RADIOLOGICAL HEALTH AMENDMENTS
25 PA CODE CHAPTERS 221, 227, AND 228

ENVIRONMENTAL QUALITY BOARD

COMMENT AND RESPONSE DOCUMENT

Proposed Rulemaking (#7-360): Article V , Radiological Health, 25 PA Code Chapters 221, 227, and 228

This is a list of organizations and interested individuals from whom the Environmental Quality Board has received comments regarding the above referenced regulation.

ID	Name/Address	Zip	Submitted 1 pg Summary	Provided Testimony	Req Final Rulemaking
1	Faye L. Capiranno, AS, RDH President PA Dental Hygienists' Association P.O. Box 606 Mechanicsburg, PA	17055			
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COMMENTS AND RESPONSES

Section 221.11 Registrant Responsibilities

Subsection (k) – "shall v. should"

Comment: This subsection replaces the word "shall" with the word "should." The preamble states this revision is "necessary due to the wide range of spectral characteristics of X-ray films on the market today, which makes it difficult for practitioners to maintain an exact match." However, it does not appear that the existing language requires an "exact match." Instead, the current language of this subsection uses the words "spectrally compatible." This subsection needs to use the word "shall" if this is to be a binding requirement. (2)

Response: The Department is retaining the existing word "shall." Subsection (k) was completely reworded and split into subsections (j) and (k). Subsection (j) reads " The screen and film system shall be spectrally compatible. Defective screens shall not be used for diagnostic radiological imaging." Subsection (k) now reads " With the exception of intraoral dental radiography, film may not be used without intensifying screen(s) for routine diagnostic radiological imaging."

Subsections (g), (m) and (n) – "reducing unnecessary exposure"

Comment: Each of these subsections contains rules designed to limit or prevent unnecessary exposure to X-rays. Are three subsections necessary? Can the three subsections be combined into a concise set of rules or a general rule? (2)

Response: The Department agrees that it is better to have rules that apply across the board whenever feasible. Although the title of Section 221.56 was "Administrative controls," in the 1998 printing of Chapter 221, the section fell under a heading of "Intraoral Dental Radiographic Systems" and was the last remnant of a group of sections applicable to dental radiography. In the final rulemaking, subsections (m) through (p) are deleted. The prohibitions contained in subsections (m), (n), and (o) exist generically in (h)(3), and (e)(4) and (m), respectively. The deleted rules, specific to dentists, are not considered to be necessary. Subsection (p) was deleted in its entirety because the technique is not currently in use. If authorized at a later date by the FDA, appropriate regulations will also be issued.

Subsection (l) --- guidelines

Comment: The existing language in this subsection states that a registrant's "quality assurance program shall be in accordance with guidelines promulgated by the ACR [American College of Radiology], the AAPM [American Association of Physicists in Medicine] or another accredited organization."

The proposed regulation revises this rule to state that a "quality assurance program shall be in accordance with guidelines established by the department [Department of Environmental Protection]."

The Preamble states:

> This change will make it easier for the Department to add and change guidelines as needed without specifically acknowledging each new quality assurance guideline issued by medical specialty organizations."

It is our understanding that the guidelines will be enforced as requirement and registrants can be cited for nonconformance to the guidelines. Only a regulation is enforceable and provides adequate notice to affected parties. Hence, the specific content or source of the guidelines should be included in the regulation. Additionally, the regulations should indicate how registrants can obtain copies of the guidelines. (2)

Response: This revision was proposed because specialty-specific quality assurance programs are proliferating as the specialties diverge from their parent disciplines; modify procedures, protocols and equipment; and discover that the QA programs of the parent discipline are no longer appropriate. The Department needs the authority to accept new QA/QC protocols without modifying the regulations to specifically name each group as it issues QA guidance to its membership. When the Department becomes aware that a professional association has promulgated new or revised QA/QC guidelines or procedures, the Department will review and, if appropriate, accept their use by registrants as written or with minor changes. In consultation with the RPAC, the Department agreed to maintain department guidelines and a list of recognized organizations and make them available on the Department's website or on request.

The Department is not aware of any way to identify each and every organization that may develop QA/QC guidance, and it is not reasonable to make one type of registrant comply with guidance appropriate to another use.

The objective of the Department's radiation regulations and inspections is

to obtain compliance, not to issue Notices of Violations. The discrepancies are brought to the registrant's attention, and the opportunity is afforded to correct deficiencies. If the registrant does not cooperate, the violations will be treated, in accordance with the Bureau of Radiation Protection (BRP) Enforcement Policy, as any other violation of the regulations. The exact consequence would depend on factors such as: willfulness, cooperation of the registrant in correcting the violation, how long it had existed, and the savings accruing to the registrant by not complying.

The final rulemaking adds that the Department will maintain a list of approved guidelines and make them available on the DEP web site and on request.

Subsection (m) – holding patient during exposure

Comment: I am requesting an amendment (to Subsection (m)) to state, "A dentist, dental hygienist, or an assistant may not hold patients or film during exposures." A dental hygienist is a licensed dental health professional that performs radiologic procedures in this Commonwealth. For your reference this is stated in the Pennsylvania Code, Title 49 (Professional and Vocational Standards), Chapter 33 (State Board of Dentistry), subsection 33.302 (Auxiliary Personnel Performing Radiologic Procedures). (1)

Response: The requested change became moot when, in the final rule, the prohibition against holding patients or film was made generic to all X-ray procedures and placed in subsection (h)(3), which does not identify any specific type of person holding the patient.

Miscellaneous Typographical Errors - Clarity

Section 221.13. Information to be submitted by persons proposing to conduct healing arts screening.

Comment: In the *Pennsylvania Bulletin*, the word "mammography" in Paragraph (14) is moved to the beginning of the sentence. It should be capitalized. (2)

Response: The correction has been made.

Section 228.36. Radiation monitoring requirements.

Comment: Also in the *Pennsylvania Bulletin*, the first five words of this section read: "LAN independent radiation monitoring system..." "LAN is an apparent error and should be replaced by the word "An." (2)

Response: The correction has been made.