

DEPARTMENT OF THE AIR FORCE HEADQUARTERS UNITED STATES AIR FORCE WASHINGTON DC

FEB 20 2008

MEMORANDUM FOR U.S. NUCLEAR REGULATORY COMMISSION ATTN: DOCUMENT CONTROL DESK WASHINGTON, DC 20555-0001

FROM: AFMOA/SG3PR 110 Luke Avenue, Room 405 Bolling AFB DC 20032-7050

SUBJECT: Reply to a Notice of Violation, NRC Inspection Report Number 30-28641/2007006 (USNRC Region IV Letter, 10 January 2008)

Attached is the permittee's final report documenting his corrective actions for the noncompliance identified in the subject Notice of Violation regarding permit number NV-00333-01/07AFP.

If you have any additional questions, then please contact either Lt Col Scott Nichelson at 210-925-5250 (electronic mail: scott.nichelson@brooks.af.mil) or Maj Robert Rodgers at 202-767-4309 (electronic mail: robert.rodgers-02@pentagon.af.mil).

ROBERT F. TODARO, Col, USAF, MC, CFS Chair, USAF Radioisotope Committee Office of the Surgeon General

Attachment: 99 MDG/CD Memo, 31 January 2008

cc: HQ AFIA/SGI (Lt Col Adams) NRC Region IV (Ms. Rachel Browder)





DEPARTMENT OF THE AIR FORCE AND DEPARTMENT OF VETERANS AFFAIRS MIKE O'CALLAGHAN FEDERAL HOSPITAL NELLIS AIR FORCE BASE, NEVADA

31 January 2008

MEMORANDUM FOR HQ AFMOA/SG3PR

FROM: 99 MDG/CD 4700 Las Vegas Blvd North Nellis AFB NV 89191

SUBJECT: Reply to Notice of Violation to Radioactive Material Permit No. NV- 00333-01/07AFP

1. The following is a response to the single Notice of Violation during the inspection conducted by the Nuclear Regulatory Commission at the 99th Medical Group on 27 September 2007.

a. 10 CFR 20.1302 (a) requires, in part, that the licensee shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 10 CFR 20.1301. 10 CFR 20.1003 states in part, that survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal or presence of radioactive material or other sources of radiation and member of the public means any individual except when that individual is receiving an occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material.

b. Contrary to the above, from approximately 8 May 2006 to 31 July 2006 (exact dates could not be established), the licensee failed to make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 10 CFR 20.1301. Specifically, the licensee operated a mobile nuclear medicine unit adjacent to the parking lot of the licensee's facility, an area accessible by members of the public. During the time period, byproduct material was used and stored within the mobile nuclear medicine unit. The licensee failed to make or cause to be made, as appropriate, surveys of radiation levels in the vicinity of the mobile nuclear medicine unit to demonstrate compliance with the dose limits for individual members of the public in 10 CFR 20.1301 as required by 10 CPR 20.1302 (a).

2. During the time period of 8 May to 31 July 2006, while the clinic's sole gamma camera was being upgraded/replaced, the Nuclear Medicine Department contracted and utilized a temporary mobile nuclear medicine unit (i.e., gamma camera in a trailer) at Mike O Callaghan Federal Hospital. All sealed radioactive sources were moved from the clinic to the mobile unit, and the radiopharmacy delivered all patient unit doses to the mobile unit during this time. Prior to clinically using the mobile unit, as confirmed by the inspector, all dose calibrator and gamma camera quality control tests were performed. In addition, an exposure survey to determine public dose was conducted on 10 May 2006 and the results. (27 mRem/yr, Atch 1) were within the limits (100 mRem/yr and less than 2 mRem in any one hour) as specified in 10 CFR 20 1301-1302. A diagram of the mobile trailer is provided at attachment 2. These survey measurements were taken post injection with all sealed sources (Inventory at Atch 3) and one additional patient dose, 25 mCi of Tc-99m (MDP) each, located within the mobile unit to ensure a representative exposure measurement. The annual public dose was calculated using gross exposure measurements, background was not subtracted. The instrument calibration certificate is provided as

attachment 4. Two patients were dosed and imaged on the day that the exposure surveys were performed. A typical patient scanning day consisted of two to three patients per day during May and increased to four to five patients per day during July. The mobile trailer did not have a waiting room, which allowed for only one patient to be dosed and imaged at a time. Therefore, the public dose measurement performed on 10 May during a low patient load is representative of the public dose during July when the daily patient load had, doubled.

