INSPECTION RECORD

Region: III **Inspection Report No.** 2015001 **License No.** 21-13564-01
Docket No. 030-02157

Licensee: Crittenton Hospital Medical Center
1101 W. University Drive
Rochester, MI 48307

Locations Inspected: 1101 W. University Drive
Rochester, MI

Licensee Contact: Judith Bender, RSO **Telephone No**. 248-652-5325

Program Code: 02120 **Priority**: 3

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

Last Inspection Date: 12/17/2012 **Date of This Inspection**: 02/25/2015

Next Inspection Date: 02/25/2018 (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval:

N/A

Summary of Findings and Actions:

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

Inspector(s) Ryan J. Craffey, Health Physicist

/RA/ Date ***05/18/15***
Signature

Luis Nieves-Folch, Health Physicist

/RA/ Date ***05/18/15***
Signature

Approved Aaron T. McCraw, Chief, MIB

/RA/ Date: ***05/18/15***
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
68	10/08/2013	Added AU
69	02/24/2014	Added AUs
70	07/08/2014	Removed authorization for HDR, AUs, and one location of use

2. INSPECTION AND ENFORCEMENT HISTORY:

The NRC last inspected Crittenton Hospital Medical Center (CHMC) on December 17, 2012. During this routine inspection, one SLIV violation of 10 CFR 71.5(a) was identified for failure to provide recurrent hazmat training in accordance with U.S. Department of Transportation requirements. This violation was reviewed during the subject inspection and is discussed further in Part II.

Prior to that, the NRC last inspected CHMC on February 17, 2012. During this escalated enforcement follow-up inspection, the inspector reviewed corrective actions taken in response to a SLIII violation of 10 CFR 35.41(a) previously identified for failure to develop written procedures to provide high confidence that each HDR administration is in accordance with the written directive.

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Crittenton Hospital Medical Center (CHMC) was authorized by NRC Materials License No. 21-13562-01 to perform diagnostic and therapeutic administrations of radiopharmaceuticals, as well as manual brachytherapy using sealed sources of byproduct material at its facility in Rochester, Michigan. At the time of the inspection, the licensee's nuclear medicine department performed approximately 7-10 diagnostic administrations each weekday, and approximately 1-2 therapeutic administrations of I-131 monthly. The licensee had not performed any manual brachytherapy since before the last inspection. The licensee maintained a Radiation Safety Committee (RSC) which met quarterly, and retained the services of a medical physics consultant who audited the program on a quarterly basis.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87131

Focus Areas Evaluated: All

The inspectors toured the facility and evaluated the licensee's measures for materials security, hazard communication and exposure control. The inspectors observed the preparation and administration of one bone scan using technetium-99m, as well as demonstrations by licensee staff of package receipt, area surveys and spill response. The inspectors reviewed the licensee's procedures for administrations of byproduct material requiring a written directive, including patient release calculations and documentation of select treatments.

The inspectors also reviewed a selection of licensee records, including RSC meeting minutes, quarterly consultant audits, monthly dosimetry reports, spill reports, and training certificates.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a model 44-38 energy-compensated GM detector calibrated on April 15, 2014, and a Thermo Scientific RadEye G Gamma Survey Meter, calibrated on January 5, 2015, the inspectors conducted independent surveys of restricted and unrestricted areas of the licensee's facility. The inspectors found no exposures to members of the public in excess of regulatory limits. The inspectors found no residual contamination except for that described in Part 4, below.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

A. Possession of Naturally Occurring Radioactive Material

During the conduct of independent surveys of the nuclear medicine department on February 25, 2015, the inspectors identified the presence of radioactivity in a disused lead container. The inspectors noted an exposure reading of approximately 0.14 millirem per hour at the container's opening, against a background of 0.01 millirem per hour.

The licensee indicated that it had discovered this container during renovations of one of the hospital's operating rooms in the fall of 2014. The licensee relocated the container to the nuclear medicine department because the container bore a tattered but still legible label indicating that the container had been used to store radioactive material; specifically, implant brachytherapy sources.

The licensee did not previously suspect that any radioactive material still remained in the container, as it appeared to be empty, save for a small amount of dirt and debris. At the inspectors' request, however, the licensee conducted wipe tests of the container during the inspection, and discovered the presence of radioactive material using its well counter. The licensee sealed the container and placed it in a locked storage cabinet until their medical physics consultant could analyze the container in more detail. The consultant found, using the licensee's thyroid uptake probe, that there remained approximately 715 microcuries of radium-226 inside the container.

The inspector noted that the licensee was not authorized to possess radium-226 in any form, and had not requested the material be added to the license as of the date of the inspection. The licensee's possession of such material therefore constituted a violation of 10 CFR 30.3(c)(2), which requires that all licensees who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for

which a license amendment is required to authorize the activities may continue to use these materials until the date of the NRC's final licensing determination, provided that the person submits an amendment request within six months of the waiver expiration. For the State of Michigan, the waiver expired on August 7, 2009, so any amendment request would be required no later than February 7, 2010.

The inspector determined that the root cause of the violation was that the licensee was not aware of the presence of residual radium-226 contamination within the lead container. As corrective actions to restore compliance and to prevent recurrence, the licensee submitted an amendment request dated April 27, 2015, to add authorization for radium-226 to its license. The licensee also stated in its request that it was working with a waste broker to dispose of the lead container.

Because (1) this was the first occurrence of a violation of this requirement at CHMC after the termination date of the waiver, (2) the failure to add this material to the license did not result in any health or safety consequence, (3) the failure was not willful, (4) the licensee's explanation that it was not aware that it possessed this material appears to be reasonable, and (5) the licensee submitted an amendment request within 30 days after being notified that such an amendment was required, the NRC is using discretion to disposition this violation as a non-cited violation (NCV), in accordance with Enforcement Guidance Memorandum 09-004, "Interim Guidance for Dispositioning of Naturally Occurring and Accelerator Produced Radioactive Materials (NARM) Requirements." However, any future violations of 10 CFR 30.3(c)(2) will be categorized as cited violations and evaluated as such.

B. Closure of Previous Violations

The licensee was previously cited in IR 03002157/2012001 for one SLIV violation of 10 CFR 71.5(a) relating to the failure to provide recurrent hazmat training in accordance with U.S. Department of Transportation requirements. The inspectors reviewed the licensee's corrective actions, which appeared to be adequate, and found that the violation had not occurred again, as all hazmat employees had been properly trained. Therefore, the NRC considers this violation to be closed.

5. PERSONNEL CONTACTED:

William Bell, Jr. – Administrative Director, Imaging & Diagnostics
Judith Bender, M.D. – Radiation Safety Officer
Marge Coucke – Radiology Supervisor
Michelle Foster – Nuclear Medicine Technologist
Michelle Kritzman – Consultant, MPC
Dan Simmonds – Nuclear Medicine Technologist

Attended telephonic exit meeting on May 4, 2015.

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