Preparing for Medical Clinic Inspection

Radiologic Health Branch (RHB) inspectors will review your program for safety and compliance with Title 17, the California Code of Regulations; Title 10, Code of Federal Regulations, Part 20 incorporated by reference; the California Health and Safety Code; and your written policies and procedures. Links to the mentioned laws and regulations are available through the Laws & Regulations page of the Radiologic Health Branch website.

- We are not inspecting for Mammography or Nuclear Medicine regulatory compliance at this time unless you were specifically asked to include these areas.

- RHB inspectors are Health Insurance Portability and Accountability Act (HIPAA) exempt, although any documents requested to be photocopied may be redacted to exclude confidential patient information. Any photos we request to take will not include facility personnel without express permission.

Documentation for Review

Provide the following documents to the inspector by email at least one week prior to the inspection:

- The facility X-ray machine inventory, showing manufacturer, model, serial number, I.D. or control/asset number, and department and room location.

- Current physics reports/annual survey or performance evaluations for each X-ray unit. Reports shall include the technical factors, instruments used and set-up used for the measurement of estimated patient dose values. This item is required for fluoroscopic, therapeutic, and Computed Tomography (CT) units, and is requested for radiographic units.

- List of Certificates and Permits for all users or supervisors of x-ray equipment to include Supervisor and Operator Certificates/Permits, Certified Radiologic Technologist (CRT) certificate and Limited Permits. Lists shall include: names, RHB permit/certificate numbers, scope of practice, and expiration dates. Copies of current certificates and permits are acceptable in lieu of a list. (California Code of Regulations, Title 17 Section 30305(e))

- An organizational list of responsible individuals (including name, title, and phone number) for the administration, management, and director(s) of diagnostic imaging, compliance, and radiation safety.

Provide the following documentation for review at the start of inspection. If documents are available electronically, please provide a laptop or other computer access for the inspector's use of document review. If all documentation is only available electronically, more than one computer will be necessary. Depending on the size and scope of your practice, not all records may be required.

- Title 17, California Code of Regulations; Title 10, Part 20, Code of Federal Regulations and the California Health and Safety Code.

- The Radiation Safety & Protection Program written policies and procedures. Policies and procedures related to radiation safety and the use of diagnostic imaging units should include, but may not be limited to, the following (Title 10, Code of Federal Regulations, Part 20 Section 1101):
    - Staff competency and training /recurrent training
    - Radiation safety training for occupational and non-occupational workers
    - Quality Assurance / Quality Control (QA/QC)
    - As Low as Reasonably Achievable Principles (ALARA)
        - Extended fluoroscopy time
        - Fluoroscopic c-arm spacer cone usage
        - Portable/mobile shielding usage and maintenance
        - Access to controlled areas
        - Patient pregnancy
    - Patient identification
    - Operator pregnancy
    - Area monitoring
    - Radiological emergencies / instrumentation and calibration
    - Annual radiation safety program audits

- Dosimetry Program records for the past three years; each report should be reviewed, initialed and dated by the lead supervising physician, RSO, other registrant designee (Title 10, Code of Federal Regulations, Part 20 Section 1502). Designation of responsible party must be in writing. The policy should include:
    - Investigative exposure levels
    - Declared pregnant worker policies.

- Weekly fluoroscopic monitoring reports for the past three years (California Code of Regulations, Title 17 Section 30307). Reports shall include the dates of the annual baseline mA and kVp determination, pass/fail criteria, and notation of:
    - Maintenance required and
    - All weeks of non-use.

- Preventative maintenance (PM) and service records for X-ray machines for the last year, or the last records if greater than one year since service.

- Quality Assurance/Quality Control Test records for the past three years.

- Current documentation of Accreditation for CT Scanners by American College of Radiology (ACR), Joint Commission, or Intersocietal Accreditation Commission (IAC). (California Health and Safety Code Section 115112)

- Method(s) used to ensure only qualified staff with current and valid permits/certificates operate X-ray equipment.

- Radiation Safety Committee (RSC) meeting notes (for the past year if RSC exists).

- Current Approval of Diagnostic Radiologic Technology School Clinical Affiliation letter (for facilities with students only).

- Venipuncture training and competency records (injection of contrast media) training records for CRT's, including certification of 10 hours of education, determination of competency, and attestation of 10 human venipunctures under qualified supervision. (California Health and Safety Code Section 106985)

The documents requested above only need to pertain to your facility, but if policies and procedures apply organization-wide or cross-campus, include them.

Overview of on-site agenda:

- Entrance meeting. Present inspection agenda and answer questions.

- Document review (of above requested documents).

- Physical review or walk-through to observe staff in the actual performance of their radiologic technology duties, rooms and locations where radiological activities occur:
    - Conduct technologist interviews (in-scope certification, knowledge of location of regulations and dosimetry records, etc.).
    - Observe ALARA procedures (dosimeter badge and protective lead use, use of room shielding, dead-man switches in shielded locations in rooms, controls against unauthorized use of portable units, etc.).
    - Observe recent radiographic images taken for diagnostic quality, use of markers, collimation to area of clinical interest only, and use of gonadal shielding.
    - Check for required postings Notice to Employees, Safety Instructions, Title 17 or instructions to access it, signage (Caution X-ray), and technique charts specific to each radiographic unit. (California Code of Regulations, Title 17 Section 30255)

- Physical testing of a selection of the total diagnostic imaging units to measure output for compliance. A minimum of one unit of each modality (room and portable radiography, and room and portable fluoroscopy) will be tested. Selection is based on the review of physicists' and PM reports, frequency of use, and availability and mobility of units.

- CT scanner and Cardio Cath Lab/Interventional Suite, and Radiation Therapy inspections are typically observations (of a procedure if scheduled), interviews with a CRT, and radiation scatter measurements.

- For bone density (DEXA) units, print a copy of the daily QA phantom report.

- Exit meeting. Present findings: violations and items of concern. Violations corrected prior to the exit meeting will be noted as such with no further action required.

Personnel requested:

- Attendance by appropriate staff at the entrance and exit meetings. Minimally, staff in attendance should include a representative from Administration as well as a representative from each department where radiological equipment is used.

- A conference room with table or desk space for document review.

- Assistance by at least one staff member during or after the document review to answer questions and provide clarifications and additional documents.

- Accompaniment by at least one staff member during the physical review for assistance and direction.

- Assistance by certified radiographic technologist or certified/permitted physician during the physical testing to operate units.

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 provider's attempt to prevent a repeat occurrence of a violation identified. A response via email is preferred.

If mammography was included in your inspection, you will also need to respond directly to the Food and Drug Administration (FDA) Mammography Quality and Standards Act (MQSA) program for Level 1 violations.