May 25, 2011

Mr. Gary Williams, Director
National Health Physics Program (115 HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

SUBJECT: NRC INSPECTION REPORT 030-34325/11-28(DNMS) ─ VA LOMA LINDA HEALTH CARE SYSTEM, LOMA LINDA, CALIFORNIA

Dear Mr. Williams:

On May 2, 2011, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at the VA Loma Linda Health Care System, located in Loma Linda, California. The inspection results were discussed with Donald Moore, Medical Center Director, and selected members of his staff at the exit meeting on May 2, 2011. The enclosed report presents the results of this inspection.

This inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements, and observation of activities in progress. Within the scope of this inspection, no violations of NRC requirements were identified.

In accordance with Title 10 of the Code of Federal Regulations (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from 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.

Should you have any questions concerning this inspection, please contact Kevin Null of my staff at (630) 829-9854.

Sincerely,

/RA/

Patricia J. Pelke, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 04-17862-01

Enclosure:
Inspection Report No. 030-34325/11-28(DNMS)

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DATE	05/24/11		05/24/11		05/24/11		05/25/11	

OFFICIAL RECORD

INSPECTION RECORD

Region III
Inspection Report No. 030-34325/2011-28(DNMS)
License No. 03-23853-01VA
Docket No. 030-34325
Permit No. 04-17862-01

Licensee (Name and Address):
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

Location (Authorized Site) Being Inspected:
VA Loma Linda Health Care System
11201 Benton Street
Loma Linda, CA 92357

Licensee Contact: Moussa Raiszadeh, Ph.D, Radiation Safety Officer
Telephone No. (909) 825-7084, Extension 2668

Priority: 2 Program Code: 2120/3610

Date of Last NRC Inspection: August 6, 2002 Date of this Inspection: May 2, 2011
Date of Last NHPP Inspection: January 13, 2010,

Type of Inspection: ( ) Initial ( ) Announced (X) Unannounced
(X) Routine ( ) Special

Next Inspection Date: May 2, 2013

Summary of Findings and Actions:
(X) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector: ***/RA/*** by Kevin G. Null for Date: 05/24/2011
R. Rick Muñoz, Health Physicist, Region IV

Approved ***/RA/*** Date: 05/25/2011
Patricia Pelke, Chief,
Materials Licensing Branch

PART I - LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

VA Loma Linda Health Care System is a permittee of the Department of Veterans Affairs (DVA) Master Materials License (MML).

A minor program change was implemented related to the temporary relocation of the hot lab on January 24, 2011, due to renovation activities of the old hot lab. These activities were approved by the radiation safety committee.

2. INSPECTION AND ENFORCEMENT HISTORY:

During the previous U.S. Nuclear Regulatory Commission (NRC) inspection conducted on August 6, 2002, no violations of NRC requirements were identified. See NRC Inspection Report No. 030-13550/02-01(DNMS) for specific details of the previous inspection.

3. INCIDENT/EVENT HISTORY:

No medical events have been reported since the last NRC inspection. According to the permittee staff that was interviewed and records reviewed, since the last NRC inspection there have been no reportable events.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

This was an unannounced inspection for VA permit 04-17862-01. VA-Loma Linda (Loma Linda) conducts its radiation safety program under a broad scope permit for research and a limited-scope for medical uses. This was an assist safety inspection for Region III which holds the Department of Veterans Affairs' Master Materials License. The inspector was accompanied by Craig L. Adams, a Program Manager with the National Health Physics Program (NHPP) during the entire inspection.

The Loma Linda permit authorizes the use of radioactive materials for medical diagnostic, therapy and research and development as defined in 10 CFR 30.4 including animal studies and instrument calibration. The radiation safety program consists of a nuclear medicine department and non-human, non-animal research laboratories. The permit authorizes radioactive material for medical diagnostic, therapeutic uses and biomedical research. The Radiation Safety Committee (RSC) reports quarterly to the Executive Council. Problems identified are tracked, corrected, documented and followed-up through the RSC. The Radiation Safety Officer (RSO) has complete stop work authority and delegation of authority with regard to radiation safety program implementation. The RSO reports directly to the Chief of Facility Management Service.

Enclosed

Nuclear Medicine Program

Loma Linda staff had relocated to a temporary hot lab and injection area located in an adjacent room to the old hot lab, which was vacated and undergoing renovation as of January 24, 2011. The inspector reviewed the results of the surveys performed of the vacated hot lab and confirmed that there was no residual contamination. Medical Physics Support Services performed acceptance testing of the CapinTec CRS-25W dose calibrator after it was relocated to the temporary hot lab.

