, 2021

Ms. Emily Combs
Vice President, Operations
Mercy Hospital – St. Louis
615 S. New Ballas Rd.
St. Louis, Missouri 63141

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002283/2020001(DNMS) AND NOTICE OF VIOLATION – MERCY HOSPITAL – ST. LOUIS

Dear Ms. Combs:

On July 27, 2020, through July 31, 2020, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your St. Louis, Missouri hospital, with continued in-office review through December 22, 2020. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review and discussions of your security program. Ms. Deborah A. Piskura, Senior Health Physicist, of my staff conducted a final exit meeting by telephone with you and Dr. Robert Turco and Mr. Christopher Gaughan of your staff on December 22, 2020, to discuss the inspection findings. This letter and its enclosures present the results of the 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.

Based on the results of this inspection, the NRC has determined that 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. The violations are of a security-related nature and are being cited in the enclosed, non-public Notice of Violation (Enclosure 1). The violations are being cited in Enclosure 1 because they were identified by the inspector. Details of the violations, as well as the corrective actions that have been taken to restore compliance, are discussed in the enclosed, non-public Enclosure 3 of the inspection report.

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

While we do not have an immediate concern with the safety and security of the radioactive material subject to 10 CFR (*Code of Federal Regulations*) Part 37, your understanding of the various NRC security requirements and your oversight of the program warrant your full attention. You are requested in your response to this letter to describe: (1) how you plan to improve the management oversight of your security program; (2) how you plan to monitor the effectiveness of your actions to improve this oversight; and (3) why you believe your corrective actions for these violations will be successful in preventing similar violations in the future.

You are required to respond to this letter regarding all of the violations and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in 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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, and Enclosure 2, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/readingrm/adams.html. However, Enclosures 1 and 3 and your response to the non-public Notice of Violation will not be made available electronically for public inspection because they contain security-related information. Please mark the top of each page of your response to the non-public Notice of Violation with "Security-Related Information – Withhold Under 10 CFR 2.390." To the extent possible, your response to the Notice of Violation should not include any personal privacy, proprietary, or safeguards information.

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

Sincerely,

David L. Pelton

Digitally signed by David L. Pelton
Date: 2021.01.21 15:54:10 -06'00'

David L. Pelton, Director
Division of Nuclear Materials Safety

Docket No. 030-02283
License No. 24-00794-03

Enclosures:
1. Notice of Violation (Non-public)
2. IR No. 03002283/2020001(DNMS) (public)
3. Security Addendum to IR (Non-public)

cc w/encl: Dr. Robert Turco , RSO
Christopher Gaughan,
Manager, Security
cc w/encl: State of Missouri (public)

Letter to Emily Combs from David Pelton dated January 21, 2021.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002283/2020001(DNMS) AND NOTICE OF VIOLATION – MERCY HOSPITAL – ST. LOUIS

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OFFICE	RIII DNMS	C	RIII DNMS	C	RIII-DNMS	C	RIII	
NAME	DPiskura:ps dap		MKunowski		DPelton			
DATE	1/12/2021		1/14/2021		1/21/2021			

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-02283
License No.	24-00794-03
Report No.	03002283/2020001(DNMS)
Licensee:	Mercy Hospital – St. Louis (main hospital)
Facilities:	615 S. New Ballas Rd. St. Louis, Missouri Mercy Medical Science Building Washington, Missouri Mercy Clinic – Zumbehl Road St. Charles, Missouri David C. Pratt Cancer Center St. Louis, Missouri Mercy Clayton and Clarkston Ballwin, Missouri Mercy Fenton Fenton, Missouri
Inspection Dates:	July 27-31, 2020 with continued in-office review through December 22, 2020
Exit Meeting Date:	December 22, 2020
Inspector:	Deborah A. Piskura, Senior Health Physicist
Approved By:	Michael A. Kunowski, Chief Materials Inspection Branch Division of Nuclear Materials Safety

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

Enclosure 2

EXECUTIVE SUMMARY

Mercy Hospital – St. Louis
NRC Inspection Report 03002283/2020001(DNMS)

The U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection of Mercy Hospital-St. Louis (the licensee) on July 27 through 31, 2020, with continued in-office review through December 22, 2020. The in-office review included an evaluation of security-related information unavailable during the onsite inspection.

The inspector identified security-related violations. Details of the security-related violations, as well as the corrective actions that have been taken to restore compliance, are discussed in the non-public Security Addendum to this Inspection Report.