3. The NRC inspector requested documentation for the exposure surveys conducted on the mobile unit. Unfortunately, the senior technologist was not able to locate the document at the time of the inspection. During late spring 2007, the permit RSO began retirement leave and the replacement RSO was geographically separated from the clinic (i.e., lived in a different state, California). During this RSO transition period, the nuclear medicine staff re-filed/re-located historical records, to include the mobile unit survey data, to a new location within the clinic proper. A week before the inspection, the former RSO returned to duty status choosing not to retire. He was not appointed as RSO at the time of the inspection, however, he assisted during the inspection to supplement the permit RSO who was physically located in California. Unfortunately, the mobile unit exposure survey records could not be located during. the inspection. The unit exposure survey records were found on 28 Jan 2008 by the senior technologist. A binder labeled, Operation of a Mobile Nuclear Medicine Trailer, was immediately created specifically to file all documents related to the nuclear medicine mobile unit. Attachment 5 is a Memorandum for Record which outlines requirements for a mobile nuclear medicine trailer operation. The binder was added to the Nuclear Medicine file plan which also includes the location where the binder will be kept The minimum documentation kept in the binder includes a copy of the nuclear medicine radioactive material permit allowing use of a mobile trailer, exposure surveys, swipe surveys, and operating instructions. Appropriate steps were also taken to ensure documentation is in the specified location at all times. Furthermore, the nuclear medicine staff was briefed on the location of the binder. All corrective actions were implemented by 31 Jan 2008.

4. Please call my point of contact, MSgt John Bustamante, at (702) 653-2843 or DSN 348-2843 if there are any questions. Thank you for giving us the opportunity to respond to this notice.

CHRISTIAN R. BENJAMIN Colonel, USAF, MC, CFS

Commander

5 Attachments:

- 1. Dose Limit to Individual Members of the Public
- 2. Diagram of Mobile Nuclear Medicine Trailer
- 3. Inventory of Sealed Sources
- 4. Certificate of Instrument Calibration
- 5. Memorandum For Record, dated 1 Feb 08

DOSE LIMIT TO INDIVIDUAL MEMBERS OF THE PUBLIC

IAW 10 CFR 20-1301-1302 the Nuclear Medicine department is obligated to show that the dose equivalent to individual members of the public does not exceed (100 mR/yr) 0 Irem/year and that the dose in unrestricted areas from external sources does not exceed (2 mR/hr) 0.002 rem in one hour.

AREA	READING mr/hr	DATE/TIME
1. North Wall	<u>0.012</u>	10 May 06 @ 0830hrs
2. South Wall	<u>0.012</u>	10 May 06 @ 0833hrs
3. East Wall	0.012	10 May 06 @ 0838hrs
4. West Wall	0.013	10 May 06 @ 0845hrs

ANNUAL LIMIT ((0.013 mR/hr*8 hr/day * 261 (365-weekends) days/year)⇒F©RMULA = 27 mR/yr >>>>Less than Max Limit of 0.1 rem/yr

HOURLY Dept. Reading- 0.013 mR/hr is Less than Max Limit of 2 mr in one hour.

METER # 128153 Ludlum

BACKGROUND READING 0.013mR/hr

MAXIMUM READING 0.013mR/hr

TECHNOLOGIST SIGNATURE:

RSO SIGNATURE:

ANTONIO CORREA, LT COL, USAFR, MC DIAGNOSTIC IMAGING

ATTO .

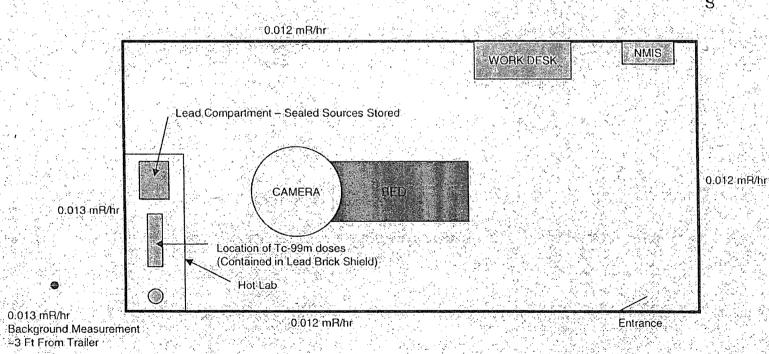
Readings were taken on a routine day, post injections, when we suspected maximum readings. BASED ON THE ABOVE SURVEYS-BOTH THE ANNUAL LIMIT AND THE HOURLY LIMIT ARE WELL BELOW MAXIMUM DOSE STANDARDS SET IN 10 CFR 201301-1302