The nuclear medicine department performs approximately 15 imaging procedures per day with four certified nuclear medicine technologists (CNMT) and one nuclear medicine health technologist using two dual head gamma cameras, one of which is a Symbia CT/gamma system. The permittee discontinued the use of Mo-99/Tc-99^{m} generators in May of 1995. Nuclear medicine uses single unit doses exclusively for bone, heart, lungs, MUGA, and HIDA and gastric emptying studies. Doses are prescribed by eight authorized user (AU) physicians listed on the permit. Single unit doses ranged from 20-30 millicuries (mCi) per patient dose. There are two treadmills in a single cardiac stress lab room. All imaging order requests are screened by the AU physician. The review protocol includes a review of the written request and a review of the appropriateness of the requested scan before the appointment with the patient is approved.

Loma Linda maintains their nuclear medicine activities, such as package survey results and utilization logs, by using PINESTAR software. A total of 50 iodine-131 administrations were given in 2010: 24 were iodine-131 doses <30 mCi and 26 were doses of iodine-131 >30 mCi. The use of iodine-131 is limited to capsule form and administered on an out-patient release basis. Patients are released in accordance with 10 CFR 35.75 (NUREG 1556, Volume 9, Appendix U and Regulatory Guide 8.39). Iodine-123 is administered approximately twice a month. A dose calibrator is used and adequately maintained and calibrated. The hot lab is keyed in conjunction with a proximity card access. Access is strictly controlled. All waste generated is disposed by decay-in-storage in the hot lab. Long term radioactive waste is maintained in three basement storage areas. During the inspection of the hot lab, the inspector observed the technologist perform a constancy test on the dose calibrator. The inspector observed that the permittee routinely used syringe shields, and the technologists were properly wearing whole-body and extremity dosimetry.

The inspector reviewed a sample of written directives for iodine-131 for the period of 2008 to February 2010. No medical events involving the administration iodine-131 doses were identified. There is no brachytherapy authorized or performed at this facility. Currently there is no PET imaging being performed either on-site or with a mobile service; however, the Loma Linda staff indicated that there were plans underway to institute a PET imaging program around November 2011.

The inspector conducted a physical inventory to verify accountability of all the sealed sources possessed (five total sealed sources: one barium-133; two cobalt-57; one cobalt 60; and one cesium-137). The inventory records did not identify inconsistencies and were adequately maintained. Survey instrumentation is calibrated in-house using an Amersham Model-773 calibrator containing a 165 mCi cesium-137 source maintained on a calibration bench in a controlled dedicated room.

Enclosed

The RSO performs 100 percent written directive review on a quarterly basis, as well as a review of the radiation safety program. The licensee exchanges whole body (WB) dosimetry badges monthly and extremity badges weekly. Proper usage of personal dosimetry was observed. All personnel exposure doses were well within regulatory and administrative limits for extremities and the WB. Administrative levels established for Loma Linda are 175 millirem (mrem) for Level-I and 250 mrem for Level-II. The highest exposures for 2010 were 268 mrem (extremity) and 181 mrem (WB). Loma Linda maintains a bioassay program for thyroid uptakes. Bioassays are performed as prescribed by procedure for routine handlers of iodine. Bi-weekly bioassays are conducted for iodine-131 and 6-24 hour bioassays are conducted for iodine-123. A representative review of bioassays performed did not indicate results approaching the established action levels. Personal monitoring devices are adequately maintained and monitored by the RSO. The RSO maintains the required radiation protection program documents. The RSO maintained an adequate radiation protection program and control of permitted material.

Radioactive material package receipt surveys and daily/weekly radiation surveys; disposal of radioactive materials; and dose calibrator records were reviewed and acceptable. The inspector interviewed AUs, nuclear medicine technologists and the radiation safety staff regarding their understanding of the radiation safety program. All individuals appeared to have a good understanding. Problems identified by the AU and RSO are tracked, corrected, documented and followed-up through the RSC.

The inspector interviewed staff to assess their comfort level in raising safety concerns and determined that employees were knowledgeable and willing to report allegations or concerns which were consistent with NRC's focus for an effective safety culture. Employees indicated that they felt free and comfortable to raise safety concerns, both to management, the RSO or NHPP without fear of retaliation. All appeared to have no apprehension in contacting the radiation safety staff or the NHPP for assistance on any matter.

Research Laboratories

Currently, there was no research being conducted which involved animal studies using radioactive material. The principle investigators are approved by the RSC through an internal permit process prior to receiving and using permitted material. No iodination was performed. All radioactive material in use and storage was properly labeled and secured.

