



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

April 24, 2017

EA-17-036

Mr. Alan Funtanilla  
Chief Administrative Services Officer  
Guam Regional Medical City  
133 Route 3  
Dededo, Guam 96929

SUBJECT: NRC INSPECTION REPORT 030-38990/2017-001

Dear Mr. Funtanilla:

This letter refers to the initial, announced inspection conducted on January 10, 2017, at your facility located in Dededo, 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 representative records, observations of materials and facilities, independent radiation measurements, and interviews with personnel. On January 10, 2017, at the conclusion of the on-site portion of the inspection, the inspector discussed the preliminary inspection findings with you, Ms. Katie Kessler, Radiation Oncology Manager, and other representatives. A final exit briefing was conducted telephonically with you on April 18, 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) receive and possess byproduct material except as authorized in a specific license issued in accordance with the regulations in Title 10 of the *Code of Federal Regulations* (CFR), Chapter I; and (2) conduct your program in accordance with your NRC materials license.

Although there were no actual safety or security consequences associated with your failure to obtain an NRC specific license prior to the receipt and possession of two strontium-90 sealed sources totaling 1.62 millicuries, the NRC considers this failure to be a significant violation. In the absence of an NRC specific license, a potential existed for the sources to have been used by individuals without appropriate qualifications, or whose qualifications the NRC had not evaluated. Additionally, there was a potential for the sources to be improperly used, stored, secured, disposed, exported, or transferred.

We believe that we have sufficient information to make an enforcement decision regarding these apparent violations. Therefore, you may accept the violations as characterized in this

letter and enclosed inspection report, and notify us of that decision within 10 days. Alternatively, before the NRC makes its final enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in this letter and enclosed 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 meeting notice and 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 030-38990/2017-001; EA-17-036," 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.

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, 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 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/**

Mark R. Shaffer, Director  
Division of Nuclear Materials Safety

Docket No. 030-38990  
License No. 56-35371-01

Enclosure: NRC Inspection Report 030-38990/2017-001

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

## NRC INSPECTION REPORT 030-35716/2017-001 DATED APRIL 24, 2017.

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 By: **JFK**

ADAMS:  
☒ Yes ☐ No

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☐ Sensitive

Keyword:  
 EA-17-036  
 NRC-002

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DATE	04/10/17	04/13/17	04/18/17	04/19/17	04/24/17		

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**U.S. Nuclear Regulatory Commission  
Region IV**

Docket No.	030-38990
License No.	56-35371-01
Report No.	030-38990/2017-001
EA No.	EA-17-036
Licensee:	Guam Regional Medical City
Location Inspected:	133 Route 3 Dededo, Guam
Inspection Date:	January 10, 2017
Exit Meeting Date:	April 18, 2017
Inspector:	Janine F. Katanic, PhD, CHP, Senior Health Physicist Materials Licensing and Inspection Branch
Observed by:	Katherine B. Duenas Guam Department of Public 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 Regional Medical City NRC Inspection Report 030-38990/2017-001**

On January 10, 2017, the Nuclear Regulatory Commission (NRC) performed an announced, initial inspection of Guam Regional Medical City (GRMC) at its facility in Dededo, Guam. The scope of the inspection included an examination of representative records, observations of materials and facilities, 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 inspection findings.

#### **Program Overview**

Guam Regional Medical City is an acute care hospital that is authorized under NRC License No. 56-35371-01 to possess and store strontium-90 sealed sources for the intended purpose of disposal. Licensed activities are authorized to be performed only at the licensee's facility located in Dededo, Guam. (Section 1)

#### **Inspection Findings**

On December 8, 2014, GRMC acquired two strontium-90 sealed sources containing a total of 1.62 millicuries. This quantity is greater than the exempt quantity of strontium-90, 0.1 microcuries, and therefore required an NRC specific license. However, GRMC did not possess an NRC specific license when it acquired the sources. Several causal factors contributed to GRMC obtaining byproduct material without an NRC license, including: lack of familiarity that the NRC has statutory authority for the possession and use of byproduct material on Guam; a misinterpretation of transportation terminology with the NRC's license requirements; and that the strontium-90 sources were unnecessary for GRMC's linear accelerator program. After the identification of the non-compliance, GRMC applied for, and received, an NRC specific license.

