UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

May 9, 2023

Edwin Sueiro Berrios, Administrator
Hospital Damas
2213 Ponce By Pass
Ponce, PR 00717

SUBJECT: HOSPITAL DAMAS - NRC INSPECTION NO. 03003521/2023001 AND NOTICE OF VIOLATION

Dear Edwin Sueiro Berrios:

This letter refers to the inspection conducted on March 6, 2023, through April 21, 2023, at your Ponce, Puerto Rico facility. 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. An exit meeting was held with Carmelo Perez, Radiation Safety Officer, and Dr. Rene Baez by telephone on April 21, 2023.

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. 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.

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 " Agency Rules of Practice and Procedure," a copy of this letter and your response, if you choose to provide one, 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 Jonathan Pfingsten of my staff at 610-337-5170 or via electronic mail at Jonathan.Pfingsten@nrc.gov.

Thank you for your cooperation.

Sincerely,

Anne E. DeFrancisco

Digitally signed by Anne E. DeFrancisco
Date: 2023.05.09 08:38:38 -04'00'

Anne DeFrancisco, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

Docket No. 030-03521
License No. 52-10270-01

Enclosure:
Notice of Violation

cc w/ enclosure
Carmelo Perez, Radiation Safety Officer

HOSPITAL DAMAS - NRC INSPECTION NO. 03003521/2023001 AND NOTICE OF VIOLATION DATED MAY 9, 2023

ADAMS ACCESION No ML23128A128.

DOCUMENT NAME: https://usnrc-my.sharepoint.com/personal/jbp1_nrc_gov/Documents/JBP1/DRSS/02 - MLAB/01 - Inspections/2023 - Inspections/03 - March/01 - Puerto Rico/05 - 52-10270-01 - Hospital Damas/L52-10270-01.2023001.NOV.docx

X SUNSI Review		X Non-Sensitive ☐ Sensitive		X Publicly Available ☐ Non-Publicly Available	
OFFICE	R1/DRSS	R1/DRSS			
NAME	JPfingsten	ADeFrancisco			
DATE	5/4/23	5/8/23			

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Hospital Damas
Ponce, PR

Docket No. 030-03521
License No. 52-10270-01

During an NRC inspection conducted between March 6, 2023, through April 21, 2023, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.24(f) states, in part, that licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of 10 CFR Part 35 shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include a representative of the nursing service.

   Contrary to the above, the licensee was authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of 10 CFR Part 35 and the Radiation Safety Committee did not include a representative of the nursing service. Specifically, as of March 6, 2023, the licensee did not include a representative of the nursing service despite being authorized for uses of byproduct materials under 10 CFR 35.300 (Subpart E) and 35.400 (Subpart F).

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

B. 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

   Contrary to the above, on numerous occasions in 2020 and 2022, the licensee's written directives were not dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)). Specifically, on August 19, 2020, on January 14, 2022, and on June 7, 8, and 10, 2022, examples were identified of written directives not being signed by the authorized user prior to the administration of I-131 sodium iodide greater than 30 microcuries.

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

C. 10 CFR 35.40.(b)(1) requires, in part, that for any administration of quantities greater than 1.11 MBq (30μCi) of sodium iodide I-131, the written directive must contain the patient or human research subject's name and the dosage.

   Contrary to the above, for the administration of a quantity greater than 1.11 MBq (30μCi) of sodium iodide I-131, the written directive did not contain the patient or human research subject's name and the dosage. Specifically, on August 15, 2022, a written directive for the administration of a quantity greater than 30μCi of sodium iodide I-131 did not contain the dosage. The licensee proceeded with the administration of a 5 mCi I-131 capsule.

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

Pursuant to the provisions of 10 CFR 2.201, Hospital Damas 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 9th day of May 2023