The biomedical research program is composed of 6 active research laboratories. There are 10 principle investigators which are approved by the radiation safety committee through an internal permit process prior to receiving and using permitted material. The research labs were using microcurie amounts of carbon-14, hydrogen-3, phosphorus-32, phosphorus-33 and iodine-125. Inspections of all active research laboratories were performed and interviews were conducted with authorized users, research technicians and laboratory assistants. All personnel were familiar with proper procedures for ordering and receiving radioactive materials, demonstrating proper contamination survey techniques, and demonstrating an understanding and knowledge of spill and cleanup protocols. After authorized user approval, radioactive material for use in the research laboratories was ordered by the radiation safety staff and delivered to the radiation safety office, surveyed and transferred to the respective

laboratory. There are no after hours deliveries of radioactive material. Instrumentation is calibrated by the radiation safety staff annually, and all survey instruments were found to be calibrated at the appropriate frequencies. Short lived radioactive waste is disposed of using the decay-in-storage method. Waste control of liquid radioactive waste was adequate including disposal of liquid effluents into the sanitary sewer system meeting the requirements of 10 CFR 20.2003. Radiation safety training is provided annually to all radiation workers by the radiation safety office. Cognizant personnel interviewed were knowledgeable and demonstrated appropriate radiation protection practices. Laboratory staff appeared to be knowledgeable with regards to the radiation safety program and operations. Research labs maintained adequate accountability and control of permitted material.

The NRC inspector conducted independent radiation surveys in all research laboratories visited and did not identify any contamination or unusual/unexpected radiation levels. The radiation safety staff demonstrated the performance of area surveys and area wipe tests of the research laboratories to detect removable contamination.

2. SCOPE OF INSPECTION:

The inspector, RSO, and technical staff discussed the radiation safety program. The licensee performed the transportation receipt protocols used to document the receipt of 13 single unit doses from the local nuclear pharmacy, Triad Isotopes that morning and also demonstrated control and disposal of waste material. Permit personnel from the nuclear medicine and research laboratories demonstrated the proper processes for the receipt, and accountability and disposal of permitted material, including proper documentation. The inspector observed the CNMT prepare doses of 10 mCi and 30 mCi administrations of MyoView for four 4 patients. Several permiteed staff individuals demonstrated and discussed the use of radiation survey instrumentation and calibration protocols; material accountability; dose ordering, preparation and administration; wipe test analysis; personal dosimetry; routine security of radioactive material; dose calibrator tests; RSC minutes; audits; and any reportable events, of which there were none. The inspector walked down the licensee's RAM waste storage and use locations and through direct observation and the conduct of independent radiological surveys, verified the presence and location of permitted material inventoried and that public annual limits were not exceeded. All permitted material was adequately secured and controlled. Material use and storage locations were properly labeled and posted in accordance with NRC requirements. No inventory differences or reporting issues were identified.

The inspector reviewed a representative sample of patient treatment records and written directives for the administration of iodine-131 for 2008 through January 2011. The inspector reviewed RSC minutes and annual audits of the radiation safety program, package receipt records, training records, survey records, leak test records, waste disposal records, and dosimetry records.

In addition, a transportation inspection of the morning delivery of fourteen Tc-99^{m} single unit doses (seven heart scans, one venogram, four bone scans, one lung scan and one MUGA) from Triad Isotopes-Loma Linda Nuclear Pharmacy was performed. No safety, security or transportation issues were identified.

Inspection Procedure(s) Used: 87131, 87134, 86740, and 87126

Focus Areas Evaluated: 03.03-03.07

The purpose of this inspection was to conduct a routine inspection of the permittee's use of permitted material. The last NRC inspection, conducted on August 6, 2002, did not identify any violations. For details regarding the previous inspection, see NRC Inspection Report No. 030-13550/02-01.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector conducted independent radiation surveys using an NRC assigned radiation survey instrument Ludlum Model 2401-P, #216052, calibration due October 25, 2011. The inspector conducted surveys in and around the hot lab, injection areas, treadmill areas, waste storage areas, and the research laboratories. Surveys in unrestricted areas were at background (0.02-0.05 mR/hr). No unusual or unexpected radiation levels were identified.

The NRC inspector concluded that no worker or member of the public received a dose of radiation in excess of the limits specified in 10 CFR 20.1201 or 20.1301.

4. VIOLATIONS, NON-CITED VIOLATIONS, AND OTHER SAFETY ISSUES**:**

No violations or safety significant findings were identified during the observations, interviews, or records review.

5. PERSONNEL CONTACTED:

#*Moussa Raiszaheg, RSO
*Alex Yi, Chief Radiologist
*#Mohan Subburaman, RSC Chair
#*Dwight Evans, Chief of Staff
#*Irme Ralataian, Medical Physicist
#Lee Salcido, CNMT
#George Ariza, Lead Technologist
#Tyrone Alarco, CNMT
#*Krystal Chamberlin, Imaging Supervisor
*Andy Hice, Chief Technologist
*Donald Moore, Director
*Shane Elliott, Associate Director
#Karen Brook, CNMT
#Doreen Cabrera, CNMT
#Marie Rowland, RN/Floor Nurse
#Cynthia Danielson, RN/Cardiac Stress Lab

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

-END-

Enclosed