Two apparent violations of NRC requirements were identified involving the licensee's failure to: (1) receive and possess byproduct material except as authorized in a specific or general license issued in accordance with the regulations in Title 10 of the *Code of Federal Regulations* (CFR), Chapter I; and (2) conduct its program in accordance with its NRC byproduct materials license when its Radiation Safety Officer (RSO) was no longer employed at GRMC. (Section 2)

#### **Corrective Actions**

A license application dated May 24, 2016, was submitted by GRMC to the NRC for a specific license. On October 19, 2016, NRC specific license Number 56-35371-01 was issued to GRMC, authorizing possession and storage with intent to dispose, of the two strontium-90 sources, and use of the strontium-90 sources incidental to inventory, leak testing, and disposal activities. The licensee is taking steps to properly transfer, export, or dispose of the sources. Following the NRC's inspection, GRMC submitted an amendment request to change its RSO. On March 27, 2017, the NRC issued Amendment No. 1 to GRMC's NRC license, authorizing another individual as the RSO. (Section 3)

## **REPORT DETAILS**

### **1. Program Overview (Inspection Procedure 87126)**

#### **1.1. Program Scope**

Guam Regional Medical City (GRMC) is an acute care hospital that is authorized under the Nuclear Regulatory Commission (NRC) License No. 56-35371-01 to possess and store strontium-90 sealed sources for the intended purpose of disposal. Licensed activities are authorized to be performed only at the licensee's facility located in Dededo, Guam. The hospital is operated by the Philippine-based healthcare company "The Medical City."

#### **1.2. Observations and Findings**

The inspector observed the storage of the licensed materials, reviewed records and documents maintained by the licensee, interviewed licensee personnel and performed 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 (87126)**

#### **2.1. Inspection Scope**

On January 10, 2017, the inspector conducted an announced, initial inspection at the licensee's facility in Dededo, Guam. The inspector observed the storage of the licensed materials, reviewed records and documents maintained by the licensee, interviewed licensee personnel and performed independent radiation measurements. Records reviewed included: procurement and receipt documentation for the strontium-90 sealed sources; sealed source certificates; and leak test results.

#### **2.2. Observations and Findings**

In 2014, GRMC acquired a linear accelerator through a vendor's Asia-based operations. As part of the package providing the linear accelerator to GRMC, the vendor arranged for a secondary vendor to provide certain associated equipment. The associated equipment included two strontium-90 sealed sources. Based on correspondence reviewed by the inspector, the two vendors communicated with the former medical physicist regarding regulatory and license requirements for the strontium-90 sources. On October 28, 2014, the former medical physicist responded to one of the vendors that the strontium-90 sources were "license exempt" in the United States. On December 8, 2014, working through the Asia-based vendor, a German-based vendor shipped two strontium-90 sealed sources to GRMC. The shipment contained one IBA Dosimetry model CDC and one IBA Dosimetry model CDP, each 810 microcuries, for a total of 1.62 millicuries of strontium-90. The sources were received by GRMC on December 14, 2014. Around this time, the former medical physicist left the employment of GRMC.

Sometime thereafter, a second medical physicist began employment at GRMC. The medical physicist became aware of the strontium-90 sources in storage at GRMC. In

late October 2015, the medical physicist contacted the NRC and related that the sources were still in their original shipping boxes, were not needed by GRMC, and inquired about proper disposal methods. It appears that the NRC, however, misdirected this call. In January 2016, the medical physicist contacted the NRC again and reached members of the NRC technical staff. The NRC technical staff identified that the sources obtained by GRMC required an NRC specific license. Title 10 CFR 30.18 states, in part, that persons are exempt from licensing if they receive, possess, use, etc. quantities that do not exceed the quantity in 10 CFR 30.71, Schedule B. Title 10 CFR 30.71, Schedule B provides that the exempt quantity of strontium-90 is 0.1 microcuries. Because GRMC possessed 1.62 millicuries of strontium-90, it therefore required an NRC specific license. The medical physicist was informed of the non-compliance and the need to submit an application to the NRC for a specific license.

### **Apparent Violation of 10 CFR 30.3(a)**

10 CFR 30.3(a) requires, in part, that no person shall transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in 10 CFR Chapter I.

Contrary to the above, from December 15, 2014, to October 19, 2016, GRMC received and possessed byproduct material and these activities were not authorized in a specific license issued in accordance with the regulations in 10 CFR Chapter I. Specifically, from December 15, 2014, to October 19, 2016, GRMC received and possessed byproduct material in two sealed sources, each containing 810 microcuries of strontium-90, an amount which required an NRC specific license, and these activities were not authorized in a specific license issued in accordance with the regulations in 10 CFR Chapter I.

