

State of California—Health and Human Services Agency California Department of Public Health



Preparing for Analyzer and Electron Microscope Inspection

Documentation for Review

- Radiation Safety and Protection Program written policies and procedures. This is a
 document that covers radiation safety specific to your facility. This shall be audited
 annually by a designated staff member to ensure it remains accurate of operations
 at the facility (Title 10, Code of Federal Regulations, Part 20 Section 1101). Links
 to the mentioned laws and regulations are available through the Laws & Regulations page of the Radiologic Health Branch website.
- Access to <u>both</u> current California Regulations Title 17 and Title 10 Code of Federal Regulations part 20.

Physical Review and Walk-Through

During the physical review an inspector will:

- Conduct operator interviews (knowledge of location of regulations and dosimetry records, operating procedures, etc.). Radiation Safety and Protection Program written policies and procedures.
- Observe As Low as Reasonably Achievable (ALARA) procedures (proper storage of dosimeter badge, dosimeter badge use, use of room shielding, deadman switches in shielded locations in rooms, controls against unauthorized use of portable units, etc.). (Title 10, Code of Federal Regulations, Part 20 Section 1101)
- Observe use of the machine by staff (if available).
- A sufficient amount of the following required postings shall be placed in various areas so that staff that work or frequent any portion of the area with x-ray machine(s) can observe them.
- A current RH-2364 Notice to Employees which can be found on our website.

Equipment Testing

During equipment testing, an actual operator must be present to operate the x-ray machine(s). An inspector will be verifying accuracy of the X-ray tube inventory, assuring proper technique is being used in regards to radiation safety, and assuring machine performance is within tolerance.

• If the facility has x-ray machine warm up procedures, please have the x-ray machine(s) warmed up prior to the equipment testing.

Analyzer and Electron Microscope Post-Inspection Process

You will be provided a copy of the inspection findings within 2 weeks of your inspection. If you do not receive the findings, please contact the inspector directly. You will be allowed 30 days to provide adequate response to the findings. The response must be in writing, and you may need to include supporting documentation such as purchase orders, service reports, or polices or procedures that outline the entity's attempt to prevent a repeat occurrence of a violation identified. A response via email is preferred.