RADIOLOGIC HEALTH BRANCH (RHB)

Radiation (X-ray) Machine Registration & Compliance

The Radiologic Health Branch (RHB) issues State certificates to medical facilities to perform mammography, registers facilities possessing radiation sources such as X-ray machines, and notifies the regulated community of radiation control changes.

For additional information, contact the Radiologic Health Branch at (916) 327-5106.

IMPORTANT - Notice of Fee Increase Effective Sept. 1, 2017.

Registration Forms:

- RH 2261N - Radiation Machine Registration for New Registrants.
  - RH 2261N Instructions
- RH 2261C - Radiation Machine Registration for Changes to Registrant or Machine Information.
  - RH 2261C Instructions
- RH 2261W - Radiation Machine Registration for Withdrawal of Registration.
  - RH 2261W Instructions

General Information

- X-ray & NMT Certification/Permit Search Tool.
- Quality Assurance Regulations - FAQs.
- Guide for X-ray Equipment above 500 kVp.
- Radiation Protection Program guidance.
- Disposal of X-ray tubes.
- X-ray Image Record Retention.
- Exemption for Hand-held Portable X-ray Systems
- Assembly Bill 510 - FAQ
- Senate Bill 1237 - FAQ

Related Links:

Computed Tomography Advisory regarding radiation exposure during Brain Perfusion Scans. Patient FAQ's.

- California Dental Association: Radiation Safety in Dental Practice Guide
- American Association of Physicists in Medicine: Computed Tomography Radiation Dose Education slides.

Mammography Facility Forms & Information:

- CDPH-8623 - Mammography Facility/Machine Certification Application.
- Mammography Facility Certification Fact Sheet
- Mammography Consumer Complaint Policy - sample

Mammography Facility Certification FAQs

▼ Where can I find out how to apply for a California mammography facility certificate?

See our Mammography Facility Certification Fact Sheet above. Also, you can e-mail us at rhblistc@cdph.ca.gov or call us at (916) 327-5106.

INSTRUCTIONS FOR RH 2261N

I. USE OF RH 2261N

Use this form only when both conditions are met:

- Your facility, business, or practice possesses one or more radiation machines, as defined below.
- Your facility, business, or practice does not already have a registration number, as defined below, issued by the California Department of Public Health, Radiologic Health Branch (CDPH-RHB).

II. IMPORTANT INFORMATION ABOUT CHANGES IN OWNERSHIP

- Registration numbers are not transferrable.
- A person, as defined below, should submit a completed "Radiation Machine Registration for New Registrants", RH 2261N, within 30 days of taking ownership of a facility, business, or practice that possesses a radiation machine.
- An existing registrant that has sold or transferred ownership of its facility, business, or practice should submit a completed "Radiation Machine Registration for Withdrawal of Registration", RH 2261W, within 30 days of transferring ownership.
- A change in ownership has occurred if, but not limited to, any of the following actions:
  - A sole proprietor becomes a partnership, limited liability company, or corporation.
  - A partnership has changed partners or becomes a limited liability company or corporation.
  - A limited liability company or corporation becomes a partnership or sole proprietor.

III. REGULATORY AUTHORITY

Title 17, California Code of Regulations, section 30110(a) requires that "every person not already registered who acquires a reportable source of radiation shall register with and pay the fee as specified in Section 30145 to the Department within 30 days of the date of acquisition".

IV. DEFINITIONS

- "Authorized Representative" means an individual who has been authorized to act on behalf of the registrant.
- "Mobile machine" is a radiation machine that is in a mobile vehicle, or is transported for the purpose of providing radiation services at a different location, but does not include a radiation machine moved from room to room at the same physical address.
- "Person" means any individual, corporation, partnership, limited liability company, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, other than the United States Nuclear Regulatory Commission, the United States Department of Energy, or any successor thereto, and other than Federal Government agencies licensed by the United States Nuclear Regulatory Commission, under prime contract to the United States Department of Energy, or any successor thereto.
- "Radiation machine" means any device capable of producing radiation when the associated control devices are operated, but excluding devices which produce radiation only by the use of radioactive material.
- "Registrant" means any person, as defined above, who is registering or who has registered with the CDPH-RHB. Federal agencies are exempt from the registration requirements.
- "Registration number" means a unique number issued by the CDPH-RHB to identify a specific registrant.

