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

April 5, 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: NRC INSPECTION REPORT 030-35716/2017-001

Dear Dr. Berg:

This letter refers to the routine, announced inspection conducted on January 9 and 13, 2017, at your facility 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) rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of an examination of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel. On January 13, 2017, at the conclusion of the on-site portion of the inspection, the inspector discussed the preliminary inspection findings with you and Mr. James M. Kay, Certified Nuclear Medicine Technologist (CNMT). A final exit briefing was conducted telephonically with you and Mr. Kay on March 9, 2017. The enclosed report presents the results of this inspection.

Based on the results of this inspection, two apparent violations have been identified and are being considered for escalated enforcement in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations involved failures to: (1) prepare written directives that were dated and signed by an Authorized User before the administration of I-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. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you and Mr. Kay at the conclusion of the on-site portion of the inspection.

Since your facility has not been the subject of escalated enforcement actions (EA) within the last two inspections, and based on our understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. The final decision will be based on you confirming on the license docket (i.e., in writing) that the corrective actions previously described to the NRC staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond, in writing, to the apparent violations addressed in this inspection report within 30 days of the date of this letter; or (2) request a predecisional enforcement conference (PEC). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. If you decide to participate in a PEC please contact Ms. Vivian H. Campbell, Chief, Materials Licensing and Inspection Branch, at 817-200-1455, within 10 days of the date of this letter to notify us of your intentions. A PEC should be held within 30 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to an Apparent Violation in NRC Inspection Report 030-35716/2017-001; EA-17-026," and should include for each of the apparent violations: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (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. Your response should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to Mr. Mark R. Shaffer, Director, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Blvd., Arlington, TX 76011-4511 within 30 days of the date of this letter. If an adequate response is not received within the time specified and an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned.

In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find an updated excerpt from NRC Information Notice 96-28 on the NRC Web site at http://www.nrc.gov/docs/ML0612/ML061240509.pdf.

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with Title 10 of the *Code of Federal Regulation* (CFR) 2.390, of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter and the enclosed inspection report 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 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 you have any questions concerning this matter, please contact Ms. Vivian H. Campbell of my staff at 817-200-1455.

Sincerely,

/RA by LLHowell Acting For/

Mark R. Shaffer, Director
Division of Nuclear Materials Safety

Docket No. 030-35716
License No. 56-27702-01

Enclosure: NRC Inspection Report 030-35716/2017-001

cc w/enclosure:
M. Thomas Nadeau, Division of Environmental Health

NRC INSPECTION REPORT 030-35716/2017-001 DATED APRIL 5, 2017.

DISTRIBUTION

RidsOeMailCenter Resource; RidsNmssOd Resource; RidsOgcMailCenter Resource;
RidsSecyMailCenter Resource; RidsOcaMailCenter Resource; RidsOigMailCenter Resource;
RidsEdoMailCenter Resource; EDO_Managers; RidsOcfoMailCenter Resource;
RidsOiMailCenter Resource; RidsRgn1MailCenter Resource; RidsRgn3MailCenter Resource;
Kriss.Kennedy@nrc.gov; Karla.Fuller@nrc.gov; Patricia.Holahan@nrc.gov;
Scott.Morris@nrc.gov; Bill.Maier@nrc.gov; Francis.Peduzzi@nrc.gov;
Mark.Shaffer@nrc.gov; Linda.Howell@nrc.gov; Jack.Whitten@nrc.gov;
Ray.Kellar@nrc.gov; Vivian.Campbell@nrc.gov; Juan.Peralta@nrc.gov;
Michael.Vasquez@nrc.gov; Michael.Hay@nrc.gov; S.Woods@nrc.gov;
John.Kramer@nrc.gov; Casey.Alldredge@nrc.gov; Marisa.Herrera@nrc.gov;
Victor.Dricks@nrc.gov; Kerstun.Norman@nrc.gov; RidsOpaMail Resource;
Russell.Arrighi@nrc.gov; Jenny.Weil@nrc.gov; Michele.Burgess@nrc.gov;
Sophie.Holiday@nrc.gov; Angel.Moreno@nrc.gov; Jeremy.Bowen@nrc.gov;
Nick.Hilton@nrc.gov; OEWEB Resource; R4DNMS_MLIB;
Leelavathi.Sreenivas@nrc.gov;

