INSPECTION RECORD

Region: III **Inspection Report No.** 2017001 **License No.** 21-13125-01
Docket No. 030-02146

Licensee: Bronson Methodist Hospital
601 John Street
Kalamazoo, MI 49007

Locations Inspected: 601 John Street, Kalamzoo, MI
252 East Lovell Street, Kalamazoo, MI
408 Hazen Street, Paw Paw, MI

Licensee Contact: Laura T. Smith, Radiation Safety Officer **Telephone No**. 586-808-3058

Program Code: 02240 **Priority**: 2

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

Last Inspection Date: 05/21/2015 **Date of This Inspection**: 01/26-27/2017

Next Inspection Date: 01/26/2019 (X) Normal ( ) Reduced

Summary of Findings and Actions:

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

Inspector(s) Ryan Craffey, Health Physicist

/RA/ Date 3/10/2017
Signature

Approved Aaron T. McCraw, Chief, MIB

/RA/ Date 3/10/2017
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
67	12/21/16	Removed Y-90 AU
66	10/25/16	Added Paw Paw, MI location of use, added Y-90 AU, removed another AU
65	07/22/16	Added Y-90 AU
64	05/20/16	New RSO
63	01/12/16	Added authorization for Y-90 microsphere administrations; removed AUs, removed manual brachytherapy and Sr-90 eye applicator authorizations

2. INSPECTION AND ENFORCEMENT HISTORY:

On May 21, 2015, the NRC conducted a routine inspection of Bronson Methodist Hospital, and identified violations of a security related nature. The status of these violations is addressed in the Security Addendum for this inspection.

On February 27-28, 2012, the NRC conducted a routine inspection of the licensee, and identified violations of a security related nature. These violations were reviewed and closed during a follow-up inspection on September 12, 2012.

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Bronson Methodist Hospital maintained authorization to use byproduct radioactive material for medical purposes at two locations on its campus in Kalamazoo, Michigan, and at a small community hospital in Paw Paw, Michigan, which had operated under a separate NRC license (Bronson Lakeview Hospital, 21-26716-01) until October 2016, when the organization folded its nuclear medicine program into the main hospital's license. At the time of the inspection, the licensee performed a full spectrum of diagnostic administrations (600-800 per month) and occasional I-131 therapeutic administrations at the nuclear department located at 601 John Street. The licensee performed diagnostic administrations only (2-6 per day) at the department in Paw Paw.

In January 2016, the licensee received authorization to perform Y-90 microsphere administrations. At the time of the inspection, the main hospital had performed twelve such administrations. Two interventional radiologists served as the primary authorized users, while the main nuclear medicine lab managed the receipt and preparation of doses and the handling of radioactive waste associated with these administrations.

The licensee also possessed and used a Nordion Gammacell 1000 Elite A self-contained irradiator at its blood bank, located at 252 East Lovell Street.

In February 2016, the licensee hired a consultant to serve as RSO, in order to assist the previous RSO (the current Chief Nuclear Medicine Technologist at the main hospital) in maintaining effective oversight of a radiation safety program that has significantly expanded since the last inspection.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87122, 87131, 87132

Focus Areas Evaluated: All

The inspector toured all three of the authorized locations of use to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector observed the preparation and administration of numerous diagnostic administrations of radiopharmaceuticals at the main nuclear medicine department and at the department in Paw Paw. The inspector also observed the receipt of packages containing radioactive material and the management of radioactive waste at both locations. The inspector also verified the inventory of sealed sources stored at the nuclear medicine lab in Paw Paw. The inspector interviewed the RSO, nuclear medicine staff, blood bank staff, and one of the two active Y-90 authorized users to discuss implementation of various licensee procedures, including those for instrument quality control, area surveys, spill response, irradiator use and maintenance, and Y-90 administrations.

The inspector reviewed a selection of records, including RSC meeting minutes, quarterly physics reports for both nuclear medicine labs, semiannual irradiator maintenance reports including area surveys and leak tests, written directives and administration checklists for all twelve Y-90 microsphere administrations to date, post-treatment SPECT scans for a selection of such administrations, inventory and decay-in-storage documentation for Y-90 microsphere waste, a selection of I-131 written directives and release calculations, hazmat refresher training for nuclear medicine staff, Co-57 flood source disposal documentation, and personnel dosimetry reports, which indicated no occupational exposures in excess of regulatory limits.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a model 44-38 energy-compensated GM detector and a Thermo Scientific RadEye G detector, both calibrated on September 20, 2016, the inspector conducted independent surveys at each of the locations inspected. The inspector found no readings that would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

The inspector identified no violations of NRC safety requirements. The inspector found that the licensee's staff were knowledgeable of licensee procedures and regulatory requirements, and implemented satisfactory ALARA practices. The inspector also found that the licensee's documentation of I-131 and Y-90 microsphere administrations

provided high confidence that these treatments had been performed in accordance with the written directives.

The inspector did, however, identify a violation of NRC security requirements. The violation was administrative in nature, and did not represent a vulnerability in the physical security of licensed material. The licensee has since taken corrective actions to restore compliance with the applicable security requirement, and to address the potential for recurrence of similar violations.

5. PERSONNEL CONTACTED:

Jamie Bobbio, Manager, Special Procedures
Beth Gostlin, Nuclear Medicine Technologist
Anthony Gurczynski, Nuclear Medicine Technologist (Bronson Lakeview)
Courtney Jacoby, Manager, Nuclear Medicine and CT
Kathy Kass, Nuclear Medicine Technologist
Heidi Miller, Nuclear Medicine Technologist
Cindy Naudler, Nuclear Medicine Technologist (Bronson Lakeview)
Matt Smetts, MD – Interventional Radiologist
Laura Smith, Consultant, RSO
Mark Watts, Chief Nuclear Medicine Technologist
Jan Yankoviak, Blood Bank Technologist

Participated in final exit meeting on February 24, 2017