UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

August 19, 2021

Ms. Dale Danowski, Vice President
St. Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606

SUBJECT: ST. VINCENT'S MEDICAL CENTER- NRC INSPECTION NO. 030-01245/ 2021001 AND NOTICE OF VIOLATION

Dear Ms. Danowski:

This letter refers to the inspection conducted from April 13-14, 2021 at your Bridgeport, Connecticut facility, with continued in-office review until July 22, 2021. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with 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 two Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC. In addition, the NRC has also determined that one additional Severity Level IV violation of NRC requirements found in 10 CFR 35.67 occurred regarding leak testing of sources at a 10 month frequency in 2018/2019 instead of the required 6 month frequency and failure to remove a source from the inventory that was transferred in 2019. This violation is being treated as a Non Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy, because: the licensee identified the violation; the licensee corrected or committed to correcting the violation within a reasonable period of time by specific corrective action committed to by the end of the inspection, including immediate corrective action and comprehensive action to prevent recurrence; the violation is not repetitive as a result of inadequate corrective action; and the violation is not willful. If you contest the NCV you should provide a response within 30 days of the date of this letter, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to the Regional Administrator, Region I; and the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC Web site 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 available to the Public without redaction.

If you have any questions regarding this matter, please contact Penny Lanzisera of my staff via electronic mail at Penny.Lanzisera@nrc.gov.

Thank you for your cooperation.

Sincerely,

Christopher G. Cahill

Digitally signed by Christopher G. Cahill
Date: 2021.08.19 13:07:30 -04'00'

Christopher Cahill, Chief
Commercial, Industrial, R&D
and Academic Branch
Division of Radiological Safety and Security
Region I

Docket No. 030-01245
License No. 06-00843-03

Enclosure:
Notice of Violation

cc w/ enclosure
Arely Clavel, Radiation Safety Officer
State of Connecticut

ST. VINCENT'S MEDICAL CENTER- NRC INSPECTION NO. 030-01245/2021001 AND NOTICE OF VIOLATION DATED AUGUST 19, 2021.

DOCUMENT NAME: https://usnrc.sharepoint.com/:w:/r/teams/Region-I-MLA/_layouts/15/Doc.aspx?sourcedoc=%7B05edf584-c28f-44c1-bb32-a9a695b6ea35%7D&action=edit&wdPid=3e5767fd **ML21231A014**

☐ SUNSI Review		X Non-Sensitive ☐ Sensitive		X Publicly Available ☐ Non-Publicly Available	
OFFICE	RI/DRSS	RI/DRSS	RI/DRSS		
NAME	PHann (PH)	PLanzisera (PL)	CCahill (CC)		
DATE	08/12/2021	8/13/2021	08/19/2021		

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

St. Vincent's Medical Center
Bridgeport, CT

Docket No. 030-01245
License No. 06-00843-03

During an NRC inspection conducted on April 13-14, 2021, with continued in-office review until July 22, 2021, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.41(a) requires, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

10 CFR 35.41(b) requires, in part, that at a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material; verifying that the administration is in accordance with the written directive, and determining if a medical event, as defined in § 35.3045, has occurred.

Contrary to the above, as of April 14, 2021, the licensee failed to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive; including verifying that the administration is in accordance with the written directive, and determining if a medical event, as defined in § 35.3045, has occurred. Specifically, the licensee's procedures developed, implemented, and maintained did not provide high confidence that Yttrium-90 microsphere administrations were in accordance with the written directive. In particular, the procedures did not: (i) clearly define the treatment site (e.g., lobe or segment); (ii) document the use of a dose calculation method other than the manufacturer's; or (iii) evaluate the effect of patient weight discrepancies documented in the patient record versus those used in dose calculations.

This is a Severity Level IV violation (Enforcement Policy Section 6.3)

B. Condition 14 of NRC License No. 06-00843-03 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the letter dated February 20, 2014.

The letter dated February 20, 2014, requires in part, that the licensee include the treatment site on the written directive and follow the manufacturer's procedures for calculating/documenting the dose to the treatment and other sites.

Contrary to the above, as of April 14, 2021, the licensee did not conduct its program in accordance with the procedures contained in the letter dated February 20, 2014. Specifically, the licensee calculated the intended dose to be delivered to a lobe or segment of the liver, however, the written directive documented "liver" only instead of specifying the lobe or segment to be treated. The licensee immediately revised the written directive form to capture the intended treatment site (e.g., lobe or segment). In addition, the licensee used a dose calculation method other than the manufacturer's

called DAVYR and did not evaluate the method against the manufacturer's method or amend their NRC license to acknowledge the evaluation and use.

This is a Severity Level IV violation (Enforcement Policy Section 6.3)

Pursuant to the provisions of 10 CFR 2.201 St. Vincent's Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, 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" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous 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.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 19th day of August 2021.