UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

July 27, 2015

Docket No. 03002631 License No. 32-04054-04

COL Ronald T. Stephens, M.D.
Commander, Medical Corps
Department of the Army
Womack Army Medical Center
ATTN: MCXC-DPM-RP
2817 Reilly Road
Fort Bragg, NC 28310-7301

SUBJECT: NRC INSPECTION REPORT NO. 03002631/2015001, DEPARTMENT OF THE ARMY, WOMACK ARMY MEDICAL CENTER, FORT BRAGG, NORTH CAROLINA SITE AND NOTICE OF VIOLATION

Dear COL Stephens:

On January 21, 2015, Robin Elliott of this office conducted an announced, reactive inspection to review the circumstances associated with a reported event (NMED No. 150027) that occurred on December 11, 2014. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. Additional information provided in your correspondence dated February 12, 2015, and during inspection briefings on March 4 and July 24, 2015, was also examined as part of the inspection. The findings of the inspection were discussed with you at the conclusion of the inspection on July 24, 2015. The enclosed report presents the results of this inspection.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice), because the violation was identified by the NRC. The violation involved the failure to notify the NRC no later than the next calendar day after the discovery of a dose to the embryo/fetus that required a report.

During our inspection briefings on March 4 and July 24, 2015, you indicated that you have modified your patient questionnaire, patient instructions, and radiation safety training program for authorized users as a result of this event. You stated that you have taken corrective and preventative actions to address the violation and that Womack Army Medical Center is committed to radiation safety and to compliance with NRC regulations and licensed conditions. Further, you stated verbally and you documented in your February 12, 2015, correspondence, that you have taken the following corrective and preventative actions:

1) The “I-131 Patient Questionnaire” was modified to include a question regarding the status of the patient with regard to pregnancy;

2) The “Radiation Safety Precautions for the Home After Release” was modified to include instructions for the patient to follow if they learn that they were pregnant at the time of the treatment which include a phone number to call during working hours and after working hours;

3) The radiation safety training materials covered with authorized users initially and annually were updated to include all events that require reporting to the NRC Operations Center. Additionally, a refresher session was held with all authorized users to address this material; and

4) The RSO obtained a pager to facilitate after hours response. The phone number for the RSO’s pager was added to the patient instructions and posted and communicated to authorized users for reference should an incident or medical event occur in the future.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed in our records and in your correspondence dated February 12, 2015. Therefore, you are not required to respond to this letter unless the description of your corrective actions in this letter and your February 12, 2015, correspondence 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 document system (ADAMS), accessible from the NRC website 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.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Robin Elliott at (610) 337-5076 if you have any questions regarding this matter.

Sincerely,

/RA/

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03002631/2015001

cc w/Encls: 1LT Kacey McGee, Radiation Safety Officer
State of North Carolina

Please contact Robin Elliott at (610) 337-5076 if you have any questions regarding this matter.

Sincerely,

/RA/

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03002631/2015001

cc w/Encls: 1LT Kacey McGee, Radiation Safety Officer
State of North Carolina

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OFFICE	DNMS/RI	N	DNMS/RI					
NAME	RElliott/rle		JPDwyer/jpd					
DATE	07/27/15		07/27/15					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Department of the Army
Womack Army Medical Center
Fort Bragg, NC

Docket No. 03002631
License No. 32-04054-04

During an NRC inspection conducted on January 21, 2015 with continued in-office review through July 24, 2015, one violation of NRC requirements' was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.3047(a) requires, in part, that a licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved by the authorized user.
>
> 10 CFR 35.3047(c) requires, in part, that the licensee notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo/fetus that requires a report in paragraph (a) in this section.
>
> Contrary to the above, as of January 1, 2015, Womack Army Medical Center (WAMC) failed to notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to an embryo/fetus that was greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material to a pregnant individual and the dose to the embryo/fetus was not specifically approved by the authorized user. Specifically, on December 31, 2014, WAMC was informed that a patient who received an Iodine-131 therapy treatment of 97.3 millicuries on December 11, 2014, was pregnant at the time of the treatment. The embryo/fetus received an unintended dose of approximately 26 rem, a dose greater than 5 rem, as a result of the administration of the treatment to the pregnant individual. Notification to the NRC Operations Center of the dose to the embryo/fetus was not made by telephone until January 8, 2015.
>
> This is a Severity Level IV violation (Enforcement Policy Section 6.9)

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. 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, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 27 day of July 2015

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03002631/2015001
NMED No.	150027
Docket No.	03002631
License No.	32-04054-04
Licensee:	Department of the Army Womack Army Medical Center
Location:	2817 Reilly Road Fort Bragg, NC 28310-7301
Inspection Dates:	January 21, 2015, exit meeting July 24, 2015
Date Follow-up Information Received:	February 12, 2015, March 4, 2015, and July 24, 2015

