UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 EAST LAMAR BLVD, SUITE 400
ARLINGTON, TEXAS 76011-4125

July 20, 2010

Department of the Air Force
ATTN: David A. Smith, Lt Col, USAF, BSC
Chief, Radiation Programs
AF/SG (AFMSA/SG3PB)
USAF Radioisotope Committee
1500 Wilson Blvd., Suite 1600
Arlington, VA 22209

SUBJECT: NRC INSPECTION REPORT 30-28641/09-002 AND NOTICE OF VIOLATION FOR WRIGHT PATTERSON MEDICAL CENTER

Dear Lt Col Smith:

This letter refers to a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on September 14-15, 2009, at Wright Patterson Medical Center, Dayton, Ohio, and the in-office review through January 29, 2010. 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 U.S. Air Force Permit OH-04682-03/01AFP were reviewed, with a focus on selected procedures and representative records, security and control of licensed material, observations of activities, and interviews of personnel. The preliminary inspection findings were discussed with Col Barbara L. Kuhn and members of her staff, including Capt Isaac Stephen, Radiation Safety Officer (RSO), at the conclusion of the onsite portion of the inspection. The inspection results were discussed with you during a final telephonic exit briefing conducted on July 8, 2010.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy included on the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html."

The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because the NRC identified it during the inspection, rather than being self-identified by the licensee. The NRC has concluded that information regarding the reason for the violation and the corrective actions taken to correct the violation and prevent recurrence is already adequately addressed on the docket in the enclosed NRC inspection report. Therefore, you are not required to respond to this letter unless the description herein 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.

If you contest the violation or significance of the violation, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region IV, 612 East Lamar Blvd., Arlington, TX 76011-4125; and (2) the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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's 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.

Sincerely,

/RA/ by Jackie Cook, acting

Jack E. Whitten, Chief
Nuclear Materials Safety Branch B

Docket: 030-28641
License: 42-23539-01AF

Enclosures:
1. Notice of Violation
2. NRC Inspection Report 030-28641/09-002
   w/Attachment

Internal distribution w/Enclosure 1 via e-mail:
A. Howell, D:DNMS
C. Cain, DD:DNMS
J. Whitten, C:DNMS/NMSB-B
V. Campbell, C:DNMS/NMSB-A
R. Browder, DNMS
J. Cook, DNMS/NMSB-B
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R4DNMS_MS-B@nrc.gov

Hard Copy:
DNMS File Room
DNMS Secretarial File

S:\DNMS\USAF\2009 insp\USAF Wright Patterson Medical Center NOV.docx
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RIV:DNMS/NMSB-B	NMSB-B	C:NMSB-B	
RSBrowder;dlf	JDCook	JEWhitten	
/RA/	***/RA/***	***/RA/ by JDCook***	
7/13/10	7/15/10	7/20/10	

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Department of the Air Force
USAF Radioisotope Committee

Docket: 030-28641
License: 42-23539-01AF

During an NRC inspection conducted on September 14-15, 2009, at Wright Patterson Medical Center, Dayton, Ohio, United States Air Force (USAF) Permit OH-04682-03/01AFP, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below.

> 10 CFR 35.643(d)(2) requires in part that source exposure indicator lights be properly operating on the remote afterloader unit, on the control console, and in the facility.
>
> Contrary to the above, the permittee did not have on September 14, 2009, a source indicator light operating properly in the facility. Specifically, when the source moved from the remote afterloader unit into the collimated position during patient treatment, the facility indicator light went to the "off" position, because the light was linked to the exposure rate in the room in lieu of the source operating position for the remote afterloader unit.
>
> This is a Severity Level IV violation. (Supplement IV)

The NRC has concluded that information regarding the reason for the violation, 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 the enclosed inspection report. 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 a Notice of Violation" 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, Region IV, 612 East Lamar Blvd., Arlington, TX 76011-4125, within 30 days of the date of the letter transmitting this Notice.

