UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

February 9, 2022

Mr. Jim Schwaiger, MD
Radiation Safety Officer
Huron Regional Medical Center
172 4th Street SE
Huron, SD 57350

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-09603/2021-001 AND NOTICE OF VIOLATION – HURON REGIONAL MEDICAL CENTER

Dear Dr. Schwaiger:

On September 1, 2021, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Huron, South Dakota, with continued in-office review through September 27, 2021. 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 adequacy of your radiation detection instrumentation. Mr. Kyle Bischoff of my staff and Mr. Ryan Craffey from the NRC's Region III Office conducted a final exit meeting by video conference with you on February 04, 2022, to discuss the inspection findings. This letter presents the results of the inspection.

During this inspection, the NRC inspectors examined activities conducted under your license related to public health and safety. Additionally, the inspectors 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 determined that three Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy, which is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations concerned the following: (1) a written directive for a therapeutic administration of samarium-153 was not signed by an authorized user, contrary to Title 10 of the *Code of Federal Regulations* (10 CFR) 35.40(a); (2) a written directive for another therapeutic administration of samarium-153 did not include the prescribed dosage, contrary to 10 CFR 35.40(b); and (3) the instrument used to measure the activity of unsealed byproduct material for administration to patients was not calibrated in accordance with nationally recognized standards or the manufacturer's instructions, contrary to 10 CFR 35.60(b).

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC website

at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with the NRC's "Rules of Practice" in 10 CFR 2.390, a copy of this letter, its enclosure, and your response 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 Mr. Bischoff or Mr. Craffey if you have any questions regarding this inspection. Mr. Bischoff can be reached at 817-200-1259 or kyle.bischoff@nrc.gov, and Mr. Craffey can be reached at 630-829-9655 or ryan.craffey@nrc.gov.

Sincerely,

Lizette Roldán-Otero Signed by Roldan-Otero, Lizette on 02/09/22

Lizette Roldán-Otero, PhD, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-09603
License No. 40-15697-01

Enclosure:
Notice of Violation

cc w/Enclosure:
John Priest, Non-Agreement State Director
South Dakota Department of Health
Licensure & Certification
4101 W. 38th St.
Sioux Falls, SD 57106

SUBJECT: NRC INSPECTION REPORT NO. 030-09603/2021-001 AND NOTICE OF VIOLATION - HURON REGIONAL MEDICAL CTR DATED-FEBRUARY 9, 2022

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NOTICE OF VIOLATION

Huron Regional Medical Center
Huron, South Dakota

License No. 40-15697-01
Docket No. 030-09603

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on September 1, 2021, with continued in-office review through September 27, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.40(a) states in part that a written directive must be dated and signed by an authorized user before the administration of any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

   Contrary to the above, on April 27, 2018, a written directive was not signed by an authorized user before the administration of a therapeutic dosage of unsealed byproduct material. Specifically, a written directive for a therapeutic dosage of 95.6 millicuries of samarium-153 was not signed by an authorized user prior to administration.

This is a Severity Level IV violation (Section 6.3.D.1).

B. 10 CFR 35.40(b)(2) states that the written directive must contain, for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration.

   Contrary to the above, on January 31, 2020, a written directive for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131 did not contain the dosage. Specifically, a written directive for a therapeutic dosage of 69.2 millicuries of samarium-153 did not contain the dosage to be administered.

This is a Severity Level IV violation (Section 6.3.D.1)

C. 10 CFR 35.60(a) states that for direct measurements performed in accordance with § 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.

   10 CFR 35.60(b) states that licensees must calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards of the manufacturer's instructions.

   Revision Y to the Owner's Manual for the Capintec, Inc. CRC-15R Radioisotope Dose Calibrator, dated July 2007, states in Chapter 6, *Acceptance & Quality Assurance Tests*, that the quarterly test consists of: [a] diagnostic test; [a] daily test; [an] accuracy test (for those nuclides that are not used in the daily test); and [a] linearity test.

   Contrary to the above, from December 2020 to September 1, 2021, Huron Regional Medical Center did not calibrate the instrumentation required in paragraph (a) of this section in accordance with national recognized standards or the manufacturer's

instructions. Specifically, the licensee had not performed linearity tests on a Capintec CRC-15R dose calibrator used to measure the activity of radiopharmaceuticals administered to patients since December 2020, a test which the manufacturer instructs users to complete quarterly.

This is a Severity Level IV violation (Section 6.7.D.4).

Pursuant to the provisions of 10 CFR 2.201, Huron Regional Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to Director, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission Region IV, 1600 E. Lamar Blvd., Arlington, Texas 76011, and emailed to Lizette.Roldan-Otero@nrc.gov within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; NRC Inspection Report 030-09603/2021-001" and should include, for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved.

Your response may reference or include previously docketed correspondence if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 19.11, you may be required to post this Notice within 2 working days of receipt.

Dated this 9th day of February 2022