Inspector: ***/RA/***
_____ July 24, 2015
Robin Elliott date
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Approved By: ***/RA/***
_____ July 24, 2015
James P. Dwyer, Chief date
Medical Branch
Division of Nuclear Materials Safety

Document Name: C:\RawFiles\ML15210A495.docx

EXECUTIVE SUMMARY

Department of the Army
Womack Army Medical Center
NRC Inspection Report No. 03002631/2015001

An announced, special inspection was conducted to review the circumstances associated with a reported event (NMED 150027) that occurred on December 11, 2014, at the Department of the Army, Womack Army Medical Center (WAMC) in Fort Bragg, North Carolina. The licensee reported the event to the NRC on January 8, 2015. The reported event involved the administration of a 97.3 millicurie iodine-131 (I-131) sodium iodide therapy dosage to a pregnant patient that resulted in an unintentional dose to an embryo/fetus. At the time of the dosage administration, the patient was unaware that she had become pregnant. The medical consultant's report stated that the age of the fetus at the time of the treatment was between two and four weeks. On December 31, 2014, the patient notified the endocrinologist that she was pregnant when she received the dosage. The endocrinologist informed the authorized user (AU) of the unintended dose to the embryo/fetus on December 31, 2014.

The root cause of the event was a false negative pregnancy test that was performed by the licensee approximately 1.5 hours before the dosage administration and the patient's lack of awareness that she was pregnant. The patient was counseled regarding the risks of the procedure and avoiding pregnancy by both her endocrinologist and Nuclear Medicine Department staff prior to administration.

WAMC staff estimated the dose to the embryo/fetus of 20.43 rads. WAMC staff concluded that the result of the dose would be either a slight increased risk of early pregnancy failure or no effect. The NRC medical consultant concluded that the dose to the embryo/fetus was 26 rad and the effect on the fetus would be either miscarriage or survival without malformation. He reported that as of February 6, 2015, an uneventful pregnancy was proceeding. He further reported that the cause of the event was a faulty pregnancy test kit. The kit reports the ability to detect pregnancy as early as 7-10 days. The patient was 2-4 weeks pregnant at the time of the test which would indicate a failure of the test.

As a result of the event, WAMC revised their patient questionnaire to inquire about the status of the patient with regard to pregnancy. In addition, the patient instructions were revised to include a statement instructing the patient to notify the Radiation Safety Officer if she learns she is pregnant following the procedure. Day and evening contact numbers were added to the instructions. Annual radiation safety training material for AUs was revised to include all events that require immediate notification to the NRC and a refresher session was held with all AUs and AUs were trained on RSO numbers to contact.

One apparent violation of 10 CFR 35.3047(c) was identified for failure to notify the NRC no later than the next calendar day after the discovery of a dose to the embryo/fetus that requires a report.

REPORT DETAILS

I. Background

WAMC is authorized by NRC License No. 32-04054-04 to use byproduct material for medical purposes, including therapeutic nuclear medicine. The licensee performs approximately 4 therapy treatments per calendar quarter using iodine-131 sodium iodide (I-131). On January 8, 2015, the licensee contacted the NRC's Headquarters Operations Center to report an exposure to the embryo/fetus of an I-131 therapy patient exceeding 5.0 rem (50 milliSievert) (mSv) dose equivalent.

II. Review of the Event

a. Inspection Scope

The inspector interviewed the referring physician (endocrinologist) and the physician authorized user (AU) involved with the administration of the I-131 dosage to determine the sequence of events that resulted in the unintentional dose to an embryo/fetus. The inspector also reviewed the licensee's records related to the event.

b. Chronology of Events

A 22-year old female patient was diagnosed with thyroid cancer and her thyroid gland was surgically removed. The patient was referred for radiopharmaceutical therapy by her endocrinologist to oblate any remaining thyroid tissue. The endocrinologist reviewed standard safety precautions for the procedure with the patient on October 21 and November 4, 2014. The Nuclear Medicine Department staff reviewed standard safety precautions with the patient again on December 8, 2014. The standard precautions included informing her that: (1) she should avoid becoming pregnant for a period of twelve months following the therapy; (2) she could not receive I-131 therapy if she was pregnant; and (3) a pregnancy test would be performed immediately prior to the administration of the I-131 dosage. The patient also signed a copy of the Radiation Safety Instructions, issued by the Nuclear Medicine Department, which stated that female patients should avoid becoming pregnant for a minimum of 12 months following the procedure. On December 11, 2014, a pregnancy test was administered by the licensee with a negative result. Approximately 1.5 hours after the pregnancy test, the patient was administered 97.3 millicuries (mCi) of I-131.

