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INFORMATION NOTICE

September 15, 2014

TO: Users and Operators of Fluoroscopic Equipment

SUBJECT: Fluoroscopy Permit Requirements

This notice is to clarify fluoroscopy permit requirements following regulatory changes that became effective October 1, 2013. As a result of those changes, fluoroscopy is no longer defined in regulation as a radiological examination, but rather as a technique used to produce visible images. Previous policies and guidance concerning fluoroscopy permit requirements are superceded by this Notice.

- Only a qualified person (permitted individual) may initially establish or re-establish spatial relationships (i.e., where the patient is in relation to the radiation source), determine exposure factors, and/or expose a patient to X-rays in a fluoroscopy mode. A licentiate may use fluoroscopy equipment independently, provided he/she holds either a Radiology Supervisor and Operator Certificate or a Fluoroscopy Supervisor and Operator Permit. The physician assistant and the radiologic technologist holding the appropriate fluoroscopy permit must be under the supervision of a permitted licentiate.
- A non-permitted person may move the equipment or the patient when the equipment is not energized.
- During fluoroscopy operated in the manual mode, a non-permitted individual may not move the patient or the equipment.
- During fluoroscopy operated in the automatic exposure control (AEC) or automatic exposure rate control (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.

- Pursuant to Title 17, California Code of Regulations (17 CCR), Section 30450(b), a certified therapeutic radiologic technologist performing fluoroscopy for therapeutic treatment planning is not required to hold a radiologic technologist fluoroscopy permit. This exception may not be construed to allow a certified therapeutic radiologic technologist to use fluoroscopy for diagnostic purposes.

BACKGROUND

Regulatory changes that became effective October 1, 2013 changed the definition of fluoroscopy. Fluoroscopy is no longer defined in regulation as a radiological examination, but rather as a technique to produce visible images. The definition is now consistent with the definition of Fluoroscopy as defined by the U.S. Food and Drug Administration in Title 21, Code of Federal Regulations (21 CFR), Part 1020.30(b). Previous policy guidance focused on defining fluoroscopy as a radiological examination rather than as a technique that is looked to in accomplishing a medical procedural goal.

The Radiologic Technology Act (Health and Safety Code, sections 106965 – 107120 and 114840 – 114896) requires anyone who administers or uses diagnostic or therapeutic X-ray on human beings in this state to be certified or granted a permit. It further requires licentiates of the healing arts who administer or use diagnostic, mammographic, or therapeutic X-ray on human beings in this state to be certified, and to act within the scope of that certification. The use of fluoroscopy equipment is a permitted scope. Specifically, technologist requirements are found and may be reviewed in 17 CCR, section 30450; physician assistant requirements are found and may be reviewed in 17 CCR, section 30456.1; and licentiate requirements are found and may be reviewed in 17 CCR, section 30463. A holder of the applicable fluoroscopy permit (i.e., a qualified person) has been tested and demonstrated that they understand how fluoroscopy equipment works, what the hazards of radiation exposure are, how externalities (non-human objects placed into X-ray beam) impact image formation and radiation exposure, what the patient body habitus is and how it impacts image formation and radiation exposure, how to use fluoroscopy equipment safely so as to protect themselves and others from unnecessary radiation exposure, and how to reduce a patient's radiation exposure during a medical procedure. Individuals not holding such permits have not demonstrated the requisite knowledge, skills, and abilities referenced above. Manual fluoroscopy equipment (or a machine equipped with AEC or AERC¹ and operated in manual mode) requires the operator to address any change in the relationship between equipment and patient, including the presence of any object placed between the tube port and image input surface, by manually changing the exposure factors so as to maintain a quality image. Equipment with AEC or AERC performs that function, but the operator must be cognizant of any change in the spatial relationship, and compensate as necessary to maintain a quality image.

¹ 21 CFR 1020.30(b). (January 1, 2014) *Automatic exposure control (AEC)* means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation. *Automatic exposure rate control (AERC)* means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation per unit time.