



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TEXAS 76011-4005

August 14, 2007

Department of the Air Force  
USAF Radioisotope Committee  
HQ AFMOA/SG3PR  
110 Luke Ave., Suite 405  
Bolling AFB, DC 20032-7050

SUBJECT: NRC INSPECTION REPORT 030-28641/07-002 AND NOTICE OF VIOLATION

Dear Lt. Col. Mark Wrobel:

The letter refers to a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on June 4 and 5, 2007, at the Wright Patterson Air Force Base (AFB), Nuclear Medicine Department. This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your NRC license. Within these areas, activities authorized under the U.S. Air Force permit number OH-04682-02/05AFP were reviewed, with a focus on selected procedures and representative records, security and control of licensed material, observations of activities, and interviews with personnel. Major Robert Rodgers from the U.S. Air Force (USAF) Radioisotope Committee (RIC) and Lt. Col. Craig Adams with the Air Force Inspection Agency (AFIA), were both present to observe the inspection. The preliminary inspection findings were discussed with Colonel James Brown at the conclusion of the onsite portion of the inspection. The NRC inspector briefed the NRC USAF Project Manager separately, on the details of the inspection. The NRC USAF Project Manager subsequently briefed the NRC Region IV Office of Enforcement and the Division of Nuclear Materials Safety management on the outcome of the inspection. The inspection results were discussed with members of your staff during a final telephonic exit briefing conducted on July 20, 2007.

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 included on the NRC Web site at [www.nrc.gov](http://www.nrc.gov); select **Public Meeting and Involvement, Enforcement**, then **Enforcement Policy**. These 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 are being cited in the enclosed Notice because they were identified by the NRC during the inspection, rather than being self-identified by the licensee.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken, to correct the violations and prevent recurrence, are already adequately addressed in the enclosed Inspection Report No. 030-28641/07-002, which is on the docket. 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 "Rules of Practice," a copy of this letter, its enclosures, 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's 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.

Should you have any questions concerning this inspection, please contact the undersigned at (817) 860-8197 or Ms. Rachel S. Browder at (817) 276-6552.

Sincerely,

**/RA/**

Jack E. Whitten, Chief  
Nuclear Materials Licensing Branch

Docket No.: 030-28641  
License No.: 42-23539-01AF

Enclosures:

- 1) Notice of Violation
- 2) NRC Inspection Report 030-28641/07-002  
w/Attachment

cc:

Lt. Col. Scott Nicholson  
Chief, Radiation Surveillance Division/  
RIC Secretariat  
AFIOH/SDR  
2350 Gillingham Drive  
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bcc w/enclosure (via e-mail distribution):

LDWert

CLCain

JEWhitten

VHCampbell

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MCMaier

GOParker

RSBrowder

RKStruckmeyer

RITS Coordinator

RIV Materials Docket File - 5<sup>th</sup> Floor

SUNSI Review Complete: RSB

ADAMS: ☒ Yes

☐ No

Initials: RSB

☒ Publicly Available

☒ Non-Sensitive

DOCUMENT NAME: C:\FileNet\ML072270322.wpd

RIV:DNMS:NMLB	RIII/DNMS/NMIB	C:DNMS/NMLB	
RSBrowder	GOParker	JEWhitten	
<b>/RA/</b>	<b>/RA per email</b>	<b>/RA/</b>	
07/30/07	08/02/07	08/14/07	

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## **ENCLOSURE 1**

### **NOTICE OF VIOLATION**

Department of the Air Force  
USAF Radioisotope Committee

Docket No. 030-28641  
License No. 42-23539-01AF

During an NRC inspection conducted on June 4 and 5, 2007, at the Wright Patterson Air Force Base (AFB), Nuclear Medicine Department, USAF Permit No. OH-04682-02/05AFP, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1902(e) requires that the licensee post each area or room in which certain amounts of licensed material, specified in §20.1902(e), are used or stored, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

Contrary to the above, on June 5, 2007, the NRC inspector identified unit doses of technetium-99m, in quantities exceeding ten times the quantity of such materials as specified in Appendix C to 10 CFR Part 20, that were stored in a locked closet which did not have a sign or signs bearing the radiation symbol and the words "Caution, Radioactive Materials."

This is a Severity Level IV violation (Supplement VI).

- B. 10 CFR 35.63(a) requires that a licensee determine and record the activity of each dosage before medical use.

