



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

REGION III  
2443 WARRENVILLE RD. SUITE 210  
LISLE, IL 60532-4352

May 19, 2015

EA-15-085

Mr. William Bell, Jr.  
Administrative Director, Imaging & Diagnostics  
Crittenton Hospital Medical Center  
1101 W. University Drive  
Rochester, MI 48307

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002157/2015001(DNMS) AND  
EXERCISE OF DISCRETION – CRITTENTON HOSPITAL MEDICAL CENTER

Dear Mr. Bell:

On February 25, 2015, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Rochester, Michigan, with continued in-office review through April 20, 2015. 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 an evaluation of the analysis performed by your medical physics consultant. On May 4, 2015, Mr. Ryan Craffey of my staff conducted a final exit meeting by telephone with you and Dr. Judith Bender of your staff to discuss the inspection findings.

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.

While onsite, the inspectors identified the presence of residual contamination inside a lead container stored at your facility. Subsequent evaluation by you and your medical physics consultant revealed that the container contained up to 715 microcuries of radium-226, a material that you had not knowingly possessed since before the NRC had authority to regulate such material. As discussed during the final exit meeting on May 3, 2015, the inspectors identified a potential violation of Title 10 of the *Code of Federal Regulations* (CFR) Part 30.3(c)(2) concerning the failure to obtain an amendment to your NRC license to possess radium-226.

The Energy Policy Act of 2005 (EPAct) expanded the definition of byproduct material to include naturally occurring and accelerator produced radioactive materials (NARM), thereby placing the material under NRC's jurisdiction. In accordance with the EPAct, the NRC issued a waiver on August 31, 2005, allowing the continued use and possession of NARM while the agency developed a regulatory framework for the regulation of the new byproduct material. On October 1, 2007, the NRC published a Federal Register Notice informing licensees of

amendments to NRC's regulation regarding the possession and use of NARM. On August 7, 2009, the NRC published a Notice of Waiver Termination for licensees in the State of Michigan which stated, in part, that the NRC was terminating the waiver for persons possessing accelerator-produced radioactive material or discrete sources of radium-226. The Notice further stated that the final rule allowed an additional 6-month period from the effective date of the final rule to apply for a license amendment (i.e., February 7, 2010).

Based on the above, the NRC has determined that a violation of 10 CFR 30.3(c)(2) occurred. The violation concerned the failure to apply for a license amendment by February 7, 2010, and amend your NRC license to include the possession of radium-226. The violation was 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 possession of this type and quantity of radioactive material without authorization by an NRC license is normally characterized as a Severity Level IV violation in accordance with the Enforcement Policy. However, because (1) this was the first occurrence of a violation of this requirement at your facility after the termination date of the waiver, (2) the failure to add this material to your license did not result in any health or safety consequence, (3) the failure was not willful, (4) your explanation that you were not aware that you possessed this material appears to be reasonable, and (5) you submitted an amendment request within 30 days after you were 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.

The inspector determined that the root cause of the violation was that you were not aware of the presence of residual radium-226 contamination within the lead container. As corrective actions to restore compliance and to prevent recurrence, you submitted an amendment request dated April 27, 2015, to add authorization for radium-226 to your license.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and to prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position (pursuant to 10 CFR 2.201). In that case, or if you choose to provide additional information, you should clearly mark your response as a "Reply to an Exercise of Enforcement Discretion, EA-15-085" and send it to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with copies to: (1) the Regional Administrator and the Enforcement Officer, Region III; and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, 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>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

W. Bell

-3-

Please feel free to contact Mr. Craffey of my staff if you have any questions regarding this inspection. Mr. Craffey can be reached at 630-829-9655.

Sincerely,

***/RA Robert G. Gattone Acting for/***

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

Docket No. 030-02157  
License No. 21-13564-01

cc: Dr. Judith Bender, Radiation Safety Officer  
State of Michigan

W. Bell

-3-

Please feel free to contact Ryan Craffey of my staff if you have any questions regarding this inspection. Mr. Craffey can be reached at 630-829-9655.

Sincerely,

***/RA Robert G. Gattone Acting For/***

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

Docket No. 030-02157  
License No. 21-13564-01

cc: Dr. Judith Bender, Radiation Safety Officer  
State of Michigan

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