

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Borgess Medical Center 1521 Gull Road Kalamazoo, Michigan 49048 REPORT NUMBER(S) 2018001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. DOCKET NUMBER(S) 030-02115	4. LICENSE NUMBER(S) 21-12275-02	5. DATE(S) OF INSPECTION March 26-27, 2018
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6. INSPECTION PROCEDURES USED 87131, 87132	7. INSPECTION FOCUS AREAS 03.01 - 03.09; 03.01 - 03.09
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02240	2. PRIORITY 2	3. LICENSEE CONTACT Paul Jursinic, Ph.D., RSO	4. TELEPHONE NUMBER (269) 373-7407
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Main Office Inspection Next Inspection Date: 03/26/2020

Field Office Inspection See below

Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection. The licensee's main hospital was a 420-bed hospital located in Kalamazoo, Michigan, with authorization to perform diagnostic and therapeutic nuclear medicine procedures as well as certain brachytherapy procedures. The licensee had not yet performed any yttrium-90 microspheres procedures and stated that they would retrain staff before doing so. At this hospital, the nuclear medicine department was staffed with two full-time and two part-time technologists. The nuclear medicine staff typically administered 300 diagnostic doses monthly and 20 iodine-131 therapy doses annually with the iodine in capsule form. The diagnostic procedures included a variety of imaging and uptake studies using doses received as unit doses or prepared from bulk technetium-99m. All unit doses and bulk material were received from a licensed nuclear pharmacy. Radiation oncology procedures were performed at the hospital by one physician authorized user and two physicists from the West Michigan Cancer Center (200 N. Park Street, Kalamazoo, MI). These procedures included approximately ten permanent prostate implant procedures annually using iodine-125 seeds. Seed receipt and shipment paperwork was maintained in the nuclear medicine department, while treatment documentation was kept at the Cancer Center.

The inspector also inspected Borgess-Lee Memorial Hospital in Dowagiac and the Heart Center for Excellence at 1722 Shaffer Street in Kalamazoo. The Dowagiac hospital last performed nuclear medicine procedures in December 2017 and decided in early March 2018 to formally cease such procedures. Licensee management stated that they would make a timely notification to NRC under 10 CFR 30.36(d) requirements; this notification was received by the NRC on April 17.

At the Heart Center, two full-time technologists administered around 400 doses monthly, limited to cardiac stress testing. Doses were received as unit doses from a licensed nuclear pharmacy or prepared from bulk cardiac testing material received from the nuclear pharmacy.

Performance Observations: The inspector observed three diagnostic imaging procedures including dose preparation and disposal, as well as package receipt surveys and wipes. Licensee staff demonstrated daily nuclear medicine checks, daily and weekly contamination surveys, and kit preparation; and described spill procedures, iodine-131 therapy procedures,
(Continued on Part 2)

Paul Jursinic
4/26/18

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(Continued)

procedures, and iodine-125 seed implant planning and performance procedures. The inspector noted no concerns with these activities. The inspector reviewed written directives for radiopharmaceutical therapies and brachytherapy procedures, and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures of regulatory concern. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings. Radiation Safety Committee meeting minutes indicated good attendance and discussion of appropriate topics.

No violations were identified as a result of this inspection.