

Radiation Safety and Protection Program Requirement Guidance

In California, all radiation sources, either radiation (X-ray) machines or radioactive material, are subject to State laws and regulations. The statutes are found in the Health and Safety Code, Division 104-Environmental Health. The regulations are found in the California Code of Regulations (CCR), Title 17, Div. 1, Chapter. 5, Subchapters 4 and 4.5. 17 CCR 30253 incorporates by reference the federal regulations specified in Title 10, Code of Federal Regulations (CFR), Part 20. Requirements in 10 CFR 20 apply to all registrants. Links to these laws and regulations are available on the website at <http://www.cdph.ca.gov/programs/Pages/RadiologicHealthBranch.aspx>.

Each registrant is required to develop, document, and implement a radiation protection program commensurate with the scope and extent of use of X-ray machines and sufficient to ensure compliance with the regulations. Additionally, the registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA). The registrant must audit the program on an annual basis to ensure it remains within the scope and extent of activities requiring the program. This document is intended for all registrants of radiation machines and is meant for guidance only.

Additional information may be found in the National Council on Radiation Protection and Measurements (NCRP) Report Number 105, Radiation Protection for Medical and Allied Health Personnel; NCRP Report Number 127, Operational Radiation Safety Program; NCRP Report Number 144, Radiation Protection for Particle Accelerator Facilities; NCRP Report Number 145, Radiation Protection in Dentistry; and NCRP Report Number 145, Radiation Protection in Veterinary Medicine. These documents may be obtained at <http://www.ncrponline.org>.

The Radiation Safety and Protection Program should include, but not be limited to, consideration of the following items:

1. Organization and Administration
2. ALARA Program
3. Dosimetry Program
 - a. Occupational Workers
 - b. Pregnant Workers
 - c. Dose to Fetus
4. Area Monitoring and Control
 - a. Area Radiation Monitoring
 - b. Instrument Calibration and Maintenance
5. Radiological Controls
 - a. Entry and Exit Controls
 - b. Posting
 - c. Disposal of Equipment

6. Emergency Exposure Situations and Radiation Accident Dosimetry
7. Record Keeping and Reporting
8. Reports to Individuals
9. Radiation Safety Training
 - a. Occupational Workers
 - b. Non-Occupational Workers
10. Internal Audit Procedures

All components of the Radiation Safety and Protection Program do not have to be contained in one consolidated document. However, all components do have to be documented and identified as being part of the Radiation Protection Program. Records of the Radiation Safety and Protection Program content, implementation and audits must be maintained for inspection by the Department.

1. Organization and Administration

Document the delegation and responsibility for each aspect of the radiation program and provisions for ensuring enforcement of radiation safety policies and procedures.

2. ALARA Program

The registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA) and document procedures addressing this requirement.

3. Dosimetry Program

All registrants are responsible for the protection of individuals that enter the registrants' controlled areas. The registrant is also responsible for ensuring that the public is protected and that the public dose does not exceed the limits found in 10 CFR 20.

Each facility must evaluate whether or not personnel monitoring for occupational exposures is required. If a facility chooses to or is required to monitor, then those who are occupationally exposed to radiation should be instructed in the following:

1. Types of individual monitoring devices used and exchange frequency.
2. Use of control badges.
3. Instructions to employees on proper use of individual monitoring devices, including consequences of deceptive exposure of the device.
4. Procedures for ensuring that the combined occupational total effective dose equivalent (TEDE) to any employees receiving occupational exposure at your facility and at other facilities does not exceed 5 rem per year

5. Procedures for obtaining and maintaining employees' concurrent occupational doses during that year.
6. Procedures for ensuring that if minors are employed, their occupational TEDE does not exceed 500 millirem per year
7. Procedures for addressing a declaration of pregnancy.
8. Procedures for maintaining documentation of dose to the embryo/fetus and associated documentation for the declared pregnant worker.

4. Area Monitoring and Control

- **Radiation Area Monitoring**

The need for area monitoring shall be evaluated and documented.

- **Instrument Calibration and Maintenance**

Instruments used to verify compliance with regulatory requirements must be appropriate for use and calibrated at required frequencies. Specify instruments to be used and procedures to verify conformity.

Maintenance of the machine should be addressed. This may be addressed in part by the operator's manual from the manufacturer.

5. Radiological Controls

- **Entry and Exit Controls**

Entry and exit from controlled areas must be adequate to ensure radiation safety. Design of emergency escape routes shall comply with applicable building codes. Document procedures addressing this requirement.

- **Posting**

Areas that are required to be posted should be identified in the Radiation Protection Program, in addition to procedures for ensuring that such areas are properly posted. Also, include procedures for ensuring that areas or rooms containing as the only source of radiation are posted with a sign or signs that read "CAUTION X-RAY". Identify who is responsible for maintaining those signs and/or labels. In addition, certain documents must be posted. This requirement is found in 17 CCR 30255(b).