ADAMS ACCESSION NUMBER: ML17067A198

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

OFFICE	NMSB-A	C:NMSB-A	ACES	RC	D:DNMS	
NAME	JFKatanic	RLKellar	MCHay	KSFuller	MRShaffer	
SIGNATURE	***/RA/***	***/RA/***	***/RA/***	***/RA/***	***/RA by LLHowell Acting For/***	
DATE	03/08/17	03/08/17	03/20/17	03/24/17	/04/05/17	

OFFICIAL RECORD COPY

U.S. Nuclear Regulatory Commission
Region IV

Docket No.	030-35716
License No.	56-27702-01
Report No.	030-35716/2017-001
EA No.	EA-17-026
Licensee:	Guam Medical Imaging Center
Location Inspected:	472 Chalan San Antonio Suite 111 Tamuning, Guam
Inspection Date:	January 9 and 13, 2017
Exit Meeting Date:	March 9, 2017
Inspector:	Janine F. Katanic, PhD, CHP, Senior Health Physicist Nuclear Materials Safety Branch A
Observed by:	Marilou O. Scroggs and Katherine B. Duenas Guam Department of Health and Social Services
Approved By:	Vivian H. Campbell Chief, Materials Licensing and Inspection Branch Division of Nuclear Materials Safety
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

Guam Medical Imaging Center
NRC Inspection Report 030-35716/2017-001

On January 9 and 13, 2017, the Nuclear Regulatory Commission (NRC) performed an announced, routine inspection of Guam Medical Imaging Center at its facility in Tamuning, Guam. The scope of the inspection included an examination of procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel to assess the licensee's compliance with the NRC's rules and regulations, and the conditions of the license. This report describes the findings of the inspection.

Program Overview

Guam Medical Imaging Center is authorized under NRC License No. 56-27702-01 to possess and use byproduct material permitted by Title 10 of the *Code of Federal Regulations* (CFR) 35.100 through 35.300. (Section 1)

Inspection Findings

During a routine, announced inspection conducted on January 9 and 13, 2017, two apparent violations of NRC requirements were identified involving the licensee's programmatic failures to: (1) prepare written directives (WDs) that were dated and signed by an Authorized User before the administration of I-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 WD. (Section 2)

Corrective Actions

The licensee reviewed 70 administrations requiring a WD and did not identify any medical events. As corrective actions the licensee: (1) revised its WD forms to remove the AU's preprinted signature; (2) established a process for the AU to review, sign, and date WDs prior to administrations of byproduct material requiring a WD; (3) developed written procedures to provide high confidence that administrations will be in accordance with the applicable WDs; (4) instituted a quarterly review of all administrations requiring a WD; and (5) will present the results of the WD review at its quarterly radiation safety committee meetings. (Section 3)

REPORT DETAILS

1. Program Overview (Inspection Procedure 87131)

1.1. Program Scope

Guam Medical Imaging Center (GMIC) is a small outpatient medical facility that is authorized under Nuclear Regulatory Commission (NRC) License No. 56-27702-01 to possess and use byproduct material permitted by Title 10 of the *Code of Federal Regulations* (CFR) 35.100 through 35.300. Licensed activities are authorized to be performed only at the licensee's facility located in Tamuning, Guam. The licensee's Radiation Safety Officer (RSO) wholly owns GMIC and is also an Authorized User (AU) on the license for certain procedures requiring a written directive (WD) under 10 CFR 35.300. The RSO is the primary AU for licensed activities. In addition to the RSO, GMIC has two other AUs, one of which is authorized for procedures requiring a WD under 10 CFR 35.300. The facility is staffed with one full-time certified nuclear medicine technologist (CNMT) and a part time administrative professional. At the time of the inspection, GMIC was the only facility providing diagnostic and therapeutic nuclear medicine services on Guam.

1.2. Observations and Findings

The inspector observed licensed activities, reviewed records, procedures, and documents maintained by the licensee, interviewed licensee personnel and conducted independent radiation measurements. Collectively, the activities observed, interviews conducted, and documents reviewed described the licensee's implementation of its radiation safety program.

2. Inspection Findings (87131)

2.1. Inspection Scope

A routine, announced inspection was conducted on January 9 and 13, 2017, at the licensee's facility in Tamuning, Guam. The inspector observed licensed activities; reviewed licensee facilities; reviewed records, procedures, and documents maintained by the licensee; interviewed licensee personnel and conducted independent radiation measurements. Records reviewed included: radiation instrumentation and surveys; radiation dosimetry; Radiation Safety Committee meeting minutes; receipt, testing, and use of radionuclide generators; and WDs for the administration of I-131 sodium iodide and therapeutic doses of unsealed byproduct material.