IT IS MANDATORY THAT THESE SURVEYS BE PERFORMED ANNUALLY

IOHN E. BUSTAMANTE, TSgt, USAF. NCOIC, Nuclear Medicine Service

MOBILE NUCLEAR MEDICINE TRAILER Mike O'CALLAGHAN FEDERAL HOSPITAL PUBLIC DOSE ASSESSMENT 10 MAY 2006

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<u> </u>	ventory of Sealed Sources				
RIGHE Biotech Pharmacy					
	Biotech Pharmacy 3940 South Eastern Av. Las Vegas, Nevada 89119 ZOO 6				
Pharmacy					
	Las Vegas, Nevada 89119 2006				
	702-791-3608				
	03-11-0332-01 Exp. 08/31/2010				
.ocation: Mike O'Callaghan Federal H	ospital Performed By: Chuck Flores				
4700 Las Vegas Blvd	Date: 04/03/2006				
Las Vegas, Nevada 89191	Time: 15:27				
Sealed Source	Activity Accounted For				
Manufactùrer: Dupont	209.000.uCl				
Product: Cs-137					
Serial Number: \$356033-097	Location Stored SOURCE LOCATED IN HOT LAB DRAVVER				
Manufacturer: CIS-US	0.285 mCi				
Product: BA-133	On: 11/01/1996				
Serial Number: A5937	Location Stored: IN DRAWER IN HOT LAB (10.54MBq.)				
Manufacturer: North American Scien	95.000 uCi				
Product: Co - 57	On: 03/01/2002				
Serial Number: 16742	Location Stored: SOURCE LOCATED IN DRAWER IN HOT LAR				
Manufacturer: North American Scien	95.000 uCi YES				
Product: Co - 57					
Serial Number: 16743	Location Stored: SOURCE LOCATED IN DRAWER IN HOT LAP				
Manufacturer: CIS-US	0.113 uCi				
Product: BA-133	On: 03/01/1996				
Senal Number: A4638	Location Stored: SOURCE LOCATED IN DRAWER IN HOT LAE				
Manufacturer. IPL	1.000 uCi YES				
Product: Cs-137 Source	On: 12/01/1996				
Serial Numbér: 3277	Location Stored: ON SURVEY METER # 133227				
Manufacturer: IPL	1.000 uCi YES				
Product: Cs-137 Source	On: 12/01/1996				
Serial Number: 3362	Location Stored: ON SURVEY METER #133221				
Manufacturer: Ludlum	1.000 uCl YES				
Product: Cs-137 Source	On: 03/01/1997				
Serial Number: 0832	Location Stored: ON SURVEY METER S/N 128153				
Manufacturer: IPL	0.500 uCl YES				
Product: Eu-152	On: 08/23/2003				
Serial Number: 780-23-30	Location Stored: IN HOT LAB DRAWER				
Manufacturer: NAS	333.020 KBq				
Product: Cs-137	On: 02/01/1997				
Serial Number: A6361	Location Stored: IN HOT LAB DRAWER				
Manufacturer: IPL	1.000 uCi YES				
Product: Cs-137	On: 07/01/2003				
Serial Number: 780-16-98	Location Stored: IN DRAWER IN HOT LAB				
Manufacturer: NAS	5.672 mCi YES				
Product: Co-57 Source	On: 10/01/2004				
Serial Number: 53740	Location Stored: IN HOT LAB DRAWER				
Manufacturer: NAS	119.600 uCi YES				
Product: Co-57 Source	On: 07/01/2004				
Serial Number: 52292	Location Stored: IN HOT LAB DRAWER				
Manufacturer: NAS	20.000 mCi YES				
Product: Co-57 Source	On: 04/20/2005				
Serial Number: 64096	Location Stored: BEHIND INJECTION ROOM DOOR				

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ST RESULTS TEST DATA: Performed by: CHUCK FLORES RADIATION SAFETY CONSULTANT Discrete March Constraints Biotech Pharmacy Licensee: Registration: 03-11-0332-01, Exp. 08/31/2010 Printed: 4/10/2006.3:28:02 PM 2 • ίæ.