D. Signature of Authorized Representative

- **Name.** Enter the name of the authorized representative.
- **Title/Position.** Enter the title or position.
- **Signature.** Enter the signature of the authorized representative.
- **Date.** Enter the date the form is signed.

NOTE: A facility, business, or practice that possesses a radiation machine must establish, implement, and maintain a radiation protection program in accordance with state requirements. **A copy of the radiation protection program must be made available for inspection upon request.** For additional information, please visit our website at: https://archive.cdph.ca.gov/pubsforms/forms/Documents/RHB-Guide-RadProtectionProgram.pdf

E. Recordkeeping/Submission

Submit all pages. Keep a copy for your records. Do not submit multiple copies of the same completed form. No payment is required at this time. **Mail the original** with supporting documents to:

ATTN: Registration and Certification Support Unit
California Department of Public Health
Radiologic Health Branch
MS 7610
P.O. Box 997414
Sacramento, CA 95899-7414

For more information, please visit our website at http://cdph.ca.gov/rhb or call (916) 327-5106.

VETERINARY USE		
Category	**Description**	**Type Code**
Radiography	Radiographic radiation machines used for routine diagnostic on animals.	XVR
Fluoroscopy	Fluoroscopic radiation machines used for routine diagnostic fluoroscopy on animals.	XVF
Dental	Radiographic radiation machines used for oral examination on animals.	XVD
Oncology – Therapy	High energy therapeutic radiation machines that use external beam radiation for treatment on animals.	XVT
CT Scanner	Computed Tomography radiation machines used on animals.	XVC
INDUSTRIAL USE		
Category	**Description**	**Type Code**
Accelerator ≥ 10 MV	Accelerators with potential energies equal or greater than 10 MV. These devices accelerate atomic particles to high energies.	XAL
Accelerator < 10 MV	Accelerators with potential energies less than 10 MV. Includes ion implanters and electron beam welders.	XAS
Diffraction/Fluorescence	Analytical devices either handheld or in a cabinet. Includes coating thickness analysis. The output from these machines is usually information regarding the chemical composition of the sample.	XDF
Electron Microscopes (all types)	All types of electron microscopes: transmission - TEM, scanning – SEM, reflection – REM, scanning transmission – STEM, low voltage – LVEM, and possibly others.	XEM
Controllers/Gauges/Schools	Industrial gauging, controlling and laboratory imaging. Includes bottle fill checkers, coroner's office radiation machines, and radiologic technology school machines used by technology students only to image phantoms.	XNF
Portable Field Radiography	Radiation machines used in industrial radiography that excludes cabinet X-ray systems and shielded room radiography machines.	XRP
Shielded Room Radiography	Machines are set-up in a room large enough to admit a person. The walls of the room are adequately shielded to protect the public.	XRS
Cabinet Radiation Systems Radiography	Cabinet X-ray systems used in the examination of the physical structure of objects. Also, radiation machines used in the detection of contraband such as package and baggage scanners, or backscatter radiation security scanners.	XRC
Research and Development (Non-Medical)*	Radiation machines used for non-healing arts research such as non-commercially available machines or prototype research. ***Use this code only if none of the other Industrial Use codes apply.**	XRD

INSTRUCTIONS FOR RH 2261C

I. USE OF RH 2261C

CAUTION: Do not use RH 2261C for changes in ownership.

Use this form when all of the following conditions are met:

- Your facility, business, or practice has an existing registration number issued by the California Department of Public Health, Radiologic Health Branch (CDPH-RHB);
- You wish to notify the CDPH-RHB of a change to your existing registrant information, registered machine information, or machine inventory (adding or removing a machine); and
- Your facility, business, or practice possesses one or more radiation machines, as defined below.

- **NOTE:** If your facility, business, or practice is no longer in possession of any radiation machines **or** all radiation machines that are still in your possession have been made incapable of producing radiation you should not use this form. **Instead**, use the "Radiation Machine Registration for Withdrawal of Registration", RH 2261W.

