

DEPARTMENT OF ENVIRONMENTAL PROTECTION
Bureau of Radiation Protection

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TITLE: Medical X-ray Procedures Operator Training Guide

EFFECTIVE DATE: September 1, 2009

AUTHORITY: Radiation Protection Act, Act of July 10, 1984, P.L. 688, No. 147, 35 P.S. §§ 7110.101-7110.703; 25 Pa. Code Radiological Health Regulations, 25 Pa. Code Chapters 215-240.

POLICY: This document provides guidance to the regulated community for ensuring compliance with the regulations in Title 25 Pennsylvania Code, Section 221.11 (Registrant responsibilities) regarding instruction of X-ray operators and Appendix A (Determination of Competence). The level of effort to maintain competence will vary commensurate with the risk.

PURPOSE: The purpose of this guidance is to ensure that skin burns, tissue damage and other radiation injuries do not occur from a lack of attention to the potential direct biological impact of the exposure parameters utilized in an x-ray procedure. In addition, the potential for adverse long-term effects to patients and operators from x-ray procedures will be minimized.

APPLICABILITY: This document applies to all individuals who operate medical x-ray equipment, other than accelerators, in the Commonwealth. Training and competency in the operation of a medical accelerator for therapy is subject to the requirements of 25 Pa. Code Chapter 228 and to review during the accelerator facility licensing process.

DISCLAIMER: The policies and procedures outlined in this guidance document are intended to supplement existing requirements. Nothing in the policies or procedures will affect regulatory requirements.

The policies and procedures herein are not an adjudication or a regulation. There is no intent on the part of the Department to give these rules that weight or deference. This document establishes the framework within which DEP will exercise its administrative discretion in the future. DEP reserves the discretion to deviate from this policy statement if circumstances warrant.

PAGE LENGTH: 4 Pages

LOCATION: Volume 4, Tab 15

DEFINITIONS:

Operators: Those medical professionals who operate x-ray producing equipment under 25 Pa. Code Chapter 221 *X-rays in the Healing Arts*. Operation of accelerators or operation only on non-human subjects is not included in the definition of “Operator”.

High-Risk Procedures: Any radiologic procedure that utilizes energies of less than 1 million electron volts (MeV), that could exceed skin doses of 200 rads (2Gy).

Low-Risk Procedures: Any radiologic procedure that is not a “High-Risk Procedure”.

TECHNICAL GUIDANCE:

It is commonly perceived that diagnostic x-ray procedures do not represent a significant risk to the patient or operator. This is not always the case. The misconception is a product of the lack of understanding of the consequences when choosing the exposure parameters for an x-ray procedure and how that choice affects the radiation’s impact on the patient’s health. The use of radiation is regulated on a basis of risk versus benefit. In medicine the benefits from the use of x-ray equipment can range from minor in the case of dental procedures to life saving in the case of cardiac angioplasty. Patients and operators of x-ray equipment are subjected to corresponding risks that range from minimal to potentially injurious. Equipment is designed to be as safe as reasonably possible. However, the key to ensuring the safe use of x-ray equipment lies in the training and competency of the operator. To avoid an unexpected adverse effect from radiation exposure, adequate operator instruction must be ensured. The minimum essential elements for determining adequate instruction are contained in Appendix A, which follows.

Once an operator is adequately instructed it is necessary to have some form of continuing education in the key areas of radiation safety, biological effects of radiation, quality assurance and quality control to ensure continuing competence. Operator training and continuing education is required based upon the potential risk to the patient and worker in the long term (e.g., cancer induction), and the potential for patients to experience injuries in the short term (i.e., skin burns and tissue damage). Noted below are the training requirements, ranked by decreasing order of possible harm to patient and practitioner alike for a given procedure. The intent of operator training is to minimize unnecessary radiation exposure, and thus reduce the risk of acute and long-term radiation effects.

I. Training Requirements**A. High-Risk Procedures:**

1. The registrant shall require each operator who performs High-Risk Procedures at its facility to be an individual who:

- a. Has certification in the applicable specialty by a professional organization accepted by the Department that includes topics in Appendix A, or
 - b. Has demonstrated a minimum of eight contact hours of training that includes the topics in Appendix A.
2. In addition, all operators performing High-Risk procedures must demonstrate three contact hours or six units of continuing education every three years in topics covered in Appendix A. Acceptable forms of continuing education include:
 - a. Continuing Medical Education (CME) / Continuing Education Units (CEU) approved seminar.
 - b. In-service training in required/related topics.
 - c. Successfully passing an administered test in required/related topics.
 - d. Competency verification (see discussion below).

B. Low-Risk Procedures:

1. The registrant shall require each operator who performs Low-Risk Procedures at its facility to be an individual who:
 - a. Is authorized by the Department of State under 25 Pa. Code Title 49 *Professional and Vocational Standards*, to administer x-rays on humans in conjunction with their profession or occupation, or
 - b. Has certification in the applicable specialty by a professional organization accepted by the Department that includes topics in Appendix A, or
 - c. Has demonstrated a minimum of four contact hours of training that includes the topics in Appendix A.
2. In addition, all operators performing Low-Risk Procedures must demonstrate two contact hours or four units of continuing education every four years in topics covered in Appendix A. Acceptable forms of continuing education include:
 - a. Continued certification / registration by a professional organization accepted by the Department.
 - b. Continuing Medical Education (CME) / Continuing Education Units (CEU) approved seminar.
 - c. In-service training in required/related topics.
 - d. Successfully passing an administered test in required/related topics.
 - e. Competency verification.

II. Documentation

Documentation for any acceptable means of completing initial or continuing education requirements shall indicate either the certification by a professional organization accepted by the Department, the certificate of attendance of the CME / CEU approved seminar, the in-service

training, the testing requirements (including the passing criteria), or the notes, discussions, and observations used as the basis for competency verification. The Department, through the Bureau of Radiation Protection (BRP), shall maintain a list of accepted professional organizations and resources whose registry, training and tests may be used as proof of compliance with initial and continuing education requirements. A copy of the list is available through the Department's BRP web page or by calling (717) 787-3720 or writing to the DEP Bureau of Radiation Protection at P.O. Box 8469, Harrisburg, PA 17105-8469.

APPENDIX A DETERMINATION OF COMPETENCE

The registrant shall ensure that training on the subjects listed in Appendix A has been conducted. The individual shall be trained and competent in the general operation of the x-ray equipment, and in the following subject areas, as applicable to the procedure(s) performed and the specific equipment utilized:

- (1) Basic Properties of Radiation
- (2) Units of Measurement
- (3) Sources of Radiation Exposure
- (4) Methods of Radiation Protection
- (5) Biological Effects of Radiation Exposure
- (6) X-ray Equipment
- (7) Imaging Recording and Processing
- (8) Patient Exposure and Positioning
- (9) Procedures
- (10) Quality Assurance Program
- (11) Regulations