

State of California—Health and Human Services Agency California Department of Public Health



EDMUND G. BROWN JR. Governor

September 30, 2014

EXEMPTION TO CALIFORNIA CODE OF REGULATIONS (CCR) Title 17 (17CCR), Section 30450(a)(1), 30450(a)(2)

The California Department of Public Health, Radiologic Health Branch (Department), is issuing this exemption to address the positioning of human patients and equipment during fluoroscopy. This exemption supersedes Policy 95-2 rev 2, Fluoroscopy Permit Requirements Policy guidance, issued January 6, 2009, and the Information Notice issued September 15, 2014. Pursuant to Title 17, California Code of Regulations, section 30104, the Department may 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.

This exemption addresses ongoing concerns that existing regulations create an unsafe patient environment during certain surgical procedures. Specially trained individuals who have received training specific to the medical procedure being performed must move the patient or the equipment as requested by the licentiate to achieve a satisfactory medical outcome. Current regulations do not permit this action. 17 CCR §30450 (a)(1) and (a)(2) provides in pertinent part that "...a radiologic technologist fluoroscopy permit issued by the Department shall be required of any radiologic technologist who exposes a patient in a fluoroscopy mode, or who does one or more of the following during fluoroscopy of a patient: (1) Positions the patient; (2) Positions the fluoroscopy equipment ..."

An acceptable alternative is available which presents similar level of patient protection and oversight of fluoroscopic patient positioning and equipment movement. Staff operating under the direct oversight of a licentiate in possession of either current and valid Fluoroscopy Supervisor and Operator permit or a current and valid Radiology Supervisor and Operator certificate ("permitted licentiate") issued by the Department, are hereby granted an exemption to requirements listed in 17 CCR 30450 (a)(1) and (a)(2), provided that all of the following conditions are met:

1. 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.

- 2. The permitted licentiate who is directing the non-permitted individual shall identify and document all specific actions the non-permitted individuals will perform.
- 3. The permitted licentiate who is directing the non-permitted individual shall document at each facility where operating under this exemption that the individual has received training consisting of all of the following:
 - a. Equipment set up and operation;
 - b. Fundamentals of radiation safety;
 - c. Significance of radiation dose, to include hazards of excessive exposure to radiation, biological effects of radiation dose, and radiation protection standards;
 - d. Expected levels of radiation from fluoroscopy equipment;
 - e. Methods of controlling radiation dose: time, distance, shielding; and
 - f. Characteristics and use of personnel monitoring equipment.
- 4. Fluoroscopy equipment being operated is operated only in the automatic exposure control (AEC) or automatic exposure rate control (AERC) mode.
- 5. 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.
- 6. The permitted licentiate(s) shall, during the Department inspection, demonstrate the ability to set up and operate the equipment and perform all actions that he/she may request a non-permitted person to perform. If the licentiate is not present at the facility during the inspection, the licentiate shall provide the facility with documentation that the permitted licentiate(s) has received training to set up and operate the equipment and can personally perform all actions he/she may request a non-permitted person to perform.

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.

Compliance with the above conditions of exemption will be evaluated during inspections conducted by Departmental personnel. A facility may demonstrate that their licentiate staff is in compliance with items 2 and 3 by providing a single policy or a set of policies that all of the licentiates sign.

As with other radiation-producing devices subject to regulation, users must adhere to all other regulations regarding the use of X-ray machines on human patients and the Standards for Protection Against Radiation, as specified in 17 CCR 30253. This exemption is valid until rescinded, or until amendments are made to 17 CCR §30450(a)(1) and/or §30450 (a)(2).

For the Department of Public Health:

<u>Signature on file</u> Gonzalo L. Perez, Chief Radiologic Health Branch