

INSPECTOR ACCOMPANIMENT CHECKLIST

MML: 03-23853-01VA	DATE: 5/11/2022
INSPECTOR: Thomas Huston	NRC REVIEWER: Allyce Bolger
PERMITTEE: VA Palo Alto Health Care System	PERMIT NO: 04-23242-01
LOCATION: Palo Alto, CA	INSPECTION TYPE: Routine
PERMIT TYPE: Broad Scope Medical – Program Code 02110 Research and Development - 03610	ANNOUNCED <input checked="" type="checkbox"/> UNANNOUNCED <input type="checkbox"/>

PRELIMINARY DISCUSSION WITH INSPECTOR	
	DONE
EXPLAIN THE EXTENT OF THE REVIEWER'S PARTICIPATION IN INSPECTION.	<input checked="" type="checkbox"/>
DISCUSS PROCEDURE FOR INTRODUCING REVIEWER TO PERMITTEE AND EXPLAINING HIS PART IN INSPECTION.	<input checked="" type="checkbox"/>
EXPLAIN METHOD TO BE USED IN EVALUATING INSPECTOR'S PERFORMANCE.	<input checked="" type="checkbox"/>

SUMMARY OF EVALUATION

INSPECTOR'S PERFORMANCE:

ADEQUATE ☒

NEEDS IMPROVEMENT ☐

COMMENTS: It was apparent from the inspection that Mr. Huston has a great safety focus and employs a performance-based, risk-informed approach to inspection planning and execution. Mr. Huston was very knowledgeable of the requirements and had a good rapport with the permittee staff. Mr. Huston discussed with the permittee the recent Confirmatory Order and provided revised "Reporting Radiation Safety Concerns" posters.

THE INSPECTOR WOULD BENEFIT FROM ADDITIONAL TRAINING IN: N/A

EVALUATION DISCUSSED WITH Ed Leidholdt, PhD **ON** 07/08/22
(SUPERVISOR) (DATE)

ITEM	OK	COMMENTS OR QUESTIONS
INSPECTOR'S PREPARATION		This was a routine inspection of the hospital. The inspection plan prepared by the inspector addressed nuclear medicine & research activities and program oversight. The inspection was announced (COVID-19 exemption) and had sent a questionnaire to the permittee to gather information in advance of the inspection to streamline onsite activities.
ADEQUATE REVIEW OF PERMIT AND COMPLIANCE HISTORY	OK	
INSPECTION PLAN OR FIELD FORM	OK	
APPROPRIATE SURVEY INSTRUMENTS CALIBRATED INSTRUMENT RESPONSE CHECK <input checked="" type="checkbox"/>	OK	
SUPPLEMENTAL MATERIALS: REGS <input checked="" type="checkbox"/> ID <input checked="" type="checkbox"/> FORMS <input checked="" type="checkbox"/> DOSIMETRY <input checked="" type="checkbox"/>	OK	
ENTRANCE		The entrance meeting covered the topics of the inspection and the expected timing of the inspection. The meeting was held at the appropriate level with hospital management personnel.
INTERVIEW CONDUCTED AT APPROPRIATE LEVEL	OK	
EXPLANATION OF INSPECTION PURPOSE, SCOPE, METHOD	OK	

INSPECTION		
USE OF APPROPRIATE FORM OR CHECKLIST	OK	The inspector utilized NRC inspection guidance and procedures to conduct a safety review of the permittee's nuclear medicine program & research activities.
"WALK THROUGH" AT BEGINNING OF INSPECTION	OK	
OBSERVATION OF OPERATION AND HANDLING OF RAM	OK	<p>The inspector made considerable effort to ensure that he saw the actual performance of licensed activities whenever possible. The inspector observed diagnostic administrations of permitted materials. Permittee staff demonstrated additional activities.</p> <p>The inspector also discussed research activities ongoing in labs onsite with the RSO and research staff.</p>
FACILITIES CHECKED FOR PROPER POSTING, LABELING	OK	
SECURITY VERIFIED	OK	The inspector observed that permitted materials were secured or under direct surveillance at all times.
WORKERS CHECKED FOR PERSONAL DOSIMETRY	OK	
WORKER INTERVIEWS RAM USERS <input checked="" type="checkbox"/> ANCILLARY WORKERS <input checked="" type="checkbox"/>	OK	The inspector interviewed a variety of staff, including management, radiation safety staff, nuclear medicine staff and research staff.
WIPES, SURVEYS, MEASUREMENTS TAKEN	OK	
ADHERENCE TO ALARA EVALUATED	OK	Surveys taken with Ludlum 3 (cal due 4/23). Inspector had to borrow a survey meter from permittee as his had stopped working.
REVIEW OF INCIDENTS, OVEREXPOSURES, ETC.	N/A	