2.2. Observations and Findings

At the time of the inspection, the licensee was performing two types of procedures requiring WDs: administrations of I-131 sodium iodide in quantities greater than 1.11 megabecquerels (30 microcuries); and therapeutic administrations of unsealed Ra-223 dichloride. During the inspection, the inspector reviewed a selected sample of WDs for these procedures performed since the previous NRC inspection on November 5, 2013. The inspector observed that the AU's signature was exactly the same and in the same place on each completed WD. The CNMT explained that for

these procedures, the patient's referring physician would call or send a requisition to GMIC indicating what procedure and activity was desired, and the CNMT would prepare the WD and speak to the AU over the intercom system and discuss the WD information for the AU's approval. The AU would give his verbal approval of the WD over the intercom system. The AU's signature was already printed on the blank WD form in the signature block, and the CNMT would write the date of the AU's verbal approval next to it and put his own initials next to the date. During the inspection, the inspector reviewed a selected sample of WDs and did not identify any medical events.

On January 13, 2017, the inspector met with the AU at the Guam Radiology Consultants (GRC) facility to obtain additional information regarding the processing of WDs and to discuss the preliminary results of the inspection. The AU explained that the intercom system is an internet protocol based system. During business hours, the AU is normally located at the GRC facility, which is less than a mile from the GMIC facility. The internet based intercom system allows the AU to be in routine contact with the CNMT at GMIC, whether the AU is located down the street, or is away from Guam. The AU stated that the practice of using the intercom for verbally acknowledging and approving WDs was a long-standing practice. The AU acknowledged that his signature was "electronically" pre-printed on the WD form in the signature block but that it was not an "electronic signature" because it does not uniquely identify the individual who affixed the signature, does not affix the date and time of the signature, does not provide evidence of the individual's intent to sign, and does not meet other characteristics of an electronic signature. The AU acknowledged that he did not review the prepared WDs prior to providing his verbal approval of the WDs, and that he based his verbal approval on the verbal information regarding the content of the WDs that was provided by the CNMT.

Apparent Violation of 10 CFR 35.40(a)

10 CFR 35.40(a) requires, in part, that a WD must be dated and signed by an AU 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, the licensee failed to prepare WDs that that were dated and signed by an AU before the administration of I-131 sodium iodide in quantities greater than 1.11 megabecquerels (30 microcuries) or any therapeutic dosage of unsealed byproduct material. Between November 5, 2013, and January 9, 2017, GMIC prepared approximately 50 WDs for the administration of I-131 sodium iodide greater than 1.11 megabecquerels (30 microcuries) and three WDs for the administration of Ra-223 as a therapeutic dosage of unsealed byproduct material, and the WDs were not dated and signed by an AU before these administrations.

The licensee's failure to have WDs dated and signed by an AU before the administration of I-131 sodium iodide in quantities greater than 1.11 megabecquerels (30 microcuries) or any therapeutic dosage of unsealed byproduct material was identified as an apparent violation of 10 CFR 35.40(a). (030-35716/2017-001-01)

Apparent Violation of 10 CFR 35.41(a)(2)

10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a WD, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the WD.

Contrary to the above, from November 5, 2013, to January 9, 2017, the licensee failed to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the WD. Instead, GMIC utilized a verbal protocol for the authorization of WDs. The AU did not review the WDs, but instead authorized the administrations based on a verbal discussion with the CNMT, who would then add the date of approval to the WD that already contained the AU's pre-printed signature in the signature block. This type of verbal protocol increased the risk for administration errors through potential miscommunication.

The licensee's failure to develop, implement and maintain written procedures to provide high confidence that each administration is in accordance with the WD was identified as an apparent violation of 10 CFR 35.41(a). (030-35716/2017-001-02)

2.3. Conclusions

Two apparent violations of NRC requirements were identified involving the licensee's failures to: (1) prepare WDs that that were dated and signed by an AU before the administration of I-131 sodium iodide 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 WD. The licensee's failures were programmatic because the deficiencies existed from November 5, 2013, to January 9, 2017, and occurred for all procedures requiring a WD during that time period.

