NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
VA Palo Alto Health Care System 3801 Miranda Avenue Palo Alto, CA 94304 REPORT NUMBER(S) 2019-004	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-34325	03-23853-01VA	January 23, 2019

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☑ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☐ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(s):

☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Jason Dykert (Region IV)	/RA/	2/15/2019
BRANCH CHIEF	Patricia J. Pelke	/RA/	2/15/2019

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87126, 87131, 87134	Manual Chapter 2800, Section 05.01.b.1.(a) through (h) (All)

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02110, 3610	2	Lance J. Phillips, C.H.P., RSO	(650) 497-9918

☐ Main Office Inspection Next Inspection Date: N/A

☑ Field Office Inspection 3801 Miranda Avenue Palo Alto, California

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine unannounced inspection of the Department of Veterans Affairs MML permittee VA Palo Alto Health Care System, licensed for radioactive materials in broad-scope medical and research uses. This inspection focused on activities performed under the permit (04-23242-01) at the one authorized location of use (main hospital campus), including diagnostic and therapeutic nuclear medicine (35.100, 35.200 & 35.300), interventional radiology using SIR and Thera-Spheres (35.1000), clinical research activities, and research and development laboratory use as defined in 10 CFR 30.4. The Radiation Safety Officer (RSO) oversees the Radiation Safety Programs at Stanford University as well. The self shielded irradiator has been removed from the hospital and permit.

The inspection reviewed compliance with NRC regulations in 10 CFR through examination of the licensee's security and control of materials, shielding in place including independent radiation measurements, safety practices by personnel, review of written directives, inventories, leak tests, dose assay equipment calibration, receipt, disposal and training records, observations of ALARA in practice, Mirion dosimetry use and direct observation of administration of a Lutathera dose, interviews with personnel and management, research container labeling, and receipt, use logs, and disposal records in research labs. Selected Written Directives were reviewed for SIR/Thera-Sphere use as well as those for use of I-131, Xofigo, and Lutathera, no issues were identified.

The most recent permit amendment approved use of Lutetium-177 in nuclear therapeutic medicine. Written directives, patient release instructions and procedures for safe use have been developed and are in a continuing improvement process with collaboration from Stanford University. Any Lu-177 waste was handled by Stanford University. Administration of the Lutathera is performed with a Graseby syringe pump delivery system. SIR or Thera-Sphere (Y-90) administration requires that a health physicist be present with the authorized users.

Only two nuclear medicine technologists were on staff at the time of inspection, continuity planning and change management were a priority for the health care system executive leadership team. There are two Radiation Safety Committees (RSCs). The Clinical RSC (human research, IRB approved) meets quarterly to review the studies, which have all been coincidental to actual therapy treatments at the time of inspection. The other RSC meets semi-annually and both RSCs roll topics up to Stanford University's Radiological Safety Board.

5 research labs were currently active utilizing I-125, S-35, P-32, C-14 and H-3. Monthly surveys and day of use surveys, use logs, inventories, and disposal records were adequate. Container labeling was consistent, and survey or counting instrumentation was calibrated. An exit meeting was held with the Director, no violations were identified.