<p>ORAL INTERVIEWS AND IF NECESSARY RECORDS VERIFICATION FOR:</p> <p>SECURITY <input checked="" type="checkbox"/></p> <p>PROCUREMENT & INVENTORY <input checked="" type="checkbox"/></p> <p>RECEIPT & TRANSFER OF MATERIAL <input checked="" type="checkbox"/></p> <p>INTERNAL AUDITS <input checked="" type="checkbox"/></p> <p>SURVEYS & MONITORING <input checked="" type="checkbox"/></p> <p>PERSONNEL DOSIMETRY, BIOASSAY <input checked="" type="checkbox"/></p> <p>QUALIFICATION AND TRAINING OF PERSONNEL <input checked="" type="checkbox"/></p> <p>EMERGENCY PLAN & PROCEDURES <input checked="" type="checkbox"/></p> <p>COMMITTEE MEETINGS, MINUTES <input checked="" type="checkbox"/></p> <p>AUTHORIZED USERS <input checked="" type="checkbox"/></p> <p>INSTRUMENT CALIBRATION <input checked="" type="checkbox"/></p> <p>DOSE CALIBRATOR TESTS <input checked="" type="checkbox"/></p> <p>UTILIZATION LOG N/A</p> <p>LEAK TESTS <input checked="" type="checkbox"/></p> <p>GENERATOR - ASSAY, BREAKTHROUGH, LOGS N/A</p> <p>WASTE MANAGEMENT, DISPOSAL <input checked="" type="checkbox"/></p> <p>RELEASE OF AIR & SEWER EFFLUENTS <input checked="" type="checkbox"/></p> <p>QA & QC; MAINTENANCE <input type="checkbox"/></p>	OK	The inspector interviewed personnel and reviewed appropriate records for a variety of topics.
INSPECTION CONDUCTED IN SUFFICIENT SCOPE & DEPTH	OK	Yes, however, the inspection lasted approximately 11 hours. Scheduling a second day onsite may have been more appropriate for a program of this size to complete all the elements at a more relaxed pace.
INSPECTION FOCUS ON PERMITTEE PERFORMANCE AND SAFETY SIGNIFICANCE	OK	

VERIFICATION OF CORRECTIONS TO PREVIOUS VIOLATIONS	N/A	
OTHER		N/A
IDENTIFIED POTENTIAL SL I-III VIOLATIONS/REPORTED TO NRC	N/A	
IDENTIFIED WILLFUL/WRONGDOING VIOLATIONS - REPORTED TO NRC	N/A	
IDENTIFICATION/HANDLING OF SAFETY CONCERNS/ALLEGATIONS	N/A	
INSPECTOR'S PROFESSIONALISM		The inspector maintained a professional relationship with permittee staff and demonstrated extensive knowledge of requirements for a medical program. The inspector evaluated concerns with good knowledge of safety.
USE OF PROPER HEALTH PHYSICS TECHNIQUES (SELF MONITORING, ETC.)	OK	
ACCURATE EVALUATION OF RADIATION SAFETY	OK	
KNOWLEDGE OF HEALTH PHYSICS & REGULATIONS	OK	
APPROPRIATE APPEARANCE FOR PERMIT TYPE	OK	
SKILL IN WORDING QUESTIONS	OK	
SUITABLE RAPPORT WITH MANAGEMENT AND WORKERS	OK	
EXIT		<p>During the exit meeting it was identified that hospital management would not be available for an exit in the afternoon and that an exit call would be scheduled for the next week.</p> <p>The inspector did debrief the clear inspection with the RSO prior to leaving the site.</p> <p>Final exit with conducted with the medical center director on 5/17/22</p>
PREPARATION FOR EXIT INTERVIEW; ASSEMBLY OF SUPPORTING MATERIAL	OK	
EXIT CONDUCTED AT APPROPRIATE MANAGEMENT LEVEL	OK	
VIOLATIONS FULLY EXPLAINED; PERMIT CONDITION OR REG CITED	N/A	
RECOMMENDATIONS CLEARLY DISTINGUISHED FROM VIOLATIONS	N/A	
IMPENDING ENFORCEMENT ACTIONS EXPLAINED	N/A	

[illegible]