The practice of utilizing verbal authorizations of WDs could have resulted in miscommunication between an AU and the CNMT regarding the dose (activity) to be administered and could have resulted in medical events. In order to provide high confidence that administrations will be in accordance with WDs, therapeutic procedures should be performed based on a WD that is reviewed, signed, and dated by the AU.

The licensee's failures were attributed to several factors, including the lack of RSO/primary AU program oversight, GMIC's routine communication practices, and a lack of understanding of NRC regulatory requirements concerning the use of WDs. The RSO/primary AU is normally located at GRC during business hours. The CNMT at GMIC is a very experienced and knowledgeable individual that is capable of working independently. As a result of the physical separation of the two facilities and the reliance on the CNMT's capabilities, the RSO/AU has had little to no direct oversight of the daily licensed activities at GMIC. However, other than the proper preparation of WDs, no safety issues were identified.

When the inspector visited the RSO/primary AU at GRC, his communication practices were observed. Various procedures and diagnostic imaging techniques that do not involve licensed activities (e.g. X-ray, MRI, primary ultrasound, etc.) are

performed at GRC. The inspector observed that the RSO/AU utilized the intercom system as a routine communication tool within the GRC facility. It was observed that GRC staff would routinely hail the RSO/primary AU over the intercom to inform him of procedural outcomes and seek guidance on procedures. Although most routine communications would be acceptable by this method, communicating approval of a WD for licensed activities is not acceptable because the WD is required to be reviewed, dated and signed by the AU. The only regulatory exception for a verbal or oral authorization of a WD is if the emergent nature of a patient's condition necessitated a verbal communication so as to not jeopardize the patient's health. Even in this situation, the WD must be documented in writing as soon as possible by the AU.

3. Corrective Actions

During the inspection, when the deficiencies were identified, the AU acknowledged that he had not been signing or dating WDs, and that GMIC did not have written procedures to provide high confidence that each administration is in accordance with the WD. The AU stated that he re-read the referenced NRC requirements and recognized that they were not being met. The AU and CNMT took immediate actions to correct the identified deficiencies.

The licensee's corrective actions are documented in letter dated January 15, 2017 (ML17037D386) and email dated February 2, 2017 (ML17037D387). Following the inspection, the licensee reviewed 70 administrations requiring a WD, going back to 2013. No medical events were identified. The licensee revised its WD forms to remove the AU's preprinted signature. There is now a blank line for either of the approved AUs to sign and date the WD form. The CNMT will either travel to the AU's office at GRC, or the AU will travel to GMIC, so that the WDs can be reviewed, signed, and dated, prior to the administration. The licensee developed procedures along with the revision of the WD forms, which together provide high confidence that administrations will be in accordance with the WDs. Additionally, the licensee has instituted a quarterly review of all procedures (100 percent) requiring a WD. That the AUs will not review their own WDs, but instead the other AU will perform the review and vice versa. The results of the review will be presented and discussed at the quarterly radiation safety committee meeting.

4. Exit Meeting Summary

A preliminary exit briefing was conducted on January 13, 2017, at the conclusion of the onsite inspection with Dr. Nathaniel B. Berg, RSO, and James M. Kay, CNMT, Clinical Director. On March 9, 2017, a final exit briefing was conducted with Dr. Berg and Mr. Kay. The licensee acknowledged the inspection findings; no proprietary information was identified.

Supplemental Inspection Information

LIST OF PERSONS CONTACTED

Nathaniel B. Berg, M.D., Owner, RSO and AU
James M. Kay, CNMT, Clinical Director

INSPECTION PROCEDURES USED

87131 Nuclear Medicine Programs, Written Directive Required

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-35716/2017-001-01	APV	Failure to ensure that written directives were dated and signed by an AU before the administration of I-131 sodium iodide greater than 1.11. megabecquerels (30 microcuries) or any therapeutic dosage of unsealed byproduct material. (10 CFR 35.40(a))
030-35716/2017-001-02	APV	Failure to develop, implement, and maintain written procedures to provide high confidence that administrations were in accordance with written directives. (10 CFR 35.41(a))

Closed

None

Discussed

None

LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
APV	Apparent Violation
AU	Authorized User
CFR	*Code of Federal Regulations*
CNMT	Certified Nuclear Medicine Technologist
DNMS	Division of Nuclear Materials Safety
EA	Enforcement Action
GMIC	Guam Medical Imaging Center
GRC	Guam Radiology Consultants
NRC	Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
RSO	Radiation Safety Officer