The licensee's failure to receive and possess byproduct material except as authorized in a specific license issued in accordance with the regulations in 10 CFR Chapter I, was identified as an apparent violation of 10 CFR 30.3(a). (030-38990/2017-001-01)

A license application dated May 24, 2016, was submitted by GRMC to the NRC for a specific license. On October 19, 2016, NRC specific license Number 56-35371-01 was issued to GRMC, authorizing possession and storage with intent to dispose of the two strontium-90 sources, and use of the strontium-90 sources incidental to inventory, leak testing, and disposal activities. In order to schedule the initial inspection, in early December 2016, the NRC inspector attempted to contact the medical physicist, who was authorized on the GRMC specific license as the licensee's Radiation Safety Officer (RSO). When these contacts were unsuccessful, the inspector reached out to GRMC's Chief Administrative Services Officer, who was listed in the GRMC license application as the Certifying Officer for GRMC. The inspector was informed that the medical physicist/RSO authorized on the NRC license was no longer serving GRMC and had been replaced by another medical physicist. The inspector arranged to perform the initial inspection of the NRC license.

On January 10, 2017, the inspector performed an announced, initial inspection of the NRC license. The inspector observed the unopened shipping boxes containing the



strontium-90 sealed sources in a locked and controlled room. Independent radiation measurements performed by the inspector did not indicate any areas of concern. The inspector was informed that the RSO had left Guam in June 2016, prior to the issuance of the NRC license. During the time period between when medical physicist/RSO left Guam and the NRC license was issued to GRMC, the individual maintained communication with the NRC regarding the GRMC license application and still had some level of oversight of the strontium-90 sources because the individual intended to return to Guam. Sometime in December 2016 (an exact date could not be established), the individual accepted other employment and permanently ceased oversight of GRMC's NRC licensed activities. After the medical physicist/RSO left, another medical physicist and the GRMC Radiation Oncology Manager had assumed responsibility for maintaining oversight and control of the unopened boxes containing the strontium-90 sealed sources. The licensee, however, did not inform the NRC of these changes or request approval of any of these individuals as the RSO.

### **Apparent Violation of License Condition 11**

License Condition 11 of NRC materials license Number 56-35371-01, issued on October 19, 2016, states that the RSO for the license is Amanda Marie Jackson, M.S..

Contrary to the above, on January 10, 2017, the individual named as RSO on NRC materials license Number 56-35371-01, issued on October 19, 2016, was no longer the RSO.

The licensee's failure to conduct its program in accordance with its NRC materials license was identified as an apparent violation of License Condition 11 of NRC materials license Number 56-35371-01. (030-38990/2017-001-02)

## **2.3. Conclusions**

Two apparent violations of NRC requirements were identified involving the licensee's failure to: (1) receive and possess byproduct material except as authorized in a specific license issued in accordance with the regulations in 10 CFR Chapter I; and (2) conduct its program in accordance with its NRC byproduct materials license.

There were no actual safety or security consequences associated with GRMC's possession of the strontium-90 sources. As confirmed by the inspector during the inspection, the strontium-90 sources were received by GRMC but the shipping boxes that the sources were shipped in were never opened by GRMC and the sources were never used. The sources in the shipping boxes had been stored in a locked, controlled room. Additionally, GRMC obtained the services of a consultant who performed tests for removable contamination on the outside of the boxes. The results did not indicate any removable contamination and the external radiation exposure from the outside of the unopened shipping boxes did not indicate any areas of concern.

Several causal factors contributed to GRMC obtaining byproduct material without an NRC license, including: lack of familiarity that the NRC has statutory authority for the possession and use of byproduct material on Guam; a misinterpretation of

transportation terminology with NRC license requirements; and that the strontium-90 sources were unnecessary for the implementation of GRMC's linear accelerator program.

A Philippines-based company operates GRMC, and as such, GRMC dealt with several Asia-based vendors for procuring its radiology equipment, including the GRMC linear accelerator. Because the linear accelerator was purchased through a vendor's Asia-based operations, GRMC was provided with the "Asia package" that included the strontium-90 sealed sources. The inspector was informed that a similar linear accelerator package for a "United States-based" customer would not have included the strontium-90 sealed sources. Based on a review of correspondence between GRMC and the vendors, it appears that the Asia-based vendor was unaware of the regulatory requirements for byproduct material possession and use on Guam. In the correspondence reviewed by the inspector, the vendor did not appear to be aware that for Guam, as a Territory of the United States, the NRC has statutory authority to regulate the possession and use of byproduct materials. The Asia-based vendor instead relied on GRMC for regulatory information related to the possession of the strontium-90 sources.