II. IMPORTANT INFORMATION ABOUT CHANGES IN OWNERSHIP

- Registration numbers are not transferrable.
- A person, as defined below, should submit a completed "Radiation Machine Registration for New Registrants", RH 2261N, within 30 days of taking ownership of a facility, business, or practice that possesses a radiation machine.
- An existing registrant that has sold or transferred ownership of its facility, business, or practice should submit a completed "Radiation Machine Registration for Withdrawal of Registration", RH 2261W, within 30 days of transferring ownership.
- A change in ownership has occurred if, but not limited to, any of the following actions:
  - A sole proprietor becomes a partnership, limited liability company, or corporation.
  - A partnership has changed partners or becomes a limited liability company or corporation.
  - A limited liability company or corporation becomes a partnership or sole proprietor.

III. REGULATORY AUTHORITY

Title 17, California Code of Regulations, section 30115 requires that "the registrant shall report in writing to the Department, within 30 days, any change in: registrant's name, registrant's address, location of the installation, or receipt, sale, transfer, disposal, or discontinuance of use of any reportable source of radiation."

IV. DEFINITIONS

- "Authorized Representative" means an individual who has been authorized to act on behalf of the registrant.
- "Incapable of producing radiation" means a radiation machine is no longer functional. **UNPLUGGING A MACHINE OR PLACING A FUNCTIONAL MACHINE IN STORAGE ONSITE OR OFFSITE, FOR USE AT A LATER TIME, DOES NOT MEAN THAT A MACHINE HAS BEEN MADE INCAPABLE OF PRODUCING RADIATION.**
- "Mobile machine" is a radiation machine that is in a mobile vehicle, or is transported for the purpose of providing radiation services at a different location, but does not include a radiation machine moved from room to room at the same physical address.
- "Person" means any individual, corporation, partnership, limited liability company, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, other than the United States Nuclear Regulatory Commission, the United

- **Room Name or Number.** Enter the room name or number where the radiation machine is installed. Enter "Multiple" if used in multiple rooms at the same physical address. Enter "Mobile" for mobile machines.

- **Changes.**
  CAUTION: Make sure to update only those items that have changed. A completed field indicates a change.
  - **Manufacturer.** Enter the **new or corrected** name of the manufacturer.
  - **Model.** Enter the **new or corrected** manufacturer's model name and/or number.
  - **Room Name or Number.** Enter the **new or corrected** room name or number where the radiation machine is installed. Enter "Multiple" if used in multiple rooms at the same physical address. Enter "Mobile" for mobile machines.
  - **Number of X-ray Tubes, Waveguides or Electron Guns.** Enter the **new or corrected** number of X-ray tubes, waveguides, or electron guns.
  - **Type Code.** Enter the **new or corrected** Type Code that matches the radiation machine's intended use. The Type Codes can be found under "Categories of Radiation Machines" starting on page 6. If none of the Type Codes match your machine, write "NA" and provide a detailed description of the machine and its use under "Additional Information".
  - **Additional Information.** Enter any relevant information about the machine that is not covered above, e.g., a detailed description of the machine and its use that does not fall under any Type Codes.

D. REMOVING REGISTERED MACHINES

- List all registered radiation machines that are no longer in your possession. Complete and attach additional copies of page 3 as needed. You should submit a completed "Radiation Machine Registration for Withdrawal of Registration", RH 2261W, if you are no longer in possession of any radiation machines **or** all radiation machines in your possession have been made incapable of producing radiation.
  - **Registered Machine.** Provide the manufacturer, model, and machine location of the registered machine you wish to remove from your registration.
    - **Manufacturer**. Enter the name of the manufacturer.
    - **Model**. Enter the manufacturer's model name and/or number.
    - **Room Name or Number.** Enter the room name or number where the radiation machine is installed. Enter "Multiple" if used in multiple rooms at the same physical address. Enter "Mobile" for mobile machines.
  - **Removal Action.**
    - **This machine is no longer in my possession.** Check this box if you have sold, transferred, donated, or disposed of the machine.
    - **This machine has been made incapable of producing radiation.** Check this box if you still possess this machine but have made it incapable of producing radiation.
    - **Removal Action Date.** Enter the date of the Removal Action. It should be in the format mm/dd/yyyy. If you do not know the actual date, enter an approximate date.
  - **Additional Information.** Enter any relevant information about the machine that is not covered above.