Contrary to the above, on June 5, 2007, the NRC inspector identified 8 of 20 records in which the permit holder had not recorded the required information for the activity of a radiopharmaceutical after making a dosage determination, before it was administered to a patient for medical use.

This is a Severity Level IV violation (Supplement VI).

The NRC has concluded that information regarding the reason(s) for the violations, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 030-28641/07-002. However, 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 Notice of Violation" and send it to the US. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region IV, and a copy to the NRC Project Manager for the USAF Master Materials License, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

Enclosure 1

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (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, proprietary, or safeguards 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 two working days.

Dated this 14<sup>th</sup> day of August 2007

U.S. NUCLEAR REGULATORY COMMISSION  
REGION IV

Docket No.: 030-28641

License No.: 42-23539-01AF

Report No.: 030-28641/07-002

Licensee: Department of the Air Force  
USAF Radioisotope Committee

Permit Holder: 88 MDG/SG  
Permit No.: OH-04682-02/05AFP  
Location: Wright Patterson Air Force Base, Ohio

Dates: June 4 and 5, 2007

Inspector: George O. Parker, Health Physicist  
Region III

Approved By: Jack E. Whitten, Chief  
Nuclear Materials Licensing Branch

Attachment: Supplemental Inspection Information

## **EXECUTIVE SUMMARY**

Department of the Air Force  
NRC Inspection Report 030-28641/07-002

A routine unannounced inspection was conducted at Wright Patterson Air Force Base (AFB) Nuclear Medicine Department, Permit Number OH-04682-02/05AFP, as authorized by the USAF Master Materials License No. 42-23539-01AF. The inspection was performed using Inspection Procedure 87131, "Nuclear Medicine Program, Written Directives Required" and focused on security and control of radioactive materials, shielding of licensed materials, comprehensive safety measures, radiation instrumentation and surveys, and management oversight.

## Report Details

### Summary of Facility

The nuclear medicine department at Wright Patterson AFB was a large program which performed approximately ten to fifteen nuclear medicine procedures a day. The primary procedures performed utilized technetium-99m under 10 CFR 35.200. Additionally, the permittee performed approximately 2-3 procedures of sodium iodide I-131, on a monthly basis. There were two authorized users listed on the permit; however, one of the authorized users had retired the week previous to the inspection. The nuclear medicine staff consisted of 4 non-commissioned nuclear medicine technologists and one civilian nuclear medicine/ultra sound technologist.

## **1. Nuclear Medicine Program (87131)**

### **1.1 Inspection Scope**

The inspector reviewed the security and control of radioactive materials, shielding of licensed materials, radiation instrumentation and surveys, and management oversight. The NRC assessment was performed based on observation of ongoing activities, interviews with personnel, and review of associated records.

### **1.2 Observations and Findings**

The nuclear medicine department did not possess a radiopharmaceutical generator. They ordered and received only unit dosages of radioactive materials prepared by a radiopharmacy. The unit dosages were delivered in "ammo-cans" by a radiopharmaceutical driver to the facility. The radiopharmaceutical driver placed the "ammo cans" in an unmarked closet within the nuclear medicine department. The permittee stated that the driver always delivered the ammo cans to the specific closet and retrieved the pharmacy returns from the same closet. The NRC regulation in 10 CFR 20.1902(e) requires, in part, that the permit holder conspicuously post a sign bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" for the quantity of material being stored in the closet. The inspector observed that the specific closet was not posted which was a violation of NRC requirements **Violation (VIO) 03028641/2007-002-01**. The nuclear medicine staff took appropriate corrective actions to mark the closet with the appropriate signs prior to the on-site inspection exit briefing.

In addition to diagnostic use, the nuclear medicine department was authorized to administer radio-pharmaceuticals to patients in accordance with a written directive. The purpose of the physician's written directive is to ensure that the prescription is carried-out correctly and completely for each administration. During the period January through May 2007, the authorized users prepared over 100 written directives for the administration of radiopharmaceuticals. The inspector reviewed approximately 20 of the written directives, at which time, he identified errors in eight of the written directives reviewed. The errors involved the documentation of the verified activity to be administered to the patient. In accordance with the regulations in 10 CFR 35.63, the permit holder must determine and record the activity of each dosage before medical use by either direct measurement of the radioactivity, or by decay-correction based on the activity determined by the radiopharmacy. The permit holder's procedures required that they verified the activity



prior to administration by using the dose calibrator. However, the errors identified on the eight written directives indicated that the authorized user had not recorded the verified activity prior to administering the radionuclide to the patient, which is a violation of 10 CFR 35.63 of NRC regulations, **(VIO) 03028641/2007-002-02**. The permittee subsequently reviewed the documentation for each of the eight written directives identified by the inspector and made prompt corrections to the records. Through additional review of each record, the NRC inspector determined that no medical events had occurred due to these errors.