As a result, the vendor reached out to GRMC's former medical physicist for clarifying information. The former medical physicist believed that the strontium-90 sources could be obtained without any type of license. It appears that the former medical physicist misinterpreted the U.S. Department of Transportation (DOT) shipping requirements with the license requirements for the possession of the strontium-90 sources. The shipping boxes containing the strontium-90 sources were shipped labelled as "Radioactive material, Excepted package, Limited Quantity of Material, UN 2910." In this regard, the specific package labeling meant that the items being shipped were "excepted" from certain DOT shipping requirements. The former medical physicist erroneously inferred that this specific DOT package labeling meant that the strontium-90 sources were excepted or exempt from any NRC licensing requirements.

During the January 10, 2017, inspection, the inspector was informed that the strontium-90 sources were not needed by GRMC and it is unlikely that they would have ever been used. Licensee representatives asserted that the methodology that uses strontium-90 sealed sources for linear accelerator dosimetry equipment calibration is a technique used in Asian countries, but is not utilized in the United States, of which Guam is a Territory, because it would not fulfil the necessary standards for calibration of this equipment. Had the former medical physicist been aware of this, it is possible that the strontium-90 sources may not have been obtained by GRMC, which would have prevented GRMC from being in non-compliance with the NRC licensing requirements.

### **3. Corrective Actions**

A license application dated May 24, 2016, was submitted by GRMC to the NRC for a specific license. On October 19, 2016, NRC specific license Number 56-35371-01 was issued to GRMC (ML16299A198 and ML16299A199), authorizing possession and storage with intent to dispose, of the two strontium-90 sources, and use of the strontium-90 sources incidental to inventory, leak testing, and disposal activities. Because GRMC does not intend on using the strontium-90 sources to calibrate its

linear accelerator dosimetry equipment, it is taking steps to properly transfer, export, or dispose of the sources.

To address the identified deficiency related to the lack of an NRC-approved RSO, following the NRC's inspection, in letter dated January 11, 2017 (ML17019A123), the licensee submitted an amendment request to remove Amanda Marie Jackson, M.S., as the RSO the NRC and requested to authorize another individual, John Y. Young, M.D., as the RSO. After a review of the proposed individual's training, experience, and qualifications, the NRC issued Amendment No. 1 to NRC materials license Number 56-35371-01, on March 27, 2017, authorizing John Y. Young, M.D., as the RSO (ML17087A539 and ML17087A541).

#### **4. Exit Meeting Summary**

A preliminary exit briefing was conducted on January 10, 2017, at the conclusion of the onsite inspection with Mr. Alan Funtanilla, Chief Administrative Services Officer; Ms. Katie Kessler, Radiation Oncology Manager; and other representatives. On April 18, 2017, a final exit briefing was conducted with Mr. Alan Funtanilla, Chief Administrative Services Officer. The licensee acknowledged the inspection findings; no proprietary information was identified.

## **Supplemental Inspection Information**

### **LIST OF PERSONS CONTACTED**

Alan Funtanilla, Chief Administrative Services Officer  
Katie Kessler, R.T. (R)(T), Radiation Oncology Manager  
Gregory Courlas, Medical Physicist, Northwest Medical Physics Center  
Susan Lou, Medical Physicist, Northwest Medical Physics Center  
Ronald Frick, CHP, Gamma Corporation

### **INSPECTION PROCEDURES USED**

87126      Industrial/Academic/Research Programs

### **ITEMS OPENED, CLOSED, AND DISCUSSED**

#### **Opened**

030-38990/2017-001-01	APV	Failure to receive and possess byproduct material except as authorized in a specific license issued in accordance with the regulations in Title 10 of the CFR, Chapter I. (10 CFR 30.3(a))
030-38990/2017-001-02	APV	Failure to conduct its program in accordance with its NRC byproduct materials license. (License Condition 11)

#### **Closed**

None

#### **Discussed**

None

### **LIST OF ACRONYMS USED**

ADAMS	Agencywide Documents Access and Management System
APV	Apparent Violation
CFR	<i>Code of Federal Regulations</i>
DNMS	Division of Nuclear Materials Safety
DOT	Department of Transportation
EA	Enforcement Action
GRMC	Guam Regional Medical City
NRC	Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
RSO	Radiation Safety Officer