On December 29, 2014, the patient suspected she was pregnant and performed a home pregnancy test. The test was positive. The patient reported to a clinic for a serum pregnancy test on December 29, 2014, to confirm the result of the home pregnancy test and this test also returned a positive result. On December 31, 2014, the patient contacted her endocrinologist and informed the endocrinologist that she was pregnant**.** On December 31, 2014, the endocrinologist contacted the AU to obtain information regarding the dose administered to the patient and its potential effect on the patient's embryo-fetus. The patient was advised of the risks to her embryo/fetus from the I-131 administered during a telephone conversation with the endocrinologist on December 31,

2014. On December 31, 2014, the AU emailed the Radiation Safety Officer (RSO) to inform him of the event.

On January 5, 2015, the RSO received the email and estimated a dose of 20.43 rads to the uterus. The RSO based his calculation on NUREG/CR-6345, which provided a factor of 0.21 rads/mCi to the uterus. The inspector determined that the dose to the uterus was a reasonable estimate for the fetal dose because conception was estimated to be 2 to 4 weeks prior to when the I-131 dosage was administered; therefore, the fetal thyroid had not yet developed at the time of the exposure. The patient was advised of the potential harmful effects of the radiation to the embryo/fetus in a face-to-face meeting with the endocrinologist on January 9, 2015.

c. Conclusions

The inspector concluded that WAMC took reasonable precautions to prevent administration of I-131 to a pregnant patient, including conducting a pregnancy test immediately prior to the I-131 treatment and instructing the patient, on at least three occasions not to become pregnant.

III. Notifications and Reports

a. Inspection Scope

The inspector interviewed the AU, the RSO and other WAMC personnel to determine when the licensee possessed sufficient information to estimate the fetal exposure. The inspector also reviewed WAMC's event notification to the NRC and their 15-day report.

b. Observation and Findings

On December 31, 2014, the endocrinologist was informed by the patient that she was pregnant and that the date of her last menses was November 7, 2014, which suggested that she was pregnant at the time of the I-131 treatment on December 11, 2014. The pregnancy was confirmed via serum pregnancy test on December 29, 2014. The endocrinologist informed the AU of these facts on December 31, 2014, and obtained risk information from the AU to provide to the patient. The AU forwarded all of the relevant information needed to report the event and calculate the dose to the RSO in an email sent on December 31, 2014. The AU stated that he knew to notify the RSO about the event but was not aware of the reporting requirement to the NRC. The RSO did not receive the email until January 5, 2015. On January 6, 2015, the RSO called the NRC Operations Center and requested assistance in determining if the event was reportable. On January 7, 2015, an NRC staffer confirmed for the licensee that the event was reportable in accordance with 10 CFR 35.3047(a). The RSO also stated that he was unaware of the reporting requirement for the dose to the embryo/fetus. The RSO filed the official event report with the NRC Operations Center on January 8, 2015.

10 CFR 35.3047(a) requires, in part, a licensee to report any dose to an embryo/fetus

that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration

of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved in advance by the authorized user. 10 CFR 35.3047(c) requires that the licensee notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo/fetus that requires a report in 10 CFR 35.3047(a).

The inspector noted that the AU is a representative of the licensee and therefore, the licensee became aware of an exposure received by the embryo/fetus on December 31, 2014, and therefore required reporting on January 1, 2015**.** The inspector also noted that, at the time of the event, the licensee's procedures required all notifications to go through the RSO; however, (1) the RSO was unaware of reporting requirements in 10 CFR 35.3047; and (2) RSO emergency contact information (e.g. cell phone or pager number) was unavailable.

10 CFR 35.3047(d) requires the licensee to submit a written report to the appropriate NRC Regional Office within 15 days after discovery of a dose to the embryo/fetus that requires a report in accordance with paragraph (a) in this section. WAMC submitted an approved but unsigned 15-day report with all the required information on January 13, 2015. The signed version of the report arrived in the Region I office on January 21, 2015. WAMC concluded that the cause of the event was failure of the patient to follow instructions and the resultant dose to the embryo/fetus of 20.43 rads slightly increased the risk of pregnancy failure.

c. Conclusions

The inspector determined that the event met the criteria of a reportable event per 10 CFR 35.3047, "Report and Notification of a Dose to an Embryo/Fetus," since the dose to the embryo/fetus exceeded 5 rem dose equivalent as a result of the administration of byproduct material to the pregnant individual and the dose to the embryo/fetus was not specifically approved, in advance, by the AU. The licensee's AU became aware of the patient's pregnancy on December 31, 2014, and possessed sufficient information to have calculated the likely exposure of the embryo-fetus, which exceeded 5 rem, on that same date. WAMC made telephonic notification to the NRC eight days after discovery of the dose to the embryo/fetus greater than 5 rem dose equivalent that was the result of an administration of byproduct material to a pregnant individual and not within the next calendar day as required by 10 CFR 35.3047(c). This is an apparent violation of 10 CFR 35.3047(c). The 15-day report was submitted in a timely manner, although originally unsigned, and contained all required information.

