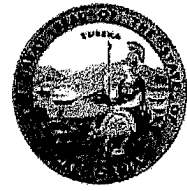




California
Department of
Health Services

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Fluoroscopy Operation & Certification Requirements

The responsibility for and authority to explain and interpret radiation control laws and regulations, and define specific areas of applicability in the State of California rests solely with the Department of Health Services, Radiologic Health Branch (Department).

California Health and Safety Code, Section 106965.

It shall be unlawful for any person to administer or use diagnostic or therapeutic X-ray on human beings in this state after July 1, 1971, unless that person has been certified or granted a permit pursuant to subdivision (b) or (c) of Section 114870 or pursuant to Section 114885, is acting within the scope of that certification or permit, and is acting under the supervision of a licentiate of the healing arts.

This is the law. It is saying that any person who exposes humans to X-ray must be appropriately certified and supervised.

Licentiate Requirements

California Code of Regulations, title 17, Section 30463

A Fluoroscopy Supervisor and Operator (S&O) permit issued by the Department shall be required of any licentiate of the healing arts who does one or more of the following:

- (a) Actuates or energizes fluoroscopy equipment.
- (b) Directly controls radiation exposure to the patient during fluoroscopy procedures.
- (c) Supervises one or more persons who hold radiologic technologist fluoroscopy permits pursuant to Section 30451.

Technologist Requirements

California Code of Regulations, title 17, Section 30450

A radiologic technologist fluoroscopy permit issued by the Department shall be required of any technologist who exposes a patient to X-rays in a fluoroscopy mode, or who does one or more of the following during fluoroscopy of a patient:

- (a) Positions the patient.
- (b) Positions the fluoroscopy equipment.
- (c) Selects exposure factors.

As an illustration, let us propose a script, a scenario, from frequently asked questions. A nurse brings a c-arm into the suite, positions it in proximity to the patient or where the patient will be, and plugs in the equipment. These actions are acceptable and do not violate the regulations. Now, if we take an additional step into the scenario. Assume that

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the physician has initiated the fluoroscopic examination by energizing the equipment and has positioned the image intensifier (II). At this point he is satisfied with the position, and gowns up, thus creating a sterile field around the patient and equipment. He proceeds with the medical procedure, but now needs to reposition the II. At this time the equipment is not energized, and he directs the nurse to move the II up or down field, and then he energizes the equipment to verify position. He may or may not need to continue positioning in this manner, i.e., beam off nurse moves II, beam on - verify position, and so forth. But if he does continue in this fashion, the equipment is not energized when the nurse moves it.

The question is this: Is the nurse performing the duties for which a duly permitted radiologic technologist is required? The answer is yes. The nurse, by acting under the direction of the physician, has become an active participant in the fluoroscopic procedure. Put another way, the fluoroscopic procedure is moving forward only by the coordinated actions of the physician and the nurse, so both individuals are performing fluoroscopy. As we know, at least two of the goals of the fluoroscopic procedure are to optimize imaging quality and effectiveness, while minimizing patient exposure. Non-permitted individuals, lacking the skill and training critical to the successful manipulation of the equipment, do not achieve these goals.

A common misconception is that the unauthorized activities can be somehow sanctioned by the presence of at least one duly permitted party. This is not true, a licentiate of the healing arts (physician) with an S & O permit, and fluoroscopy permit, is allowed to operate the fluoroscopic equipment entirely on his/her own, or may choose to involve a radiologic technologist who possesses the necessary permit. Another aspect involves facilities employing duly permitted CRTs to operate c-arms under the supervision of physicians possessing neither S & O Permits, nor fluoroscopy permits: CRTs can never perform radiography or fluoroscopy independent of the supervision of a duly permitted licentiate of the healing arts. Non-permitted individuals are not authorized to participate in the "fluoroscopic procedure" as previously defined.

For your information, California Health & Safety Code, section 115210 provides authority for the Department to request a city attorney, a district attorney, or the Attorney General, to institute on behalf of the people of California any civil action necessary to carry out this chapter, including, but not restricted to, the enforcement of liens, the obtaining of injunctions, or the imposition of civil penalties.

