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

June 6, 2016

EA-16-121
NMED No. 150643 (Open)

Ms. Christine Raaf, RN
Vice President of Outpatient Services
Columbus Regional Hospital
2400 East 17th Street
Columbus, IN 47201

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03001597/2016001(DNMS) AND EXERCISE OF DISCRETION – COLUMBUS REGIONAL HOSPITAL

Dear Ms. Raaf:

On April 26, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Columbus, Indiana institution, with continued in-office review through May 24, 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 inspection also included a review of your report of two missing cesium-137 sources identified by your staff on November 12, 2015. The in-office review included a review and discussion of your security policies and your procedures for the use of strontium-82/rubidium-82 generators. Ms. Deborah Piskura of my staff conducted a final exit meeting by telephone with Dr. Michael Parrott, of your staff, on May 24, 2016, to discuss the inspection findings. The enclosed inspection report presents 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 identified two Severity Level IV violations of NRC requirements. The violations were evaluated in accordance with the NRC Enforcement Policy, which is available on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. Although these Severity Level IV violations of Title 10 of the *Code of Federal Regulations* (CFR) 35.60 and 35.63 were identified and the issues were discussed during the final exit meeting, your program met all of the criteria in NRC's Enforcement Guidance Memorandum (EGM) 13-003 for use of enforcement discretion; therefore, the NRC is exercising enforcement discretion and will not issue any enforcement action for these violations.

The NRC also identified one unresolved issue concerning the two missing cesium-137 sources. Because this issue remains under NRC review, no response for this letter is required at this time. You will be notified in separate correspondence of the results of our review. Please be advised that the number and characterization of the unresolved issue described in the enclosed inspection report may change as a result of further NRC review.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter 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.

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,

/RA/

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

Docket No. 030-01597
License No. 13-01631-05

Enclosure:
IR No. 03001597/2016001(DNMS)

cc w/encl: Michael J. Parrott, Ph.D.,
Radiation Safety Officer
State of Indiana

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Division of Nuclear Materials Safety

Docket No. 030-01597
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Enclosure:
IR No. 03001597/2016001(DNMS)

cc w/encl: Michael J. Parrott, Ph.D.,
Radiation Safety Officer
State of Indiana

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OFFICE	RIII-DNMS		RIII-EICS		RIII-DNMS		RIII	
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DATE	6/27/2016		6/6/2016		6/6/2016			

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-01597
License No.	13-01631-05
Report No.	03001597/2016001DNMS)
EA No.	EA-16-121
Licensee:	Columbus Regional Hospital
Facility:	2400 East 17th Street Columbus, Indiana
Inspection Dates:	April 26, 2016, with continued in-office review through May 24, 2016
Exit Meeting Date:	May 24, 2016
Inspector:	Deborah A. Piskura, Senior Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Columbus Regional Hospital
NRC Inspection Report 03001597/2016001(DNMS)

On April 26, 2016, with continued in-office review through May 24, 2016, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine, unannounced inspection of Columbus Regional Hospital (the licensee) to review licensed activities under NRC License No. 13-01631-05. The purpose of the inspection was to ensure that all licensed activities performed by the licensee were conducted safely and in accordance with NRC requirements. The inspection also included the review of the licensee's report of two missing cesium-137 sources. The licensee reported these sources as missing on November 12, 2015, and described the circumstances and its efforts to locate these sources in a followup written report, dated December 7, 2015.

During the inspection, one unresolved item was identified involving the circumstances surrounding the missing sources. The unresolved item will continue to be reviewed by NRC.

Two violations of NRC requirements were identified during this inspection involving the licensee's use of strontium-82/rubidium-82 generators. Although violations of Title 10 of the *Code of Federal Regulations* (CFR) 35.60 and 10 CFR 35.63 were identified, which, in accordance with the NRC Enforcement Policy, would normally be categorized at Severity Level IV, the licensee met all of the criteria in NRC Enforcement Guidance Memorandum (EGM) 13-003, "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Doses," dated April 18, 2013. These violations occurred because it is not possible for a user of a strontium-82/rubidium-82 generator to fully comply with the NRC regulations in 10 CFR 35.60 and 10 CFR 35.63, as currently written. Because the licensee met all of the criteria in EGM 13-003, the NRC is exercising enforcement discretion and will not issue any enforcement action for these violations.

