Fluoroscopy Operator Training for Colorado Healing Arts Facilities

Module 1: Background and Justification for Training Program
This educational program is being offered to provide training to medical practitioners who perform or supervise the performance of diagnostic procedures utilizing fluoroscopic x-ray units. There are many justifications and benefits to this training. Some are linked to regulatory requirements but others are directly related to patient and staff safety as well as improvements in image quality.

**Justification for Training**

- Regulatory requirements (CDPHE)
- FDA Advisory
- Joint Commission requirements
- Reduce risks to patient and staff by reducing radiation exposures
- Improve image quality
CDPHE Regulations (Effective July 1, 2010)

“...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.”

CDPHE reg 2.6.1
CDPHE regulations, effective July 1, 2010, require those who are involved with fluoroscopy either directly or in a supervisory role, to have specific training.

**CDPHE Regulations**
(Effective July 1, 2010)

“For fluoroscopy equipment used in examination of a living human, “adequately trained” shall mean that ... each healing arts facility shall make a written determination that any individual who either supervises a fluoroscopy procedure or operates a fluoroscopy imaging system has adequate training in its safe operation, ...”

CDPHE reg 2.6.1.5
CDPHE regulations require specific training be given and that written documentation of such training be maintained by each facility. This training program is designed to meet these requirements.

CDPHE Regulations
(Effective July 1, 2010)

“... 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.”

CDPHE reg 2.6.1.5
CDPHE regulations require all fluoroscopic imaging to be supervised by an individual who has received appropriate training in fluoroscopic imaging.

**CDPHE Regulations**

*(Effective July 1, 2010)*

“Supervision and use of a 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.”

CDPHE reg 6.5.1.2
CDPHE regulations require fluoroscopic exams to be conducted only under "direct supervision" by a medical practitioner who is currently licensed in the state of Colorado.

CDPHE Regulations
(Effective July 1, 2010)

“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”

CDPHE reg 6.5.1.2(1)
The CDPHE defines “direct supervision” very specifically. The only individuals who are allowed to physically operate the exposure pedal on fluoroscopy equipment in Colorado are licensed practitioners or registered Radiologic Technologists. A registered Radiologic Technologist or Radiology Assistant could only do so under the “direct supervision” of a licensed practitioner who is properly trained under the state regulations.

CDPHE Regulations
(Effective July 1, 2010)

“Direct supervision” means the supervisor is present in the facility and immediately available to observe, correct, assist and direct the supervisee throughout the performance of a procedure, as needed, but is not always required to be present in the room.”

CDPHE Part 1 definitions
CDPHE regulations also require all interpretations of fluoroscopic studies to be made only by practitioners who are currently licensed in the state of Colorado.

CDPHE Regulations
(Effective July 1, 2010)

“Interpretation of both real-time and stored fluoroscopic images shall be by a physician, chiropractor, podiatrist or veterinarian who has a current active State of Colorado license to practice the healing arts.”

CDPHE reg 6.5.1.2(3)
Due to several reports of serious skin injuries resulting from the use of diagnostic fluoroscopy, the FDA issued a Public Health Advisory in 1994.

**FDA Public Health Advisory**

"Physicians performing these procedures should be aware of the potential for serious, radiation-induced skin injury caused by long periods of fluoroscopy during these procedures."

"It is important to note that the onset of these injuries is usually delayed, so that the physician cannot discern the damage by observing the patient immediately after the treatment."

"Even typical dose rates can result in skin injury after less than one hour of fluoroscopy."

The Joint Commission added “Prolonged Fluoroscopy” resulting in doses of at least 15 Gy (1500 rads) to their list of reviewable Sentinel Events in 2006. Thus, facilities should have a method of monitoring patient exposures in order to estimate skin doses. Personnel who perform fluoroscopy exams should be familiar with their facility’s monitoring methods and applicable policies. The Joint Commission correctly notes that skin injuries due to high radiation doses are often not seen for months or years after the event and that such exposures are almost always PREVENTABLE.

Joint Commission Reviewable Sentinel Event

Prolonged Fluoroscopy (cumulative dose >1500 rads to a single field) is on the Joint Commission list of events that are reviewable under its Sentinel Event Policy:

- could be associated with death or major permanent loss of function.
- outcomes often do not occur for months or years after the event itself.
- events are considered to be preventable.
In 1989, the National Council on Radiation Protection (NCRP) issued its Report #100, “Exposure of the U.S. Population from Diagnostic Medical Radiation.” They estimated the magnitude of several actions that could reduce radiation doses from fluoroscopy. The potential benefit from optimizing operator technique can be significant.

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NCRP 1989
NCRP report #160, published in 2009, details the “Ionizing Radiation Exposure of the Population of the United States.” The relative contribution of radiation dose from medical sources to the general public in the U.S. has increased dramatically since the early 1980’s. It is clear that exams involving radiation are being used more frequently or that higher dose procedures are being used, perhaps a combination of both. It is incumbent upon practitioners to be informed and to use radiation as prudently as possible.
NCRP160 also detailed the relative contribution of different types of medical radiation exposures. In 2006, interventional fluoroscopy accounted for approximately 15% of the total medical exposures and 7% of the total effective radiation dose to the U.S. population.
It is important to note that not only is this training program designed to give practitioners the knowledge to limit radiation doses to patients and personnel but also to optimize fluoroscopic image quality. Some dose reduction measures also can lead to improvement in image quality.

**Image Quality Improvement**

- Proper use of equipment allows the practitioner to take full advantage of image quality and dose reduction features
- Dose reduction often can mean image quality improvement
In conclusion, there is ample justification for this training program. Not only are state regulations now requiring such training for fluoroscopy operators, but there is no question that improper use of diagnostic fluoroscopy can lead to significant patient skin injuries. Even the newest fluoroscopy equipment, while capable of excellent image quality, can lead to high skin doses if the operator is not proficient on how to use such equipment properly and safely.