Enforcement action will be taken against non-permitted individuals discovered to be performing these tasks. Physicians providing the direction/supervision for uncertified people who are acting without permits or outside the scope of their permits, are "aiding and abetting" illegal activity. Facility administration has the responsibility to ensure that radiologic procedures conducted throughout the facility are performed in compliance with all applicable regulations and is subject to enforcement action as well.

Certification and Supervision Requirements for Certified Radiologic Technologists and Licentiates who will be Operating and/or Supervising the Operation of Fluoroscopy Equipment

California Code Of Regulations, title 17, Section 30100

(l) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, . . .

(w) "Source of radiation" means a discrete or separate quantity of radioactive material or a single radiation machine.

(aa) "User" means any person who is licensed to possess radioactive material or who has registered as possessing a reportable source of radiation pursuant to groups 1.5 and 2 of this subchapter, or who otherwise possesses a source of radiation which is subject to such licensure or registration.

Supervision -- general supervision vs. direct &/or immediate supervision

California Health and Safety Code, section 114850(g): "Supervision" means responsibility for, and control of, quality, radiation safety, and technical aspects of all X-ray examinations and procedures.

There are no definitions of general supervision the Health and Safety Code that apply broadly to the Radiologic Technology Act. However, section 106985(c), dealing with venipuncture by certified radiologic technologists defines general supervision, for purposes of that section, to mean the direction of procedures authorized by this section by a licensed physician and surgeon who shall be physically present within the facility and available within the facility where the procedures are performed, in order to provide immediate medical intervention to prevent or mitigate injury to the patient in the event of adverse reaction.

A search of California Code of Regulations yields similar results. Subchapter 4.6 deals with nuclear medicine technology. In section 30501, "Direct supervision" means that the supervisor is physically present in the same room with the certified technologist, nuclear medicine, special permit holder or student of nuclear medicine technology at the time the nuclear medicine technology procedure is being performed. And in Section 30502, general supervision means that the supervisor is responsible for, and has control of, all of the following:

- (1) Quality, technical and medical aspects of all nuclear medicine technology procedures.
- (2) Radiation health and safety of patients, ancillary personnel and other persons.
- (3) Ascertaining that certified technologists, nuclear medicine, maintain their competency . . .

The responsibility to explain and interpret radiation control laws and regulations, and define specific areas of applicability in the State of California rests solely with the Department of Health Services, Radiologic Health Branch (Department). The Department usually applies these definitions of supervision broadly, but in practice that is seldom necessary because the need for supervision and the type of supervision is controlled by other factors.

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In addition to the certification requirements

California Code Of Regulations, title 17, Section 30305(b) (1), requires that the user shall assure that all X-ray equipment under his jurisdiction is operated only by persons adequately instructed in safe operating procedures and competent in safe use of the equipment.

California Code of Regulations, title 17, Section, 30253 incorporates the regulations governing standards for protection against radiation in **title 10, Code of Federal Regulations, part 20, sections 20.1001 through 20.2402 and Appendices A through G. 10, Code of Federal Regulations, part 20, section 20.1101** requires that each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. Among other things, the licensee [user] 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 is reasonably achievable (ALARA); and The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

California Code Of Regulations, title 17, Section 30305(b)(2) requires the user to provide safety rules to each individual operating X-ray equipment under his control, including any restrictions of the operating technique required for the safe

Certification and Supervision Requirements for Certified Radiologic Technologists and Licentiates who will be Operating and/or Supervising the Operation of Fluoroscopy Equipment

operation of the particular X-ray apparatus, and require that the operator demonstrate familiarity with these rules. These Safety rules must be signed by the supervising licentiate and dated. The Department considers these to be part of the radiation control program so they must be reviewed at least annually as required by 10, Code of Federal Regulations, part 20, section 20.1101

Certified radiologic technologists with a fluoroscopy permit may perform certain fluoroscopy procedures on patients without a licentiate being immediately available, provided the supervising licentiate with an appropriate supervisor and operator permit / certificate, provided standard operating procedures (safety rules) document criterion, or guidelines, to determine whether the technologist may do the procedure without direct supervision and specify limits on technique factors. The expectation is that the procedure will be recorded to be interpreted by the supervising licentiate at a later time. A licentiate present in the room at the time of the procedure is presumed to be supervising and must possess a fluoroscopy supervisor and operator certificate/permit.