

CDPH X-ray Radiation Updates

Radiologic Health Branch

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Radiologic Health Branch (RHB)

Radiation Machines

Radioactive Materials (RAM)

Mammography

Therapy

Medical Physicists

Field Inspections
Enforcement
Compliance

Authorized
Medical Physicist
(RAM)
Industrial
Licensing
Medical Licensing

General Licensed Devices

Field Inspections
Enforcement
Compliance



Radiologic Health Branch Webpage

www.cdph.ca.gov/rhb



Mammography Updates

Per <u>17 CCR § 30315.10</u>

- "Mammogram" means an X-ray image of the human breast.
- "Mammography" means the procedure for creating a mammogram for the purposes of screening, diagnostic, interventional or research mammography.



Per <u>17 CCR § 30315.20</u>

- Mammography Machine Certification
 - It is illegal to perform mammography without a <u>valid</u> and <u>current</u> state mammography machine certificate.
- Facility Registration must be current for the State Mammography Machine Certificate to be valid.
- All dedicated units used to create a mammogram must have a State Mammography Machine Certificate.



Mammography Facilities Webpage

- Check for updates
- Refer to the Resources Section on the requirements for various types of applications.
- Submit all applications/inquiries to: RHBRMT@cdph.ca.gov



Breast CT

Dedicated Breast Computed Tomography Unit (DBCT)

- Meets definition of mammogram and mammography
- Article 4.5. Requirements for the Use of X-Ray in Mammography
- State Mammography Machine is required
- Additional CT requirements per California Health and Safety Code (HSC), Sections 115111, 115112, and 115113



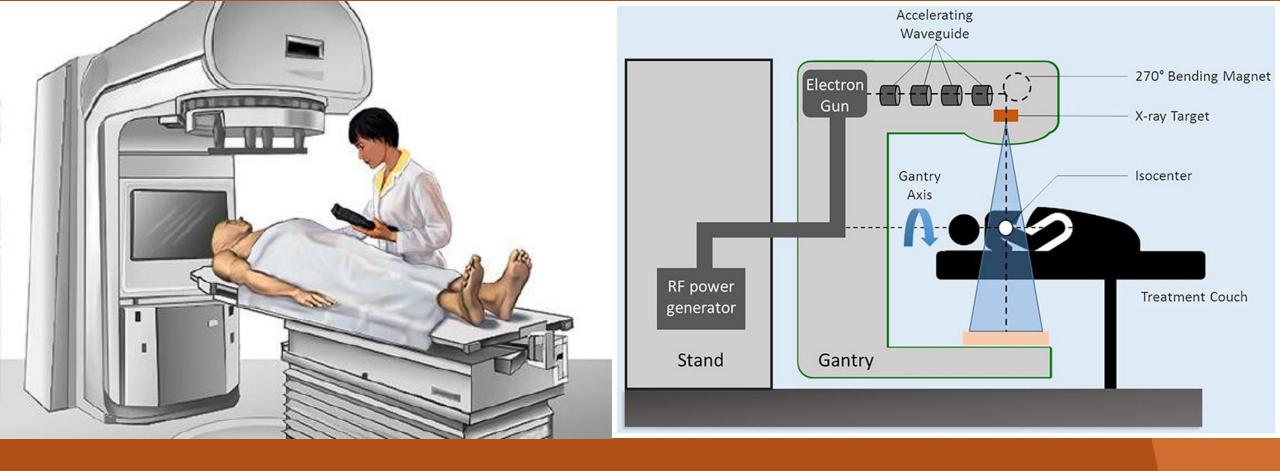
Mammography Medical Physicists

Main Physicists Webpage

- Mammography Physicist Webpage
- Check for updates
- Renewal Applications
 - Can submit 8 hours of CT training to update RHB records
- Online Lists
 - Indicate Approved Modalities

er	Expiration Date	DBT	CT
	5/9/2025	No	Na
	5/9/2013	No	No
	8/8/2007	No	No
	4/16/2027	Yes	No
	7/8/2026	Yes	No
	8/8/2007	No	No
	8/8/2007	No	No
	2/5/2027	Yes	No
	4/28/2026	Yes	No
	7/23/2027	Yes	No
	11/7/2026	Yes	No
	12/8/2027	Yes	No
	8/8/2007	No	No
	3/17/2026	Yes	No
	5/9/2026	Yes	No
	8/8/2007	No	No
	8/2/2019	Yes	No
	8/8/2010	No	No
	8/8/2028	Yes	No
	5/9/2028	Yes	Yes
	8/8/2007	No	No
	5/9/2025	Yes	No
	5/9/2028	Yes	No
	8/8/1997	No	No
	4/5/2027	Yes	No
	5/20/2024	Yes	No
	1/13/2029	Yes	No
	11/8/2026	Yes	No
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Therapy Updates

