RAD SAFETY–FLUORO
Fluoroscopy Who Can, Who Can’t

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Fluoroscopy Beginnings . . .


Today . . .
1937: Division 2. Healing Arts

Chapter 5. Medicine

Known as the Medical Practice Act

Amended numerous times; as recently as 2014.

Chapter 5. Medicine

Article 3. License Required and Exemptions.

Section 2050. The Division of Licensing shall issue one form of certificate to all physicians and surgeons licensed by the board which shall be designated as a "physician's and surgeon's certificate."

Section 2051. The physician's and surgeon's certificate authorizes the holder to use drugs or devices in or upon human beings and to sever or penetrate the tissues of human beings and to use any and all other methods in the treatment of diseases, injuries, deformities, and other physical and mental conditions.
Laws and Regulations . . .

  - Required all healthcare providers using x-ray to register their devices with the CA Health Department and report what shielding devices were used to protect doctors/patients.
  - Assembly Bill 879 outlawed coin-operated foot x-ray machines in shoe stores.

- 1965 Senate Bills 848 and 849
  - 849: Amended the Medical Practice Act to require physicians and podiatrists to take courses in radiology and radiation safety, and to pass an examination given by CA Health Department. Signed into law by Governor Edmund G. “Pat” Brown.

- “. . . This legislation is designed to make sure that each exposure is done properly, safely and skillfully. There is much evidence that improperly trained people operate medical x-ray machines; presently the law does not require any training or education for x-ray machine operators . . .”

  - Press release by Senator Walter Stiern, DVM upon introducing SB 849
Laws and Regulations . . .

1965 Senate Bills 848 and 849 (cont.)

- 848: A companion bill that would require x-ray technicians and other licentiates (chiropractors) to have the same training courses and examination.
- SB 848 would also have created the X-Ray Technician’s Advisory Council:
  - Four physicians
  - One radiologic physicist
  - Two x-ray technicians
  - One chiropractor
- Resubmitted as SB 751 (died) and again as AB 633 (died) and again as SB 935 (vetoed by Governor Ronald Reagan.

1968 Senate Bill 1056

- A rewritten version of SB 848 that would require x-ray technicians and other licentiates (chiropractors) to have the same training courses and examination.
- Renamed previously created Radiation Safety Board as the Radiologic Technology Certification Committee:
  - Four physicians
  - One radiologic physicist
  - Two x-ray technicians
  - One chiropractor
- Signed into law as Radiation Control Act.

Fluoroscopy becomes an issue . . .

- Concern was expressed by RTCC members about the practice of fluoroscopy in California.
  - Survey
  - Perceived training/experience deficiencies
  - Subject matter content proposed by RHB
  - Regulations proposed by RHB
- RHB was very different from its current makeup.
RTCC Recommendation

- "Beef up" RT Program educational content to address fluoroscopy in greater depth.
  - School Directors explained issues involved with changing curriculum content
  - Process would take approximately two-years.
- Provide a process to allow the development of requisite training courses.
- Issue "temporary" permits for existing CRTs who successfully passed an RHB-developed test.
- Establish a "sunset provision" for temporary permits. RT certificates issued after the "sunset" date would represent explicit inclusion of mandated educational content.

RHB Action

- CCR title 17, 30450. Permit Requirement
  - Required CRTs to possess a Permit to perform certain fluoroscopy-related tasks
  - NO "sunset" clause
- CCR title 17, 30423. Radiologic Technologist Permit Schools
  - 40 hours of classroom instruction
  - 15 hours of laboratory experiments with phantoms

But what about . . .

- California Health and Safety Code
  - Section 114870(b)(1) requires the Department to provide for certification of radiologic technologists, without limitation as to procedures or areas of application, except as provided in Section 106980. Separate certificates shall be provided for diagnostic radiologic technology, for mammographic radiologic technology, and for therapeutic radiologic technology.
Other law . . .

- California Health and Safety Code
  - Section 106980 prohibits CRTs from:
    - The use of diagnostic, mammographic, or therapeutic X-ray equipment except under the supervision of a certified supervisor or operator.
    - The interpretation of any radiograph or a diagnosis based upon it.
    - The reporting of any diagnosis to a patient except as ordered by a licentiate of the healing arts.
    - The use of any title or designation indicating or implying the right to practice any of the healing arts.

Interpretations . . .

- CA RHB Policy No. 95–2 rev 1 (July, 2000):
  - Reaffirmed certification/permitting requirement for administering/using diagnostic/therapeutic x-ray on human beings.
  - Reaffirmed definition of fluoroscopy as “a radiological examination utilizing fluorescence for the observation of the transient image.”
  - Reaffirmed that a fluoroscopy permit is required for any CRT who:
    - Positions the patient
    - Positions the fluoroscopy equipment
    - Selects exposure factors

Interpretations . . .

- CA RHB Policy No. 95–2 rev 1 (cont.):
  - Reaffirmed that a fluoroscopy supervisor and operator permit is required for any licentiate who:
    - Actuates or energizes fluoroscopy equipment
    - Directly controls radiation exposure to the patient during fluoroscopy procedures.
    - Supervises one or more persons who hold radiologic technologist fluoroscopy permits pursuant to section 30451.
  - Reaffirmed that supervision means “responsibility for, and control of, quality, radiation safety, and technical aspects of all x-ray examinations and procedures.”
Interpretations . . .

CA RHB Policy No. 95–2 rev 1 (cont.):
- Provided practical examples using various scenario descriptions.
- Affirms that a CRT with a fluoroscopy permit may perform fluoroscopy under standing orders from a Radiology Supervisor and Operator without a radiologist in the room.
- Reminds users of additional requirements found in Sections 30255, 30305, 30253 of Title 17 and 106980 of the Health and Safety Code.