H. RECORDKEEPING/SUBMISSION

Submit all pages. Keep a copy for your records. Do not submit multiple copies of the same completed form. No payment is required at this time. **Mail the original** with supporting documents to:

ATTN: Registration and Certification Support Unit
California Department of Public Health
Radiologic Health Branch
MS 7610
P.O. Box 997414
Sacramento, CA 95899-7414

For more information, please visit our website at http://cdph.ca.gov/rhb or call (916) 327-5106.

VETERINARY USE		
Category	**Description**	**Type Code**
Radiography	Radiographic radiation machines used for routine diagnostic on animals.	XVR
Fluoroscopy	Fluoroscopic radiation machines used for routine diagnostic fluoroscopy on animals.	XVF
Dental	Radiographic radiation machines used for oral examination on animals.	XVD
Oncology – Therapy	High energy therapeutic radiation machines that use external beam radiation for treatment on animals.	XVT
CT Scanner	Computed Tomography radiation machines used on animals.	XVC
INDUSTRIAL USE		
Category	**Description**	**Type Code**
Accelerator ≥ 10 MV	Accelerators with potential energies equal or greater than 10 MV. These devices accelerate atomic particles to high energies.	XAL
Accelerator < 10 MV	Accelerators with potential energies less than 10 MV. Includes ion implanters and electron beam welders.	XAS
Diffraction/Fluorescence	Analytical devices either handheld or in a cabinet. Includes coating thickness analysis. The output from these machines is usually information regarding the chemical composition of the sample.	XDF
Electron Microscopes (all types)	All types of electron microscopes: transmission - TEM, scanning – SEM, reflection – REM, scanning transmission – STEM, low voltage – LVEM, and possibly others.	XEM
Controllers/Gauges/Schools	Industrial gauging, controlling and laboratory imaging. Includes bottle fill checkers, coroner's office radiation machines, and radiologic technology school machines used by technology students only to image phantoms.	XNF
Portable Field Radiography	Radiation machines used in industrial radiography that excludes cabinet X-ray systems and shielded room radiography machines.	XRP
Shielded Room Radiography	Machines are set-up in a room large enough to admit a person. The walls of the room are adequately shielded to protect the public.	XRS
Cabinet Radiation Systems Radiography	Cabinet X-ray systems used in the examination of the physical structure of objects. Also, radiation machines used in the detection of contraband such as package and baggage scanners, or backscatter radiation security scanners.	XRC
Research and Development (Non-Medical)*	Radiation machines used for non-healing arts research such as non-commercially available machines or prototype research. ***Use this code only if none of the other Industrial Use codes apply.**	XRD

Medical and Dental Quality Assurance (Q.A.) Regulations
Frequently Asked Questions

Text of regulations

California Code of Regulations, Title 17, Public Health

§ 30305.1. Quality Assurance General Provisions

§ 30308.1. Quality Assurance for Radiographic Installations (Other Than Mammography, Dental, and Veterinary Medicine)

§ 30311.1. Quality Assurance for Dental Radiography

Questions and Answers

1. Where can I learn how to perform quality assurance testing and find additional information?

   Additional information can be found on the Conference Radiation Control Program Directors website at http://www.crcpd.org/page/Publications.

   For radiographic machines:
   http://c.ymcdn.com/sites/www.crcpd.org/resource/collection/F6C8667F-1251-4450-9E84-A768C0BC2699/QC-Vol3-Web.pdf.

   For podiatric facilities:
   http://c.ymcdn.com/sites/www.crcpd.org/resource/collection/ F6C8667F-1251-4450-9E84-A768C0BC2699/QC-Vol2-Web.pdf.

   For dental facilities:
   http://c.ymcdn.com/sites/www.crcpd.org/resource/collection/F6C8667F-1251-4450-9E84-A768C0BC2699/QC-Vol1-Web.pdf.

2. Our clinic uses only digital radiography/computed radiography in our X-ray department. Are there new Q.A. requirements for users who do not process film to record their radiographic images?

   No. These regulations apply only to users who chemically process film to record their radiographic images.

3. We process our films manually. Do these regulations apply to us?

   Yes. Section 30305.1 applies to all users who chemically process film using either manual or automatic processing. Section 30308.1 applies to users who develop clinical radiographs for diagnostic purposes with

the emulsion that has softened during the development process.