The following apparent violation was identified:

10 CFR 35.3047(a) requires that a licensee report any dose to an embryo/fetus that is greater than 50 milliSieverts (mSv) (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

10 CFR 35.3047(c) requires that the licensee notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo-fetus that requires a report in paragraph (a) in this section.

Contrary to the above, as of January 1, 2015, Womack Army Medical Center (WAMC) failed to notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to an embryo/fetus that is greater than 50 mSV (5 rem) dose equivalent that is a result of an administration of byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved by the authorized user. Specifically, on December 31, 2014, WAMC was informed that a patient who received an Iodine-131 therapy treatment of 97.3 mCi on December 11, 2014, was pregnant at the time of the treatment. The embryo/fetus received an unintended dose of approximately 26 rem, a dose greater than 5 rem, as a result of administration of the treatment to the pregnant individual. Notification to the NRC Operations Center of the dose to the embryo/fetus was not made by telephone until January 8, 2015.

IV. Licensee's Corrective Actions

a. Inspection Scope

The inspector interviewed the AU, the RSO, and other members of WAMC's staff and reviewed documentation of the corrective actions taken in response to this event.

b. Observations and Findings

To assist in identifying pregnancy, WAMC revised their procedures to identify individuals who may not have practiced sexual abstinence prior to therapeutic doses. WAMC stated that they added a question to their patient questionnaire asking the patient if there is any possibility she could be pregnant, to initiate a dialogue regarding her sexual relations since her last menses. They further stated, that if a patient indicated she engaged in unprotected sexual intercourse since her last menses, WAMC would delay the therapy even if a negative pregnancy test was obtained.

While not the cause of the reporting delay in this case, WAMC revised their written instructions provided to therapy patients to include the day and evening phone numbers for the RSO. The instructions direct the patient to call the RSO if she learns that she was pregnant during the administration of the radiation therapy. This communication will assure that the RSO receives timely notification of the exposure and is able to notify the NRC in the required time period. The RSO stated that he did not have a cell phone or pager for receiving emergency notifications; however, subsequent to the event a request for a pager was submitted and one was issued to the RSO to facilitate emergency communications.

WAMC modified their initial and annual training materials to include all events that require notification of NRC. Training was held with all AUs to review the material and assure they are clear on the reporting requirements and how to contact the RSO,

including the numbers to call. The refresher training was completed by March 13, 2015.

c. Conclusions

The inspector determined that the corrective actions taken by WAMC after the event appeared to be reasonable.

V. Medical Consultant's Review

The NRC staff contracted with a medical consultant to review the possible health effects associated with the dose to the embryo/fetus as a result of this event. The medical consultant's report concluded that the dose to the embryo/fetus was 266 mGy (approximately 26 rad). The medical consultant stated that the dose would result in either miscarriage or survival without malformations. As of February 6, 2015, the medical consultant reported that the pregnancy continues and is uneventful. He further concluded that the beta-hCG pregnancy test should have been positive 7-10 days after fertilization according to the manufacturer and much published data, but no anomaly of lab hCG test was noted.

VI. Exit Meeting

Inspection de-briefs were conducted during the on-site inspection on January 21, 2015 and on March 4, 2015. Transmission of corrective and preventive actions occurred on February 12, 2015. A final exit meeting was conducted on July 24, 2015.

PARTIAL LIST OF PERSONS CONTACTED

Womack Army Medical Center, Fort Bragg, North Carolina
+*#COL Stephens (Commander of the Hospital)
+*#COL Morgan (Deputy Commander for Clinical Services)
#COL Lammie (Assistant Deputy Commander for Clinical Services)
#LTC Bedno (Incoming Chief of Preventive Medicine)
#MAJ Kinkead (Executive Officer for Womack)
+*#LTC Song (Chief, Nuclear Medicine)
#CSM Gomez (Senior Enlisted Member).
^*#1LT McGee (Radiation Safety Officer)
+SGT Croy (Nuclear Medicine Technologist)

+Present at entrance meeting on January 21, 2015
*Present at preliminary exit meeting on January 21, 2015
#Present at exit briefing on March 4, 2015
^Present at exit meeting on July 24, 2015