Therapy Facilities

- Our <u>Therapy Facilities Webpage</u>
 - Check for Updates
- Therapeutic X-ray Equipment <u>></u>500kVp
 - Stage 1 Authorization for Physical Measurements
 - Must obtain before the turning the machine on
 - Stage 2 Authorization to Treat
 - Must obtain before treating patients
 - Stage 3 Final IMRT Authorization
 - Must provide 12 months of area monitoring reports
- Checklists on our webpage



Therapeutic Medical Physicists

Main Physicists Webpage

- Therapy Physicist Webpage
- Check for updates
- New and Renewal Applications
 - Email a copy of the application and check RHBRMT@cdph.ca.gov
 - Include Name and/or TSP/TCP number on the check (especially when the check is from a facility/company)
 - Fees are not refundable. It is your responsibility to ensure that you meet application criteria prior to application submittal. Refer to <u>17 CCR § 30313.45</u> for details.
- Online Lists



Therapeutic Medical Physicists

Two Types of Therapeutic Medical Physicists

- Therapeutic Survey Physicist (TSP)
 - Protection Surveys
 - Can only supervise TSP candidates
- Therapeutic Calibration Physicist (TCP)
 - Machine Calibrations
 - Protection Surveys
 - Can supervise both TCP and TSP candidates





CDPH – Q & A – Radiation Machines



What is the current turnaround time for CDPH shielding plan review and approval for new LINAC?

MEDICAL LINEAR ACCELERATORS

Authorization to Measure

- Shielding Evaluation
- 60 Days from the receipt of a complete application

Authorization to Treat

- Calibration Report, Protection Survey, RPSP, Registration
- 30 Days from the receipt of a complete application

Authorization to Treat – Addendum Final IMRT

- 12 months of Area
 Monitoring & Patient Logs
- 30 Days from the receipt of a complete application





Has CDPH updated any requirements for secondary barrier calculations (e.g., T, U factors) based on current workload guidance or TG reports?

No updates on any secondary barrier calculations requirements

Follow NCRP 151

STRUCTURAL SHIELDING DESIGN AND EVALUATION FOR MEGAVOLTAGE X- AND GAMMA-RAY RADIOTHERAPY FACILITIES





Are electronic shielding reports (PDFs) with digital signatures accepted, or are wet-signed hard copies still mandatory for final approval?

Digital Signatures and/or Wet-signed Signatures are ACCEPTED.

Submit all applications with supporting documents to:

RHBRMT@CDPH.CA.GOV





Does CDPH require initial CT fluoroscopy training and re-certification documentation for medical physicists?

None for CT and Fluoroscopy.

Mammography Medical Physicists:

- Equipment Evaluations
- Annual Surveys

Therapy Medical Physicists:

- TCP
 - Machine Calibrations
 - Protections Surveys
- TSP
 - Protections Surveys





Are there updated guidelines for physicist training in stereotactic systems (SRS/SBRT) or proton therapy specific to California?

No updated guidelines.

Medical Physicist must be:

- TCP
 - Machine Calibrations
 - Protections Surveys
- TSP
 - Protections Surveys





What are the requirements for registration and shielding approval for emerging modalities such as FLASH radiotherapy, PET/MR systems, and TBI vaults with mobile shielding?

X-ray Machine
Registration
requirements – applies
to ALL machines that
produce X-ray.

Registration Portal Link

Authorization Requirements for Medical Use Only (>500kVp)

Three-Stage of Authorizations

Details on Requirements → RHB
Therapy Facilities Webpage





Is CDPH currently developing guidance for biologically guided radiotherapy (BgRT) or real-time adaptive LINACs (e.g., Ethos, MRIdian)?

X-ray Machine
Registration
requirements – applies
to ALL machines that
produce X-ray.

Registration Portal Link

Authorization Requirements for Medical Use Only (>500kVp)

Three-Stage of Authorizations

Details on Requirements → RHB
Therapy Facilities Webpage





Does CDPH require out-of-state physicists performing acceptance testing or commissioning to register or notify CDPH in advance?

Must meet all requirements and must be fully-approved

Medical Physicist must be:

- TCP
 - Machine Calibrations
 - Protections Surveys
- TSP
 - Protections Surveys





Does CDPH offer a grace period or conditional approval while awaiting license amendments or equipment registrations?

