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INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

April 12, 2001

Honorable David E. Hess, Acting Chairman
Environmental Quality Board
Rachel Carson State Office Building
400 Market Street, 16th Floor
Harrisburg, PA 17105

Re: Regulation #7-360 (IRRC #2169)
Environmental Quality Board
Radiological Health

Dear Acting Chairman Hess:

Enclosed are our Comments. They will soon be available on our website at www.irrc.state.pa.us.

Our Comments list objections and suggestions for consideration when you prepare the final version of this regulation. We have also specified the regulatory criteria which have not been met. These Comments are not a formal approval or disapproval of the proposed version of this regulation.

If you would like to discuss these Comments, please contact my office at 783-5417.

Sincerely,

A handwritten signature in black ink that reads "Robert E. Nyce".

Robert E. Nyce
Executive Director
evp
Enclosure

cc: Honorable Arthur D. Hershey, Majority Chairman, House Environmental Resources and Energy Committee
Honorable Camille George, Democratic Chairman, House Environmental Resources and Energy Committee
Honorable Mary Jo White, Chairman, Senate Environmental Resources and Energy Committee
Honorable Raphael J. Musto, Minority Chairman, Senate Environmental Resources and Energy Committee
Sharon Trostle, Regulatory Coordinator, Department of Environmental Protection
Barbara Sexton, Director Policy Office, Department of Environmental Protection

Comments of the Independent Regulatory Review Commission

on

Environmental Quality Board Regulation No. 7-360

Radiological Health

April 12, 2001

We submit for your consideration the following objections and recommendations regarding this regulation. Each objection or recommendation includes a reference to the criteria in the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) which have not been met. The Environmental Quality Board (EQB) must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered by March 12, 2003 the regulation will be deemed withdrawn.

1. Section 221.11. Registrant responsibilities. - Reasonableness; Clarity.

Subsection (k) -- "shall v. should"

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.

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

Each of these three subsections contains rules designed to limit or prevent unnecessary exposure to x-rays. Are three separate subsections necessary? Can the three subsections be combined into a concise set of rules or a general rule?

Subsection (l) -- guidelines

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 accrediting 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 requirements 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 regulation should indicate how registrants can obtain copies of the guidelines.

2. Miscellaneous Typographical Errors. - Clarity.

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

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

Section 228.36. Radiation monitoring requirements.

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.”

APR-12-2001 THU 10:13 AM

FAX NO.

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INDEPENDENT REGULATORY REVIEW COMMISSION

WRIGHT

To: Shirley ~~Hartman~~
or Cindy Lauderbach
or Denise Henke

Agency: Environmental Quality Board
Phone: 7-2814
Fax: 705-4980

From: Kristine M. Shomper
Administrative Officer

Company: Independent Regulatory Review
Commission

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Date: April 12, 2001
of Pages: 4

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Comments: We are submitting the Independent Regulatory Review Commission's comments on the Environmental Quality Board's regulation #7-360. Upon receipt, please sign below and return to me immediately at our fax number 783-2664. We have sent the original through interdepartmental mail. You should expect delivery in a few days. Thank you.

Accepted by: *Shirley Wright* Date: *4/12/01*