26. What is a residual fixer test?

This test evaluates how well the rinse phase of processing has removed the fixer from the film. Residual fixer chemicals left on films after processing can render radiographs useless within five years due to chemical staining.

27. How do you test for fixer retention (residual fixer)?

This can be accomplished by obtaining a fixer retention test kit that includes a residual hypo test solution and a hypo estimator test strip.

A drop of solution is placed on the emulsion side of a freshly processed film. After waiting two minutes, the area where the solution has dried is compared to the hypo estimator. Residual hypo in the film must be less than 5.0 micrograms per square centimeter.

28. What is Optical Density (O.D.)?

Optical Density, or simply density, is the degree of blackening of the film after exposure to X-rays and processing. The higher the optical density, the darker the film appears.

29. How do you measure Optical Density?

Optical density is measured with a device called a Densitometer. This equipment should be calibrated periodically against industry reference standards in accordance with its manufacturer recommendations.

30. What is Base plus Fog?

This is the level of pre-existing density of an unexposed X-ray film.

31. Where is Base plus Fog measured?

Base plus Fog is measured on any unexposed area of the film.

32. What equipment is needed to measure Base plus Fog?

Base plus Fog is measured with a device called a Densitometer. This equipment should be calibrated periodically against industry reference standards in accordance with its manufacturer standards.

33. What is a Densitometer?

A densitometer is a device used to read the optical density of an image or

than mammographic, dental, or veterinary use. Section 30311.1 applies to users who chemically process intra-oral films for dental radiography of human beings. Section 30305.1 applies to all users.

12. Must we stop processing X-ray films if any of the Q.A. parameters are exceeded?

Yes, until the problem is identified and corrective actions have been implemented.

13. Must we establish a Q.A. manual?

No. Your procedures must be adequate to ensure that the tests are performed correctly. Documentation of the results, problems identified, corrective actions taken, and assessment of the effectiveness of the corrective action must be available for inspection, but they need not be contained in a single manual.

14. How long must we keep Q.A. records?

Q.A. records must be maintained for at least one year from the date the test was performed.

15. What type of Q.A. records do we need to keep?

- All the Q.A. test records specified in these regulations
- Documentation of problems detected
- Documentation of corrective actions taken
- An assessment of the effectiveness of the corrective actions

16. Are electronically stored versions of the Q.A. records acceptable?

Yes; as long as the records can easily be accessed by the person responsible for doing the Q.A. test, facility staff taking X-rays, the X-ray Supervisor and Operator, and are available at the time of the inspection.

17. What does assessing the "Effectiveness of the Corrective Actions" mean?

It means determining whether the corrective actions have fixed the problem, to include repeating any test that had results falling outside the criteria specified, to determine if the action taken corrected the problem identified.

18. If we fail to conduct Q.A. tests at the required interval, must we stop processing X-ray films?

Yes, until it has been determined that the processor is operating within the

Darkroom fog is darkening of the film that does not come from being exposed to an X-ray source.

41. What factors contribute to fog on an X-ray film?

- Improper film storage, such as excessive heat or humidity
- Accidental exposure to white/bright light
- Improper processing
- Using film past the documented expiration date
- Light leaks in the darkroom

42. Our facility does not currently own a sensitometer or a densitometer. Will we be required to purchase a sensitometer and a densitometer?

No. You are not required to own the equipment necessary for performance of the Q.A tests. You must ensure that the tests are performed accurately and have access to the necessary equipment at the required test intervals.

43. What is Contrast in an X-ray film?

Contrast is the difference in O.D. between areas of interest in an X-ray film. Subject contrast is the differential attenuation of the X-ray beam by the subject being radiographed. Film contrast is a characteristic of the film.

44. What factors affect Contrast in an X-ray image?

- Subject contrast
- Film contrast
- Processing
- Base plus Fog

45. If we use both digital processing and chemical film processing for dental radiography, do these regulations apply to us?

Yes, but only for the intra-oral film radiography use. These regulations apply to users who chemically process film, either manually or with an automatic processor, to record their radiographic images.

46. What should the dental reference film look like and how long are we required to keep the daily Q.A. film?

The reference film should be a standard exposed dental film image meeting the interpreting dentists' criteria for image density, contrast, sharpness and overall quality to which subsequent dental X-ray films are compared to assess image quality consistency.