REPORT DETAILS

1 Program Overview and Inspection History

Mercy Hospital-St. Louis is authorized under NRC Materials License No. 24-00794-03 for materials permitted in Title 10 of the Code of Federal Regulations (CFR) Sections 35.100, 35.200, 35.300, 35.400, 35.500, 35.1000 limited to yttrium-90 microspheres, iridium-192 in a high dose rate remote afterloader (HDR) unit and miscellaneous sealed sources used for reference and instrument calibration. This licensee was a large medical institution and conducted licensed activities at its main hospital in St. Louis, Missouri and 14 locations in the metropolitan St. Louis area. The licensee established a radiation safety committee to review and approve authorized physician users and medical physicists. The daily radiation safety activities were managed by a contract radiation safety officer (RSO), three contract health physics professionals, and one office assistant.

The licensee's nuclear medicine department at the main hospital was staffed with eleven technologists who rotated to select offsite clinics or care facilities listed on the NRC license. Collectively, the nuclear medicine departments performed approximately 10,000-12,000 diagnostic nuclear medicine procedures annually, which included a full spectrum of diagnostic imaging studies. The majority of licensed activities was performed by the main hospital (250-300 studies monthly). The licensee performed a full spectrum of studies and received unit doses and bulk quantities of technetium-99m from a licensed radiopharmacy. The hospital administered numerous radium-223 metastatic bone dichloride injections and iodine-131 dosages (capsules only) for whole body follow up studies, and hyperthyroid and thyroid cancer treatments; all patients were released in accordance with the criteria specified in 10 CFR 35.75.

The licensee administered approximately 20-30 yttruim-90 microsphere treatments annually using the Sirtex SIR-Spheres® brachytherapy system. The licensee typically administered an average prescribed dosage of approximately one gigabecquerel (GBq) (with a range of 0.1 to 3.3 GBq, or 2.7 to 89 milliCuries). The licensee instituted a multi-departmental approach for the use of yttrium-90 microspheres. The team included an interventional radiologist/authorized user, a nurse, and a nuclear medicine technologist assisted by radiologic technologists. The licensee received its yttrium-90 microspheres from the vendor from which it assayed and stored the prepared dosages within the main nuclear medicine laboratory. The team administered all microspheres treatments in the interventional radiology suite.

The radiation therapy activities under this license were performed at the main hospital campus at the David C. Pratt Cancer Center. The department used its HDR unit to administer approximately 700 patient treatments per year; the majority of these treatments was for breast, skin surface, and gynecological cancers. All HDR patient treatments were administered by the attending radiation oncologist, an authorized medical physicist, a nurse, and a therapy technologist. Service, maintenance, and source exchanges were performed by the HDR device manufacturer.

The last routine inspection was conducted on July 25-27, 2017, with continued in-office review through August 7, 2017; no violations of NRC requirements were identified during the inspection. Three security-related violations were identified during the previous

routine inspection on August 24-28, 2015, with continued in office review through November 9, 2015. The licensee's corrective actions for the previous security-related violations were reviewed during the last routine inspection in 2017.

2 Management Oversight and the Radiation Safety Committee

2.1 Inspection Scope

The inspector reviewed the licensee's management of the radiation safety program and the radiation protection program reviews. The inspector interviewed selected licensee staff, the consultant physicist, and the RSO. The inspector also reviewed selected audit reports for 2018 and 2019.

2.2 Observations and Findings

The licensee established a radiation safety committee, which met quarterly to review and approve authorized physician users and medical physicists. The meeting minutes indicated the committee member attendance and the topics. The licensee approved its physician users and medical physicists in accordance with the training and experience criteria listed in 10 CFR Part 35. The inspector reviewed selected radiation safety committee meeting minutes and documentation of training for selected authorized users. The radiation safety committee established a quorum for its meetings held at least quarterly to review events, program audit results, and approve uses, facilities, and users. Audits of the radiation safety program were discussed in the meeting minutes.

The licensee retained the services of a consulting group who staffed the radiation safety office. The radiation safety office conducted audits of the radiation safety program on a quarterly basis which included the main hospital and all offsite locations.

2.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspector identified no violations of NRC requirements.

3 Other Areas Inspected

3.1 Inspection Scope

The inspector reviewed other aspects of the licensee's radiation protection program which included high dose rate brachytherapy activities, security of licensed material, personnel monitoring, training, physical inventory and leak testing of sealed sources, labeling of containers, and postings. The inspector interviewed selected individuals, toured the licensee's facilities, examined the licensee's containers, and reviewed selected records.