Must meet all requirements and must be fully-approved

No grace period

No conditional approval





How many facilities in California now offer contrast-enhanced mammography?

Currently, none.





What preparations does a facility have to make to offer contrast-enhanced mammography?

Currently, no guidance available.

Check Mammography Facilities Webpage for any updates





Do mobile mammography vans require additional or special oversight? What are the common challenges?

Mobile Mammography Additional Requirements

- Physical address of each location
- Contact info of responsible person
- Unit fixed in mobile van or transported to examination area?
- QA tests after each relocation

Common Challenges

- Registration
- Unit in a mobile van used only at the facility's registered location
- Inspection



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What are the 2025 updates to the frequency of CDPH inspections for LINACs, CT simulators, and fluoroscopy systems?

- California Health and Safety Code 115085
 - Mammography = Annual
 - High Priority = 3 years
 - Medium Priority = 4.25 years
 - •Dental = 5 years



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- What specific documentation is required to demonstrate compliance during a CDPH inspection of a newly commissioned LINAC?
- Authorization to Measure
- Authorizations to Treat
- Accreditation Paperwork
- Radiation Safety Program
- Annual Machine Calibrations
- Measurement Equipment Calibrations
- Licenses, permits, certificates (radiologists, technologists, physicists)
- Dosimetry Records
- Daily QC



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Has CDPH adopted AAPM TG-142 Addendum recommendations into required QA documentation during site inspections?

- AAPM TG 142 has not been adopted into regulations
- TG-142 may be a requirement from your accrediting body





What are the current California CT Dose Notification and Alert thresholds for adult and pediatric patients?

- California Health and Safety Code 115113
- Repeating of a CT exam, wrong patient, or wrong body part with a dose exceeding:
 - 5 rem effective dose
 - 50 rem to an organ or tissue
 - 50 rem shallow dose to the skin



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- What is the compliance expectation for facilities with multiple scanners? Must each CT scanner have its own set of dose notification values?

- The RHB event reporting dose notification values follow California Health and Safety Code 115113
- The standard adult brain, adult abdomen, and pediatric brain CTDI and DLP are to be determined for each scanner.



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- Does CDPH accept third-party dose monitoring platforms (e.g. Radimetrics, Imalogix) for CTDIvol and DLP tracking in lieu of manual logs?

- Yes, the Department accepts multiple forms for CTDIvol and DLP tracking.
- Consult ACR or AAPM for recommended platforms
- RHB does not advocate a specific platform. This is a facility decision.





Do you think the CT dose reporting legislation has been effective at protecting patients?

- The intent of HSC 115113 is to track reportable events and for facilities to adjust procedures to minimize future events from occurring.
- The dose values from 115113 are based on the NRC medical event reporting criteria.



- ?
- What is CDPH's current stance on delegation of physicist QA tasks to non-TCP physicist, dosimetrists, or RTs for routine machine QA?
- Performed by Physicist, supervised by TCP
 - 24 month calibration of therapeutic X-ray system (TCP)
 - Initial radiation protection shielding survey (TCP/TSP)
- Performed by TCP
 - Develops and approves spot check procedure (machine calibration TCP)
 - Consultation of erratic or inconsistent spot check results
- Can be performed by non-TCP
- **CDPH**
- Weekly spot checks

- ?
- What are the current enforcement actions or penalties for non-compliance found during CDPH inspections (e.g., missing annual QA, expired calibrations)?

- The Radiation Control Law, Radiologic Technology Act, and the nuclear medicine technology certification laws give CDPH authority to take specific actions, including denying, suspending, or revoking authorizations and levying of civil penalties, for violations of these laws and their implementing regulations.
- RHB actively takes escalated enforcement actions and assesses whether other penalties will be levied. However, our goal is to first educate and bring users into compliance before more punitive actions are taken, and to prevent future violations. In general, more punitive actions are taken when laws, as opposed to regulation, are violated or patient, worker, and public health and safety are jeopardized. But the action taken is based on the specifics of an individual case and the applicable law or regulation.



RHB Links to Webpages

- RHB Main Home Page
- X-ray Machine Registration Webpage
- Medical Physicists Authorizations Webpage
 - Mammography Medical Physicists Requirements (<u>Initial/Renewal</u>)
 - Therapeutic Medical Physicists Requirements (<u>Initial/Renewal</u>)
- Mammography Machine Certification
- Therapeutic Machine Authorizations
 - Machine Authorization Checklists
 - Radiation Protection Program Guidance
- <u>Inspection Information</u>
- Radioactive Materials (RAM) Licensing
 - RAM Authorized Medical Physicist



Any Questions?

RHB Contact Us Page