Conspicuously post:

1. A current copy of the 17 CCR, incorporated sections of 10 CFR 20, and a copy of operating and emergency procedures applicable to work with sources of radiation (If posting of documents specified above is not practicable, the registrant may post a notice which describes the document and states where it may be examined.)
2. A current copy of [Department Form RH-2364 \(Notice to Employees\)](#) in a sufficient number of places to permit individuals working in or frequenting any portion of a restricted area to observe a copy on the way to or from such area.
3. Any notice of violation involving radiological working conditions or any order issued pursuant to the Radiation Control Law and any required response from the registrant.

Disposal of Equipment

Registrants shall report in writing to the Department the sale, transfer, or discontinuance of use of any reportable source of radiation. See the Guidance for Disposal of X-ray Machines available <http://www.cdph.ca.gov/programs/Pages/RadiologicHealthBranch.aspx>.

Other Controls

The registrant should evaluate the need for other controls in addition to those mentioned above. The following items should be considered:

1. Types of controls used to reduce or control exposure to radiation, such as positioning aids, gonadal shielding, protective aprons, protective gloves, mobile shields, etc.
2. Procedures for routine inspection/maintenance of such controls.

6. Emergency Exposure Situations and Radiation Accident Dosimetry

Identify any possible emergency exposure situations or radiation accidents and document procedures to address such, to include dose assessment.

7. Record Keeping and Reporting

All record keeping and reporting requirements are specified in regulations. Document the applicable requirements and commitments to compliance. The facility must also maintain all records of the Radiation Protection Program, including annual program audits and program content review. The following items should also be identified:

1. The person responsible for maintaining all required records.

2. Where the records will be maintained.
3. The format for maintenance of records and documentation.
4. Procedures for record keeping regarding additional authorized sites (mobile providers).

8. Reports to Individuals

The Registrant shall provide reports of individual exposure when requested in accordance with 17 CCR 30255. Document procedures addressing this requirement.

9. Training

- **Operating and Safety Procedures**

All registrants are required to have a written operating and safety procedure manual. This may be the operating manual that comes with a radiation unit which may include safety procedures. However, if safety procedures are not included in the manual they must be developed. These safety procedures must be posted on the machine or where the operator can observe them while using the machine.

Document all training your employees, both occupationally exposed and non-occupationally exposed workers, are required to have before using radiation machines including continuing education. Also, document other training you provide to your employees or visitors such as radiation safety and protection program review, safety meetings, formal classroom training, etc.

Some of these requirements are found in the 17 CCR 30255(b) (1). Specifically, each registrant shall:

1. Inform all individuals working in or frequenting any portion of a controlled area of the use of radiation in such portions of the controlled area;
2. Instruct such individuals in the health protection problems associated with exposure to radiation, in precautions or procedures to minimize exposure, instruct such individuals in, and instruct them to observe, to the extent within their control, the applicable provisions of Department regulations for the protection of personnel from exposures to radiation occurring in such areas;
3. Instruct such individuals of their responsibility to report promptly to the registrant any condition which may lead to or cause a violation of department regulations or unnecessary exposure to radiation, and of the inspection provisions of 17 CCR 30254;

4. Instruct such individuals in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and advise such individuals as to the radiation exposure reports which they may request pursuant to 17 CCR 30255.

- **Quality Assurance Programs**

Document and explain quality assurance programs for your radiation machine(s). The explanation should include the types of checks that are done, the interval at which they are done, what actions are taken if problems are noted, and who is responsible for those checks.

Such checks should be performed on the machine to ensure that it is functioning properly and that all safety controls are in effect.

Regulations

Maintenance of all applicable regulations is required.

10. Internal Audit Procedures

The Registrant must audit the Radiation Protection Program on an annual basis. Documentation of the annual audits may be requested during inspection. The following items should be addressed depending on the scope of the radiologic health protection problems:

1. Identification of inspection types and program audits conducted, to include radiation machines, personnel and procedures.
2. Identification of the individual(s) who are responsible for performing inspections and/or audits.
3. Identification of where and at what intervals the inspections and/or audits are conducted.
4. Procedures for conducting the inspections and/or audits.
5. Instructions on identification of proper use of instrumentation if staff performs machine maintenance or fluoroscopic monitoring.

The regulatory agency for radiation safety is the Radiologic Health Branch of the Department of Public Health and can be contacted at the following addresses and phone number:

Department of Public Health
Radiologic Health Branch
P.O. Box 997414, MS-7610
Sacramento, CA 95899-7414

Email: RHInfo@cdph.ca.gov
(916) 327-5106

www.cdph.ca.gov