REPORT DETAILS

1 Program Overview and Inspection History

The licensee is authorized to use licensed material permitted by 10 CFR Sections 35.100, 35.200, 35.300, and 35.400. The nuclear medicine department was staffed with four nuclear medicine technologists who performed approximately 225 diagnostic procedures monthly. The nuclear medicine department operated a separate positron emission tomography (PET) center. The department administered numerous iodine-131 dosages for treatment of hyperthyroidism and thyroid cancers as well as whole body follow-up studies. The licensee received unit doses, bulk vials of technicium-99m for kit preparation, and iodine-131 capsules from a licensed radiopharmacy. Nine physicians were listed as authorized users.

The licensee's use of Section 35.400 materials was limited to cesium-137 temporary implants for gynecological cancers. The last case was implanted approximately two years ago. Occasionally, the department administered phosphorus-32 and radium-223 for cancer treatments. The department was staffed with two medical physicists and five physician authorized users (AUs).

The NRC previously inspected the licensee's activities on August 15, 2013, and August 23, 2010, with no violations noted.

2 Missing Cesium-137 Sources

2.1 Inspection Scope

The inspector reviewed the licensee's investigation of the reported missing sources. The inspector also interviewed select licensee personnel, reviewed select records, and observed related equipment and facilities.

2.2 Observations and Findings

On November 12, 2015, the licensee notified the NRC and reported two sources as missing. On the morning of November 12, 2015, the lead nuclear medicine technologist arrived for work and proceeded to perform the routine morning quality assurance/quality control tests on the dose calibrator. The lead nuclear medicine technologist attempted to perform the daily dose calibrator constancy check and discovered that the cesium-137 reference source was missing from its shield within the dedicated storage cabinet. The lead nuclear medicine technologist performed an immediate inventory of all sources within the hot lab and noted that the cesium vial reference source and the cesium button source (an exempt quantity) were apparently missing.

Once the licensee realized that these sources were apparently missing, the licensee staff conducted a physical search, including surveys, for the missing sources. The licensee searched the hot lab and general areas of the nuclear medicine department, the hospital trash, personal work areas and offices. The licensee searched and surveyed the local area landfill but did not locate the missing sources. The landfill confirmed no alarms or waste from the hospital site had tripped the radiation alarms at the landfill entrance. The licensee reviewed its closed-circuit television (CCTV) footage but could not identify the whereabouts of the missing sources.

The NRC evaluation of the missing cesium-137 sources that the licensee reported to the NRC on November 12, 2015, is an unresolved issue.

2.3 Conclusions

The inspector identified one unresolved issue concerning the missing cesium-137 sources that occurred on or around November 11, 2015. The NRC considers this matter an unresolved issue and will continue to review it.

3 Notifications and Reports

3.1 Inspection Scope

The inspector reviewed the licensee's notifications to the NRC. In addition, the inspector reviewed the licensee's written report describing the missing cesium sources.

3.2 Observations and Findings

On November 12, 2015, the licensee notified the NRC Region III office of the missing sources. The licensee provided its written report of the missing sources to the NRC in a report dated December 7, 2015, (ML15348A295) detailing its search efforts and corrective actions. The written report included the information required by 10 CFR 20.2201(b).

3.3 Conclusions

The licensee made all of the notifications and reports as required by 10 CFR 20.2201(a)(1)(ii) within the specified time period. The licensee's written report included all of the required information.

4 Use of Strontium-82/Rubidium-82 Generators

4.1 Inspection Scope

The inspector interviewed the Radiation Safety Officer (RSO) and select nuclear medicine staff. The inspector reviewed select records and the reports from the vendor of the strontium-82/rubidium-82 generator. The inspector toured the nuclear medicine and PET imaging areas and observed the strontium-82/rubidium-82 generator.

4.2 Observations and Findings

The licensee used a strontium-82/rubidium-82 generator for cardiac PET imaging. The licensee performed approximately 80 PET studies per month. Users of this strontium-82/rubidum-82 generator are unable to comply with certain NRC requirements in 10 CFR Part 35.

The licensee implemented all of the criteria in NRC Enforcement Guidance Memorandum (EGM) 13-003, "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages." The AUs for medical uses under 10 CFR 35.200 who used Rb-82 chloride, and the

RSO successfully completed the manufacturer's training specific to the manufacturer and model of generator and infusion cart that was used, which included: (1) elution and quality control procedures needed to determine Rb-82 activity and the Sr-82 and Sr-85 breakthrough levels; (2) dose calibrator calibration procedures; and (3) safety procedures for the clinical use of Rb-82 chloride. The licensee's quality control procedures for calibrating the radiation detector in the infusion cart included: (1) performance of the Rb-82 activity constancy check comparison with Rb-82 measured in a calibrated dose calibrator; (2) how to adjust the infusion cart readout setting; and (3) when these tests are required by the manufacturer. The licensee maintained documentation that all AUs using Rb-82 and the RSO have satisfactorily completed such training. The licensee also recorded the activity of each dosage administered, as provided by the infusion cart.