If you contest the violation or significance of the violation, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region IV, 612 East Lamar Blvd., Arlington, TX 76011-4125; and (2) the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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's Web site at: www.nrc.gov/reading-rm/pdr.html or 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 2 working days.

Dated this 20th day of July 2010

Enclosure 1

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket:	030-28641
License:	42-23539-01AF
Report:	030-28641/09-002
Licensee:	Department of the Air Force USAF Radioisotope Committee
Permit Holder:	Wright Patterson Medical Center
Permit:	OH-04682-03/01AFP
Location:	Dayton, Ohio
Dates:	September 14-15, 2009
Inspector:	George O. Parker, Senior Health Physicist Region III
Accompanied:	Rachel S. Browder, Project Manager, USAF MML Region IV
Approved By:	Jack E. Whitten, Chief Nuclear Materials Safety Branch B
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

Department of the Air Force
NRC Inspection Report 03028641/09-002

This inspection was a routine, unannounced inspection at Wright Patterson Medical Center, Dayton, Ohio, Permit OH-04682-03/01AFP, authorized by U.S. Air Force Master Materials License 42-23539-01AF. The inspection was performed using Inspection Procedures 87131, "Nuclear Medicine Programs," and 87132, "Brachytherapy Programs." The inspection focused on security and control of radioactive materials, radiation instrumentation and surveys, shielding of radioactive materials, comprehensive safety measures, and management oversight. The inspection identified one violation of NRC requirements, which is documented in the enclosed Notice of Violation and involves the failure to have a source indicator light operating properly in the facility as required by 10 CFR 35.643(d)(2) for procedures utilizing the remote high dose rate afterloader unit. The source indicator light is a safety requirement that prohibits the possibility of an overexposure to a worker. Specifically, when the sealed source moved from the afterloader unit into the collimated position during patient treatment, the facility indicator light went to the "off" position, because the light was linked to the exposure rate in the room in lieu of the source operating position for the high dose rate afterloader unit. This is a safety requirement that prohibits the possibility of overexposure to a worker.

REPORT DETAILS

Summary of Facility

Permit OH-04682-03/01AFP for Wright Patterson Medical Center (medical center) authorized 10 CFR 35.100, §35.200, §35.300, §35.400, and §35.600 modalities. The nuclear medicine department operated with four technicians and performed approximately 15 procedures per day. The medical center was recently authorized a GammaMed 232 high dose rate (HDR) afterloader on its permit, for therapeutic procedures. The medical center also performed prostate manual brachytherapy procedures using a Theragenics seed implant device. The permittee utilized a Department of Veterans Affairs expert from Seattle to perform a post-review of all prostate manual brachytherapy procedures.

1 Nuclear Medicine Programs (87131)

1.1 Inspection Scope

The security and control of radioactive materials, shielding of licensed materials, labeling and posting requirements, radiation surveys, physical security of radioactive materials, and management oversight were reviewed by the inspectors to verify that licensed activities were conducted in accordance with NRC regulations and provisions of USAF License 42-23539-01AF. 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. The department ordered and received only unit dosages of radioactive materials prepared by a nuclear pharmacy. The inspectors performed a tour of the nuclear medicine department and observed members of the nuclear medicine staff performing injections of radiopharmaceuticals. In addition, the permittee staff demonstrated radiopharmaceutical package receipt procedures for the inspectors. Techniques employed by the staff demonstrated good handling practices as well as adequate knowledge of radiation safety. Staff members demonstrated proper radiological waste handling practices. The annual audit of the radiation protection program content and implementation was performed as required by 10 CFR 20.1101(c) and the results of the audit were reviewed by management.

1.3 Conclusions

The inspectors did not identify any violations or safety concerns.

2 Brachytherapy Programs (87132)

2.1 Inspection Scope

The radiation safety program, training of personnel, physical security of radioactive materials, and management oversight were reviewed by the inspectors to verify that licensed activities were conducted in accordance with NRC regulations and provisions of USAF License 42-23539-01AF. The NRC assessment was performed based on observation of ongoing activities, interviews with personnel, and review of associated records.

