

STATE OF COLORADO

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Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department
of Public Health
and Environment

PROCEDURAL GUIDANCE

Hazardous Materials and Waste Management Division

Radiation Control Program, X-Ray Certification Unit

SUBJECT: Interpretation of the operation of fluoroscopy equipment used in the examination of a living human in the State of Colorado and identified in 6 CCR 1007-1, Part 2 and Part 6 of the *Colorado Rules and Regulations Pertaining to Radiation Control*.

Basis and Purpose:

6 CCR 1007-1, Part 2, Section 2.6.1. states that any operators of fluoroscopy equipment used for the examination of a human must meet the applicable requirements in Part 2, Sections 2.6.1.1 through 2.6.1.4. In addition, each healing arts facility must have adequately trained individuals supervising and operating fluoroscopy equipment.

The Regulations in Part 2, Section 2.6.1.5 state that individuals must be adequately trained in the safe operation of any fluoroscopy machine, to include stationary and C-Arm varieties. Each facility has the responsibility to document and keep records of the training of all individuals supervising or operating fluoroscopy equipment as required in Section 2.6.1.1. Any fluoroscopy equipment being operated at healing arts facilities such as hospitals, outpatient clinics, physician offices, pain management or surgical centers are required to follow Part 2, Sections 2.6.1.1 and 2.6.1.5.

The Regulations outline the basic and general regulatory requirements for such fluoroscopy systems. Limited scope operators are not allowed in Regulations to do fluoroscopy as written in Part 2, 2.6.1.4 (2).

The Regulations reference five general topics that must be covered in the documented training program. The amount of training or method of training is not stipulated in the regulations. This is up to the discretion of the facility and/or the medical physicist. Each facility shall be responsible for ensuring that all five topics are covered in the training of those supervising or operating fluoroscopy systems and documented.

The facility/registrant in collaboration with the medical physicist may develop a training program to meet the requirement of the Regulations. For those facilities/registrants that do not have a medical physicist on staff or by contract, may contact the Department for suggestions of implementation as outlined in this guidance. The registered medical physicist may use this guidance to assist in the implementation and documentation of training in fluoroscopy.

This procedural guidance may be utilized for the training of all individuals supervising and performing fluoroscopy procedures which include physicians licensed in Colorado, Radiologist Assistants and radiologic technologists. The Department recognizes that some supervisors or operators of fluoroscopy equipment have had training in some of the topics listed in Section 2.6.1.5. The Department requires that the training of each individual supervising or performing fluoroscopy procedures include all five sections as written in Section 2.6.1.5 (1 – 5) and be documented in the facilities records and these records be available for review. It will be the agreement between the facility and the medical physicist as to how this training will be provided and what methodology will be used.

Those individuals performing fluoroscopy procedures as a Radiologist Assistant shall review the Department's procedural guidance document for the Radiologist Assistants/Radiologist Practitioner Assistant.

Scope:

The guidance applies to all imaging systems designated as fluoroscopy equipment. The guidance explains the type of training each individual supervising or performing a fluoroscopy procedure must have. Evidence of this training must be documented and kept on file at the facility.

Supporting Regulations:

Part 2, Section 2.6.1 states “In any facility regulated by or requiring registration under these regulations, the registrant shall allow only individuals who are adequately trained in radiation safety and the safe and effective use of the machine to operate any radiation machine.”

Regulation:

Part 2, Section 2.6.1.1 states “The facility shall document evaluation of the qualifications of each individual permitted to operate any radiation machine at the facility.

Part 2, Section 2.6.1.1 (1), states “Each operator shall meet all radiation safety training and experience requirements of the respective State of Colorado professional licensure board, as applicable and any applicable requirements of this Part 2.”

Part 2, Section 2.6.1.1. (2), states “Consistent with 2.4.1.1 (3)(b), the registrant shall maintain a list of operators (or have a policy in place that specifies how such a list will be provided on request) who have been determined to be adequately trained in accordance with these regulations. Subparagraph (a) states “For fluoroscopy equipment used in examination of a living human, a list of qualified individuals shall be maintained as required by 2.6.1.5. Subparagraph (b) states “the list of all operators qualified for fluoroscopy shall be updated at least annually as part of the radiation safety program required by 4.5.

Part 2, Section 2.6.1.1 (3), states “Records of such evaluations shall: (a) include current certifications of qualifications; (b) Be maintained by the facility and (c) Be produced for examination upon request during any inspection conducted under the requirements of these regulations.”

Part 2, Section 2.6.1.5, states “For fluoroscopy equipment used in examination of a living human, “adequately trained” shall mean that in addition to meeting all the applicable requirements in 2.6.1.1 through 2.6.1.4, each healing arts facility shall make a written determination that any individual who either supervised a fluoroscopy procedure or operates a fluoroscopy imaging system has adequate training in its safe operation, including documented training in the following:

1. Fundamental principles of radiation protection;
2. Biological effects of ionizing radiation;
3. Safe operation of fluoroscopy equipment for each mode of operation to be used;
4. Dose reduction techniques for fluoroscopy and;
5. Applicable radiation regulations.

Part 6, Section 6.5.1.2, states “Supervision and use of fluoroscopic x-ray system for the purpose of localization to obtain images for diagnostic purposes shall be by an individual who has adequate radiation safety training and experience.”

Part 6, Section 6.5.1.2 (1), states “A physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts shall directly supervise use of a fluoroscopic x-ray system.”

Part 6, Section 6.5.1.2 (2), states “Training and experience shall be as provided in 2.6.1, in particular 2.6.1.5 and any applicable appendix to Part 2, and 6.3.1.9.”

Interpretation:

Each facility/registrant shall be required by Regulation to keep records of all individuals and their qualifications according to Section 2.6.1.1 (2) and Part 6, Section 6.5.1.2 (1). The Department has determined that any licensed physician supervising or performing fluoroscopy must have adequate training documented. The Department will require a Radiologist Assistant to show evidence of being adequately trained to perform fluoroscopy procedures. The Department has also determined that any radiologic technologist that may be required to perform fluoroscopy procedures, have documented training according to the Regulations.

Documentation shall include topics according to Section 2.6.1.5,

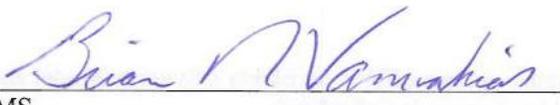
1. Fundamental principles of radiation protection.
2. Biological effects of ionizing radiation.
3. Safe operation of fluoroscopy equipment for each mode of operation to be used.
4. Dose reduction techniques for fluoroscopy and;
5. Applicable radiation regulations.

The Regulation clearly states in Section 2.6.1.4 (2) that the limited-scope x-ray machine operator may not perform radiologic procedures involving the administration or utilization of fluoroscopy.

The Department does not recognize at this time, physician assistants, certified nurse anesthetist, nurse practitioners or any other allied health professionals to be adequately trained to supervise or perform fluoroscopy procedures based on their licensure qualifications alone. These individuals must document adequate training as required by Section 2.6.1 to operate or supervise the operation of any x-ray equipment

Any training program that meets the requirements in Section 2.6.1.5 may be used to fulfill the requirement of training in the safe operation of the use of fluoroscopy imaging systems. The Department has recognized some programs already in effect as meeting the requirement of Section 2.6.1.5. The Department can provide to the registrants, lists of approved programs.

This Guidance may be revoked pending any changes to the Regulations by this Department. Any questions or comments regarding this document should be addressed to the X-Ray Certification Unit at 303-692-3427, by fax at 303-759-5355 or by sending an email to Brian.Vamvakias@state.co.us.

Authorized by: 
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