3.2 Observations and Findings

The inspector observed the administration of several diagnostic nuclear medicine procedures. The inspector observed the administration of one dosage of yttrium-90 SIR-Spheres for a patient treatment. The inspector also observed the licensee staff administer one patient treatment utilizing its HDR unit. The inspection included

observations of dose calibrator checks, security of byproduct material, use of personnel monitoring, package receipts and surveys, and patient surveys at the conclusion of HDR and yttrium-90 administrations.

The inspector examined a sampling of sealed sources in the licensee's possession. Each source container was noted to bear a clearly visible label identifying the radionuclides and source activities. The licensee's consultant performed inventories and leak tests of the sealed sources and documented the results in his reports.

The inspector observed that the licensee posted caution signs, NRC Form 3, and license documents in accordance with 10 CFR Parts 19 and 20. The inspector also observed that the areas where licensed material was used and stored were appropriately posted with "CAUTION-RADIOACTIVE MATERIALS" signs. Each nuclear medicine hot lab was also posted with emergency/decontamination procedures and an approved dosage chart. During facility tours, the inspector noted no evidence of eating, drinking, smoking, or cosmetic application in areas where licensed material was used.

The inspector observed that licensee personnel maintained constant surveillance of licensed material. In addition, the nuclear medicine hot lab remained secured. The inspector determined that the consultant provided annual training to all staff working with or in the vicinity of licensed material. Through interviews, the inspector determined that the licensee staff understood security requirements for licensed material.
The inspector observed licensee personnel prepare, assay, and administer several unit dosages for various diagnostic testing procedures. The inspector reviewed written directives for several iodine-131 and yttrium-90 patient treatments. The licensee documented the written directive, the verification of the patient identity, and dosage verification. No medical events were identified.

The licensee monitored radiation exposure to nuclear medicine technologists using whole body and extremity personnel dosimeters provided by an accredited laboratory. The dosimeters were exchanged monthly. All technologists were advised of their exposure data at least annually. The inspector reviewed a sampling of dosimetry reports and determined that all monitoring results were below Part 20 occupational exposure limits.

The licensee possessed several calibrated survey instruments used by the nuclear medicine staff. Confirmatory surveys by the inspector indicated radiation levels consistent with licensee survey records and postings.

The inspector also reviewed records of annual radiation safety training, sealed source leak tests, and annual maintenance/service reports for a blood irradiator. All records indicated that the respective items were performed at the required frequencies.

3.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspector identified no violations of NRC requirements.

4 Exit Meeting Summary

The inspector discussed the preliminary inspection findings, as described in this report, with licensee management during the onsite preliminary exit meeting conducted at the licensee's facility on July 31, 2020. A final exit meeting was held with the licensee by telephone on December 22, 2020. The inspector discussed the activities reviewed, the inspection findings, and the violations. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in the inspection report as proprietary in nature.

LIST OF PERSONNEL CONTACTED

*Ken Andrews, Radiation Safety Office (by telephone)
*#Emily Combs, RN, Vice President, Operations
Jeffery Craft, M.D., Ph.D., Radiation Oncologist
*Jamie Eisenberg, CNMT, Radiation Safety Office
Derek Freund, M.S., Authorized Medical Physicist
Jean Gu, M.Sc., Authorized Medical Physicist
Amina Hodzic, CNMT, Supervisor, Nuclear Medicine
*Brian Johnson, Manager, Imaging Services (by telephone)
*Kevin Kretzer, Radiation Safety Office
Kurt Mauer, M.D., Interventional Radiologist
*Julie Ross, RT(R), MBA, Director, Imaging Services
*Jon Sullivan, Director Imaging Services (by telephone)
*Shannon Turek, CNMT, Manager, Nuclear Medicine and PET
*#Robert F. Turco, Ph.D., Radiation Safety Officer

Several medical technologists, nuclear medicine technologists, physicians and other professional staff were also contacted during the inspection.

*Attended the on-site exit meeting on July 31, 2020
#Attended the final telephonic exit meeting on December 22, 2020

INSPECTION PROCEDURES USED

IP	87130	Nuclear Medicine Programs Written Directive Not Required
IP	87131	Nuclear Medicine Programs Written Directive Required
IP	87132	Brachytherapy Programs