2.2 Observations and Findings

The permittee was recently authorized a GammaMed 232 HDR afterloader. At the time of the inspection, a limited number of patients had been treated. The inspectors reviewed the records for all the procedures which had been performed. In addition, the daily quality control checks of the HDR were observed. The inspectors had the opportunity during the inspection to observe the permittee staff and the Authorized User perform a scheduled treatment for one of the patients. It was noted during the performance of the procedure that a violation of 10 CFR 35.643(d)(2) occurred, for failure to have a functioning source exposure indicator light operating in the facility. The source indicator light is a safety requirement that prohibits the possibility of an overexposure to a worker. (03-028641/09-001)

More specifically, while observing the procedure from the console, it was noted that, when the source travelled to the collimator for the treatment period, the source exposure indicator light outside of the door to the procedure room failed to illuminate. When the source travelled back to the HDR afterloader, the source indicator light was illuminated. The permittee stated that the vendor had installed the source exposure indicator light; however, the light was triggered by the exposure rate in the treatment room in lieu of the source being outside of the locked storage compartment of the HDR afterloader. The permittee committed to installing a properly functioning source exposure indicator light in the facility and would station personnel to restrict access at the entry door when the HDR was in operation until an indicator light could be installed. During a subsequent site visit by the Region IV USAF MML Project Manager on January 28, 2010, the permittee demonstrated that the source exposure indicator light was functioning as required by 10 CFR 35.643(d)(2).

The permittee staff had performed a few prostate manual brachytherapy procedures using a Theragenics seed implant device. The permittee utilized a Department of Veterans Affairs expert from Seattle to perform a post-review of all prostate manual brachytherapy procedures. The permittee treated the prostate to D90 and performed a post-CT scan at 30 days. The inspectors reviewed all of the cases that had been performed and no discrepancies were noted in the review.

2.3 Conclusions

One violation was identified during the inspection. The violation related to the failure to have a source indicator light operating properly in the facility as required by 10 CFR 35.643(d)(2). Specifically, when the source moved into the collimated position during patient treatment, the facility indicator light went to the “off” position because the light was linked to the exposure rate in the room in lieu of the source operating position for the remote afterloader unit. During a subsequent site visit by the Region IV USAF MML Project Manager on January 28, 2010, the permittee demonstrated that the source exposure indicator light was functioning as required by 10 CFR 35.643(d)(2). Therefore, this violation is considered closed.

3 Exit Meeting Summary

On September 15, 2009, the inspectors presented the preliminary inspection results to Col Barbara L. Kuhn and other members of the medical center staff, including Capt Isaac Stephens, Radiation Safety Officer. A final exit briefing was held telephonically with the USAF Radioisotope Committee on July 8, 2010, to discuss the findings of this inspection.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Col (Dr.) Barbara L. Kuhn, Squadron Commander 88th MDG/MDOS
Lt Col (Dr.) Darin K. Morgan, Flight Commander 88th MDG/SGOX
Lt Col (Dr.) Gregory J. Morse, Chief Nuclear Medicine
Maj (Dr.) David Hoopes, Authorized User, Therapy
Capt Isaac Stephen, Radiation Safety Officer

INSPECTION PROCEDURE USED

IP 87131, Nuclear Medicine Programs
IP 87132, Brachytherapy Programs

ITEMS OPENED, CLOSED, OR DISCUSSED

Opened

30-28641/09-001	SLIV	failure to have a source indicator light operating properly in the facility as required by 10 CFR 35.643(d)(3)

Closed

30-28641/09-001	SLIV	failure to have a source indicator light operating properly in the facility as required by 10 CFR 35.643(d)(3)

Discussed

None

LIST OF ACRONYMS USED

CFR	*Code of Federal Regulations*
HDR	high dose rate
Notice	Notice of Violation
NRC	U.S. Nuclear Regulatory Commission
SLIV	Severity Level IV
USAF	United States Air Force