

**Final Technical Guidance 291-4200-001**  
**Medical X-ray Procedures Operator Training Guide**

**COMMENT AND RESPONSE DOCUMENT**

## Technical Guidance 291-4200-001 Medical X-ray Procedures Operator Training Guide

This is a list of organizations and interested individuals who provided comments to the draft form of technical guidance 291-4200-001.

ID	Commentator	Submitted Electronic Comment	Submitted Written Comment
1	Steven M. Ettinger, M.D. President, PA Chapter Amer. College of Cardiology	February 5, 2007	
2	Robert D. Forrest, CHP Assoc. Director Env. Health & Rad. Safety University of Pennsylvania	February 23, 2007	
3	Mohan Doss, Ph.D. Diagnostic Imaging Fox Chase Cancer Center	March 1, 2007	
4	Janice Wirth Director, Medical Imaging Alle-Kiski Medical Center	February 27, 2007	
5	John C. Pammer, DC-DACBR	August 7, 2006	
6	Linda K. Himmelberger, DMD President, PA Dental Assoc.		February 1, 2007
7	Sharon Miller, MS RT(R) Medical Imaging & Rad. Science Mount Aloysius College	March 8, 2007	

## COMMENT AND RESPONSES

### General Support

**Comment:** “The PaACC (*Pennsylvania Chapter American College of Cardiology*) supports the objectives of document # 291-4200-001 to ensure that skin burns, tissue damage and other radiation injuries do not occur from lack of attention to the potential direct biological impact of the exposure parameters utilized in an x-ray procedure.” (1)

“A colleague and myself reviewed the material it is very well structured. This is long overdue I hope this includes physician’s office, Out Patient Centers etc.” (7)

**Response:** The Department appreciates the comments and particularly welcomes the support of the PaACC, as the majority of radiation injuries occur in the “high risk” field of cardiology. As far back as September 9, 1994, the U.S. Food and Drug Administration had issued an advisory warning about certain cardiac procedures “Avoidance of Serious X-ray Induced Skin Injuries to Patients During Fluoroscopically-Guided Procedures.” Operator training was listed as one of the factors in minimizing risk. The current National Academy of Sciences review of the biological effects of radiation, or BEIR VII report, assumes all radiation exposure presents some risk. Therefore, it is necessary for the training guidance to apply to all x-ray operators, including those in “low risk” activities.

### Recognition of Professional Certification as Satisfying Training Requirements

**Comment:** The guidance includes a provision for initial training requirements to be met by certification by professional organizations recognized by the Department and continuing education requirements to be met by maintenance of certification or through continuing education training provided by organizations recognized by the Department. Several commentators asked that their professional certification and training be recognized by the Department. (1) (3) (5) (6)

**Response:** The Department originally proposed to list recognized organizations under an Appendix B. Because such a list is fluid and subject to modification, there will be no Appendix B. The guidance has been revised to show that such a list will be available on the Department’s website electronically, or a printed copy can be obtained by telephone or mail. In assembling this list, the Department included recognition of the organizational components that satisfied the requirements in the guidance for listing.

The request for recognition of the Canadian College of Physicists in Medicine (3) was not approved, however. This guidance addresses only the use of x-rays on human subjects. In response to this apparent confusion of scope and purpose, the guidance was clarified to explicitly reference applicability to operators of x-ray equipment used on human subjects.

### **Definition of Operator**

**Comment:** Another issue of scope revolved around the definition of “Operator.” Objections were raised to making anyone “in control of” medical x-ray equipment subject to this guidance. Some commentators believe the applicability should be limited only to those who physically operate x-ray equipment and not attendant physicians or others who may provide direction to the operator. (2) (4)

**Response:** The Department agrees and removed reference to “in control of.”

### **Definition of High Risk**

**Comment:** “High Risk” was defined as a procedure “...that is likely to exceed 200 rad (2 Gy).” Use of the word “likely” was objected to as x-ray procedures are not routinely performed with the expectation of causing injury. (2)

**Response:** The Department agrees and has replaced “likely” with “could.” Could implies a reasonable expectation of not causing injury without being a certainty.

### **Determining Credit for In-House Training**

**Comment:** “If training is in written form how does one determine the number of hours it is worth? The DEP has stated on several occasions that the Wagner fluoroscopy training program would be considered to be 8 hours. How would similar written training programs be evaluated?” (2)

**Response:** The Department recognizes that evaluating in-house training will be part subjective. Training need not be identical, but is expected to cover essentially the same subject areas. The requirements have been rewritten to provide more certainty of demonstrating compliance. “Hours” has been replaced with “Contact Hours,” which are quantifiable. Those who choose to satisfy training requirements through Continuing Education Units (CEUs) will find it easier to demonstrate, as a minimum number of CEUs has now been specified.

### **Determining Credit for Professional Certification**

**Comment:** “The number of hours equivalent for each certification should be listed. For instance, it should specify that the Chiropractic and Dental certifications are equivalent to 4 hours of training, because they are in no way preparing personnel for high use operations allowed by the 8 hour training.” (2)

**Response:** This is unnecessary. Training must satisfy the subjects in Appendix A. It is not the intent of this guidance to let podiatrists perform dental x-ray procedures or chiropractors operate invasive cardiac x-ray equipment, etc. The content of the material covered in Appendix A is specific to the particular medical discipline covered by professional certification.

### **Matching Continuing Education Credits to Professional Certification Cycles**

**Comment:** “PDA recommends that the continuing education guide be modified to suggest two credits in two years, to coincide with the licensing board’s typical bi-annual licensure renewal period.” (6)

**Response:** The Department recognizes that different certifying bodies have different cycles for recertification. For those connected to this guidance it may range from annual to every ten years. The Department has revised the Low Risk recertification requirement to 2 contact hours or 4 CEUs every four years in order to be more flexible to the majority of the regulated community. This is more reasonable in light that High Risk will require 3 contact hours or 6 CEUs every three years.

### **Request to Exempt Physicians from Initial Training if Low Risk**

**Comment:** The commentator suggests that physicians by virtue of their licensure possess sufficient training to meet the initial training requirements for Low Risk procedures and should be exempt. (4)

**Response:** The Department recognizes that the Department of State determines the requirements for professional licensure, not only of physicians but any “auxiliary personnel” as well. The Department agrees that anyone, physician or auxiliary personnel who satisfies the requirements of the Department of State Professional and Vocational Standards to practice in their discipline, is deemed to have met the initial training requirements to perform medical x-ray procedures in their field. The guidance has been revised to reflect this.

### **Time frame for Implementation**

**Comment:** “There appears to be no timeline associated with this training document. Institutions with large number of “Operators” may need a significant amount of time to become compliant.” (4)

**Response:** The Department recognizes that time is needed to evaluate personnel against the guidance and arrange for any necessary training. An implementation date of September 1, 2009 has been assigned. It should result in a grace period of at least six months from the publication of this guidance.