CA RHB Policy No. 95–2 rev 2 (January 2009)
- Clarifies that because “fluoroscopy” is a radiologic examination, the fluoroscopy limitations imposed on CRTs and licentiates, alike, must be followed “while procedure is in progress”.
- Further clarifies in Example 3 tasks that a non-permitted CRT may perform.
- Further clarifies that “Once the fluoroscopic examination has begun with the initiating exposure, the nurse or medical assistant may not perform tasks associated with the exposure of the patient to radiation for the duration of the examination.”

CA RHB Policy No. 95–2 rev 2 (cont.)
- Adds additional examples:
  - Fluoroscopy permit is not required to operate a therapy simulator.
  - Explicitly prohibits Cardiovascular Technologists, nurses or other non-CRTs from performing any of the tasks reserved for CRTs who possess a fluoroscopy permit.
  - Includes the admonition that “The Department issues citations to individuals who perform fluoroscopy without possessing the required certifications, as well as to those responsible for allowing the violations to occur.”
  - Reminds users of the “aiding and abetting” sections of the Health and Safety Code.
Recent developments. . .

- CA RHB Information Notice (9–15–2014):
  - As a result of regulatory changes effective October 1, 2013, fluoroscopy redefined as “. . . a technique used to produce visible images.” This definition is consistent with the definition of fluoroscopy in Title 21 CFR Part 1020.30(b).
  - Only a qualified person (permitted individual) may initially establish or re-establish spatial relationships (i.e. where patient is in relation to the radiation source), determine exposure factors and/or expose a patient to x-rays in a fluoroscopy mode.
  - Allows a non-permitted person to move the equipment or the patient when the equipment is not energized. (note the use of the work “move” and not “position”)

- CA RHB Information Notice (cont.):
  - Further clarifies that when fluoroscopy is operated in the AEC or AERC mode, a non-permitted individual may move the patient or the equipment at the request of and under the direct oversight and personal supervision of a qualified person. The qualified person must review and approve of any changes to the spatial relationship and technical factors that resulted from the actions taken by the non-permitted individual before the qualified person exposes, or continues to expose, the patient to x-rays.
  - Further clarifies that therapeutic radiologic technologists may perform fluoroscopy for therapeutic treatment planning but not for diagnostic purposes.

- CA RHB Exemption Notice (9–30–2014)
  - Supersedes Policy 95-2 rev 2 and the Information Notice of 9–15–2014) based on the Department’s right to “grant exemptions from the applicable requirements of Title 17 as it determines are authorized by law and will not result in any undue hazard to health, life, or property.”
  - Addresses ongoing concerns that existing regulations create an unsafe patient environment during certain surgical procedures by prohibiting specially trained individuals who have received training specific to the medical procedure being performed from moving the patient or the equipment to achieve a satisfactory medical outcome.
CA RHB Exemption Conditions:

- Positioning the patient or the fluoroscopic equipment by non-permitted individuals shall be performed at the request of a permitted licentiate who is physically present and personally directs such actions.
- The permitted licentiate who is directing the non-permitted individual shall identify and document all specific actions the non-permitted individuals will perform.
- The permitted licentiate must document training of non-permitted individuals.

CA RHB Exemption Conditions (cont.):

- The permitted licentiate shall document at each facility where operating under this exemption, the following training:
  - Equipment set up and operation
  - Fundamentals of radiation safety
  - Significance of radiation dose to include hazards of excessive exposure to radiation, biologic effects of radiation dose and radiation protection standards
  - Expected levels of radiation from fluoroscopy equipment
  - Methods of controlling radiation dose: time, distance and shielding
  - Characteristics and use of personnel monitoring equipment

CA RHB Exemption Conditions (cont.):

- Fluoroscopy equipment being operated is operated only in the automatic exposure control (AEC) or automatic exposure rate control (AERC) mode.
- The permitted licentiate shall review and approve, before exposure of the patient to x-rays, any changes to the spatial relationship and technical factors that resulted from the actions taken by the non-permitted individual.
- The permitted licentiate(s) shall, during a Department inspection, demonstrate the ability to set up and operate the equipment and perform all actions that s/he may request a non-permitted person to perform.
Recent developments...

- CA RHB Exemption Conditions (cont.):
  - The licentiate who is physically present and directing the actions permitted by this exemption is responsible for ensuring that all conditions of this exemption are met for each occurrence.
  - Under no circumstance may the non-permitted individual:
    - determine exposure factors;
    - expose a patient to x-rays in a fluoroscopy mode; or
    - independently establish spatial relationships between the patient and the radiation source.

Recent developments...

- Rescission of Exemption (December 19, 2014)
  - The California Department of Public Health, Radiologic Health Branch (Department), is rescinding the Exemption to California Code of Regulations, Title 17 (17 CCR), Section 30450 (a)(1) and (a)(2), issued by the Department on September 30, 2014. This rescission is effective immediately.
  - If you feel that you have a continuing medical need for such an exemption that cannot be satisfied in any other way, please notify the Department. Your request will be evaluated on a case by case basis in accordance with 17 CCR Section 30104.

Signed by Gonzalo L. Perez, Chief, Radiologic Health Branch

In a Nutshell...
Future Direction? . . .

- Adhere to Health and Safety Code Section 114870(b)(1), removing the requirement for separate fluoroscopy permit.

- Acknowledge, in regulation, the Radiography Program Curriculum promulgated by the ASRT and approved by JRCERT.
  - Within the ASRT curriculum, radiography includes fluoroscopy.

Don’t Forget . . .

- Adhere to Health and Safety Code Section 114870(c)(1)(A):
  - “Provide, as may be deemed appropriate, for granting limited permits to persons to conduct radiologic technology limited to the performance of certain procedures or the application of X-rays to specific areas of the human body, except for mammography . . . .”