UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

June 6, 2017

EA-17-026

Nathaniel B. Berg, M.D., DABR
Radiation Safety Officer
Guam Medical Imaging Center
472 Chalan San Antonio, Suite 111
Tamuning, Guam 96913

SUBJECT: NOTICE OF VIOLATION AND NRC INSPECTION REPORT 030-35716/2017-001

Dear Dr. Berg:

This refers to the routine, announced inspection conducted on January 9 and 13, 2017, at your facilities located in Tamuning, Guam. The purpose of the inspection was to examine activities conducted under your license as they relate to public health and safety, the common defense and security, and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel.

In the NRC letter transmitting the inspection report, dated April 5, 2017 (Agencywide Documents Access and Management System (ADAMS) Accession ML17067A198), we provided you with the opportunity to address the apparent violations identified in the inspection report by attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated April 24, 2017 (ADAMS Accession ML17139D383), you provided a written response to the apparent violations.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations cited in the Enclosure involved failures to: (1) prepare written directives that were dated and signed by an Authorized User before the administration of iodine-131 sodium iodide in quantities greater than 1.11 megabecquerels (30 microcuries) or any therapeutic dosage of unsealed byproduct material; and (2) develop, implement and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Although no medical events or actual safety consequences occurred because of these failures, the NRC considers these violations to be significant. The written directive practices observed during the inspection and documented in the inspection report could have resulted in miscommunication regarding the quantity of radioactive material to be administered and actual safety consequences or medical events, and could not reasonably be expected to provide high confidence that administrations would be performed in accordance with the written directives. The failures described in the Notice occurred for each of the 53 administrations that required a

written directive between November 5, 2013, and January 9, 2017. Therefore, the NRC has concluded that this constitutes a programmatic failure, and because the violations had common causal factors as described in the inspection report, they have been categorized in accordance with the NRC Enforcement Policy as a Severity Level III problem.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $7,000 is considered for a Severity Level III problem. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the NRC Enforcement Policy. Your corrective actions included the: (1) revision of the written directive form; (2) establishment of a process and procedure for written directives to be reviewed, signed, and dated by an authorized user prior to the administration of byproduct material requiring a written directive; (3) development of written procedures to provide high confidence that administrations will be performed in accordance with the applicable written directives; and (4) routine performance of a review of all administrations requiring a written directive.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of these Severity Level III violations constitutes an escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is adequately addressed on the docket in your letter dated April 24, 2017, and in the subject inspection report. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," 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 Public Document Room and in the NRC's 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 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). The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions.

If you have any questions concerning this matter, please contact Ms. Vivian H. Campbell of my staff at 817-200-1455.

Sincerely,

/RA/

Kriss M. Kennedy
Regional Administrator

Docket: 030-35716
License: 56-27702-01

Enclosure:
Notice of Violation

cc w/enclosure:
M. Thomas Nadeau, Administrator
Division of Environmental Health
Guam Department of Health and Social Services
123 Chalan Kareta
Mangilao, GU 96913-6304

NOTICE OF VIOLATION AND NRC INSPECTION REPORT 030-35716/2017-001 DATED XXXXX, 2017

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DOCUMENT NAME: S:\RAS\ACES\ENFORCEMENT_EA CASES - OPEN\Guam Medical Imaging EA-17-026\NOV_EA-17-026 Guam Medical Imaging Center.docx
ADAMS ACCESSION NUMBER: **ML17130A810**

☒ SUNSI Review: By: JFK | ADAMS: ☒ Yes ☐ No | ☐ Non-Publicly Available ☒ Publicly Available | ☒Non-Sensitive ☐ Sensitive | Keyword: By: EA-17-026

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NOTICE OF VIOLATION

Guam Medical Imaging Center
Tamuning, Guam

Docket No. 030-35716
License No. 56-27702-01
EA-17-026

During an NRC inspection conducted on January 9 and 13, 2017, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 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 (30 microcuries) or any therapeutic dosage of unsealed byproduct material.

   Contrary to the above, between November 5, 2013, and January 9, 2017, the licensee failed to prepare written directives that were dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (30 microcuries) or any therapeutic dosage of unsealed byproduct material. Specifically, the licensee prepared approximately 50 written directives for the administration of I-131 sodium iodide greater than 1.11 megabecquerels (30 microcuries), and three written directives for the administration of Ra-223 as a therapeutic dosage of unsealed byproduct material, and the written directives were not dated and signed by an authorized user before these administrations.

B. 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.

   Contrary to the above, between November 5, 2013, and January 9, 2017, for an administration requiring a written directive, the licensee failed to develop, implement and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee failed to develop, implement and maintain written procedures to provide high confidence that each administration is in accordance with the written directive and instead utilized a verbal protocol for the authorization of written directives.

This is a Severity Level III problem (NRC Enforcement Policy Section 6.3.c.2).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is adequately addressed on the docket in the letter from the licensee dated April 24, 2017 (Agencywide Documents Access and Management System (ADAMS) Accession ML17139D383), and in NRC Inspection Report 030-35716/2017-001.

You are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a “Reply to a Notice of Violation; EA-17-026,” and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional

Administrator, U.S. Nuclear Regulatory Commission, Region IV, 1600 E. Lamar Blvd., Arlington, Texas 76011 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC Web site 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.

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

Dated this 6th day of June 2017