Title 10 CFR 35.60 requires the licensee to calibrate instrumentation used to measure the activity of the dosage before it is administered to each patient. This calibration may either be performed in accordance with nationally recognized standards or calibration instructions provided by the manufacturer. However, the licensee was unable to calibrate a strontium-82/rubidium-82 generator unit in accordance with the regulations because there are currently no nationally recognized standards or specific calibration procedures for calibrating detectors in a dynamic mode (i.e., while liquids are flowing past the detector). Until standards or procedures are developed, the licensee cannot comply with Section 35.60.

Title 10 CFR 35.63 requires the licensee to determine the activity of each dosage administered before medical use. Due to the 76 second half-life of rubidium-82 and direct infusion of the rubidium-82 (from the dosage cart) into the patient, users of this generator system are unable to measure a patient dosage of Rb-82 prior to administration.

Although violations of 10 CFR 35.60 and 10 CFR 35.63 were identified, which, in accordance with the NRC Enforcement Policy, would normally be categorized at Severity Level IV, the licensee met all of the criteria in NRC Enforcement Guidance Memorandum (EGM) 13-003, "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Doses," dated April 18, 2013. These violations occurred because it is not possible for users of strontium-82/rubidium-82 generator to use this device in accordance with the NRC regulations. Because the licensee met all of the criteria in EGM 13-003, the NRC is exercising enforcement discretion and will not issue any enforcement action for these violations.

4.3 Conclusions

Two violations of NRC requirements were identified involving the licensee's use of strontium-82/rubidium-82 generators for cardiac PET imaging. In accordance with the criteria in EGM 13-003 described above, the NRC will disposition these violations by exercising enforcement discretion and will not pursue any enforcement action.

5 Other Areas Inspected

5.1 Inspection Scope

The inspector reviewed other aspects of the licensee's radiation protection program, which included management oversight, personnel monitoring, surveys, security of licensed material, labeling of containers, and postings. The inspector interviewed selected individuals, toured the licensee's facilities, examined the licensee's containers and reviewed selected records.

5.2 Observations and Findings

The RSO evaluated radiation exposures and provided personnel monitoring. The inspector reviewed dosimetry reports for 2013 to year-to-date 2016 and noted no worker exceeded the regulatory limits.

The inspector observed that the licensee personnel maintained constant surveillance of its licensed material. Licensed materials within the nuclear medicine and the brachytherapy hot labs remained secured. The licensee conducted radiation surveys of its areas where licensed material was used and stored.

The licensee retained the services of a consultant who reviewed the radiation safety program on a quarterly basis. The licensee established a radiation safety committee which met on a quarterly basis to review and discuss the radiation protection program.

The licensee reviewed the radiation protection program annually. The inspector reviewed the audit report for 2015 and noted that the review contained aspects similar to an NRC inspection.

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 radiation safety and security requirements for licensed material.

The inspector reviewed written directives for three iodine-131 patient treatments. The licensee documented the written directive, the verification of the patient identity, dosage verification and patient release calculations. The inspector also reviewed written directives and treatment plans for three cesium-137 temporary implants. The inspector reviewed the licensee's source inventories, patient room and patient surveys, nursing instructions and postings. No medical events were identified.

The inspector examined the 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 a copy of NRC Form-3. The inspector also observed that the rooms where licensed material was used and stored, were properly posted with "CAUTION-RADIOACTIVE MATERIALS" signs. The nuclear medicine hot lab was also posted with emergency/decontamination procedures and an approved "dosage chart."

5.3 Conclusions

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

6 Exit Meeting Summary

The inspector discussed the preliminary inspection findings, as described in this report, with licensee management during the exit meeting conducted on April 26, 2016. The inspector also discussed the exercise of enforcement discretion and the unresolved item with the RSO during a final telephone exit conference on May 24, 2016. 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

Licensee:
Bill Algee, RT(R), Manager, Radiology
Alex Georgiades, M.S., Medical Physicist
#Kent Johnson, RT(R), Director, Radiolgoy
+#Michael J. Parrott, Ph.D., Radiation Safety Officer
Stacy Phillips, CNMT
#Christine Raaf, RN, Vice President, Outpatient Services
Michelle Wagner, CNMT

Attended exit meeting on April 26, 2016
+ Individual contacted by telephone on May 24, 2016

INSPECTION PROCEDURES USED

IP 87103, “Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing”
IP 87131, “Nuclear Medicine Programs-Written Directive Required”
IP 87132, “Brachytherapy Programs”