The inventory for radioactive materials was adequately documented and maintained by the nuclear medicine department. The permittee performed surveys of the facility as required by the permit and NRC regulations. In reviewing the survey records, the inspector noted that the survey maps did not currently reflect the permittee's facility. The permittee indicated to the inspector that they would update the survey maps to reflect a recent renovation of the facility in order to accurately reflect the appropriate survey locations. The inspector interviewed the nuclear medicine staff regarding the safe use of unsealed byproduct materials. The inspector determined that the nuclear medicine staff had used the necessary shielding for syringes and vials to protect workers and members of the public from unnecessary radiation. The nuclear medicine department performed the required annual audits of the radiation protection program in accordance with the provisions of 10 CFR 20.1101. Additionally, a medical physicist conducted an assistance visit at intervals not exceeding 24 months as required by permit condition 26. During the final exit briefing, the USAF Radioisotope Committee (RIC) (Licensee) indicated they were revising the audit checklist used by the medical physicist(s) to ensure that all elements for the control of licensed materials were captured in the checklist. Additionally, the Licensee stated to the NRC Project Manager that they were planning to perform a staff assistance visit as follow-up to the NRC inspection.

In reviewing the permittee's management structure and their involvement in the radiation safety program, the inspector determined that there was sufficient management support and oversight to administer the nuclear medicine program. The inspector determined that the Radiation Safety Committee had met on a regular basis and had discussed issues regarding the nuclear medicine program and radiation safety program. ALARA practices were implemented by the permittee when appropriate.

### 1.3 Conclusions

Two violations were identified during the inspection. These violations related to the posting of locations containing radioactive materials as required by 10 CFR 20.1902(e) and a failure to properly record the activity of a radiopharmaceutical in accordance with 10 CFR 35.63(a), prior to administering the dosage of a radiopharmaceutical to a patient for medical use. Once the violations were identified, the permittee made prompt corrective actions for each identified violation. Through additional review of each written directive record where an identified error was observed, the NRC inspector determined that no medical events had occurred due to these documentation errors. The proposed revision to the medical physicist's audit checklist by the Licensee, and the planned staff assistance visit should be sufficient actions to provide a level of assurance to the NRC that the permit holder is implementing a program that is protective of health and safety and is compliant with NRC regulations.

## **2. Exit Meeting Summary**

On June 5, 2007, the inspector presented the preliminary inspection results to Colonel James Brown and other members of the nuclear medicine staff. A final exit briefing was held telephonically with the USAF RIC on July 20, 2007, to discuss the findings of this inspection.

## **ATTACHMENT**

### **PARTIAL LIST OF PERSONS CONTACTED**

Colonel James Brown, Authorized User  
Colonel Angelita Gabatine, Authorized User (retired)  
1st Lt. Leidel, Permit Radiation Safety Officer (by phone)  
Major Hanny, Assistant Radiation Safety Officer  
Ms. Carol Ault, Nuclear Medicine Technician/Ultra Sound Technician

### **INSPECTION PROCEDURES USED**

87131 Nuclear Medicine Programs, Written Directive Required

### **ITEMS OPENED, CLOSED OR DISCUSSED**

#### **Opened**

03028641/2007-002-01	VIO	Failure to post radioactive materials area.
03028641/2007-002-02	VIO	Failure to record the dosage prior to administering to patient.

#### **Closed**

03028641/2007-002-01	VIO	Permit Holder posted radioactive materials area.
03028641/2007-002-02	VIO	Permit Holder corrected written directives by recording the proper dosage. Further review ensured there were no medical events that occurred due to errors in the written directives.

#### **Discussed**

None

### **LIST OF ACRONYMS USED**

CFR	Code of Federal Regulations
Notice	Notice of Violation
RIC	Radioisotope Committee
VIO	Violation