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Certificate of Instrument Calibration

Detector Type: Sci	llum ntillation 2 oF	Spital Model: 19 Detector Model: Sci Humidity: 47 Dedicated Check Soi	% Pressure:	ID #: 044 Serial No. 128153 Serial No. n/a 30.00 inHg uR/hr Window: Fixed
Scale Multiplier	Distance (cm)	Calculated Reading	Measured Reading	Correction Factor
	263.0 340.0	.mR/hr 8.0 2.0	mR/hr 8.07 2.19	0.99 0.91
	174.1 348.2	uR/hr 800 200	uR/hr 751 217	1.07 0.92
	168-3 336-7	80 20	75 21	1.07 0.95

ANTONIO CORREA, LT COL, USAFR, MC DIAGNOSTIC IMAGING

Mid-America Calibrations, Inc. 808 SW Nautica Court Lee's Summit, Missouri 64082 816.537.4147 Calibrated By:

Date Calibrated: J Date Due: J NRC License # 24-32531-01

June 24, 2005 June 24, 2006

The above instrument was calibrated with a J.L. Shepherd Model 28-SA calibrator, serial #10018, 1.2 Ci Cs+137, 3M 4F6H, source serial # 2824 or a Ludium Model 500-2 Pulser, serial #127533... The output is traceable to the NES (N.I.S.T.) and all instruments are calibrated in accordance with MIL-STD 45662A and ANSI N323-1978.



DEPARTMENT OF THE AIR FORCE AND DEPARTMENT OF VETERANS AFFAIRS MIKE O'CALLAGHAN FEDERAL HOSPITAL NELLIS AIR FORCE BASE, NEVADA

31 January 2008

MEMORANDUM FOR THE RECORD.

FROM: Nuclear Medicine Department

SUBJECT: Mobile Nuclear Medicine Trailer Use Requirements

1. Upon delivery and set up of a mobile nuclear medicine trailer at Mike O'Callaghan Federal Hospital nuclear medicine personnel will do the following:

a. Perform an acceptance survey of the trailer. The acceptance survey will include a walkthrough of the trailer to insure there was no damage to the trailer during transportation and set up. An exposure survey will be conducted inside the trailer to insure the trailer is radiologically clean. The acceptance survey will be conducted prior to final acceptance of the trailer by the hospital.

b. Draw or obtain a diagram of the mobile trailer. Indicate the location of the hot lab, the source storage location, the location of the Tc-99m doses prior to dosing, the camera location, etc.

c. The sealed sources will be moved from the nuclear medicine department and placed in the lead container located inside the mobile trailers' hot lab. The lead container will be surveyed at that time and the results of the survey documented and placed in the mobile trailer binder.

d. Move the Capintec CRC-15R dose calibrator from the nuclear medicine department to the mobile nuclear medicine trailer. After the dose calibrator is set up; run all the required tests on the dose calibrator and ensure it is ready for use. These tests include constancy, accuracy, linearity and geometry. Document the test data in the mobile trailer binder.

e. Ensure the radiopharmaceutical laboratory is informed where to delivery the radioactive material package during normal duty hours. Perform acceptance testing of the package according to nuclear medicine written procedures.

f. Place a copy of all nuclear medicine operating procedures in the mobile trailer.

g. Perform the weekly swipes and daily exposure surveys required by your radioactive material permit and permit application.

h. Perform a public dose survey of the exterior of the trailer after all radioactive sources, the Tc-99m doses are present, and/or a dosed patient is present. The measurement should be performed during a worst case scenario. First ensure the meter being used is within calibration and then take a background measurement approximately 10 to 15 feet from the side of the trailer away from the hot lab. Annotate the location of the background measurement on the trailer diagram. Then take measurements along the outside of all four sides of the trailer and record the highest reading obtained from each side of the trailer and annotate all four values on the trailer diagram. Use the maximum gross exposure reading obtained from the four sides for the public dose measurement (do not subtract background). This provides a conservative estimate of the annual public dose. Multiply the maximum exposure reading times 8 hours in a day times 5 days a week times 52 weeks in a year. This will be the annual public dose in mRem/yr. The maximum exposure reading should also be less than 2 mRem/hr.

i. Contact the consulting medical physicist at Travis AFB prior to seeing patients for any additional requirements.

2. A copy of this Memorandum will be the first page in the Mobile Nuclear Medicine Binder. Directly under this page will be the Nuclear Medicine radioactive material permit.

JOHN E BUSTAMANTE, MSgt, USAF Flight Chief Diagnostic Imaging