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

October 26, 2000

Honorable James M. Seif, Chairman
Environmental Quality Board
Rachel Carson State Office Building
400 Market Street, 16th Floor
Harrisburg, PA 17105

Re: Regulation #7-350 (IRRC #2138)
Environmental Quality Board
Radiological Health

Dear Chairman Seif:

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,

Robert E. Nyce
Executive Director
cae
Enclosure

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

Comments of the Independent Regulatory Review Commission

on

Environmental Quality Board Regulation No. 7-350

Radiological Health

October 26, 2000

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 If the final-form regulation is not delivered by September 25, 2002, the regulation will be deemed withdrawn.

1. Section 215.1. Purpose and Scope. – Clarity.

Subsections (e) and (f)

Subsection (e) incorporates several parts of Chapter I of Title 10 CFR by reference. However, it also provides that notwithstanding the requirements incorporated by reference, regulated parties are not relieved from complying with the "laws of the Commonwealth," including the Radiation Protection Act and the Low-Level Radioactive Waste Disposal Act. Subsection (f) provides that if a section of the CFR incorporated by reference "is inconsistent with the *Pennsylvania Code*, the *Pennsylvania Code* controls to the extent Federal law does not preempt the Commonwealth law." Additionally, if a section of the CFR incorporated by reference exceeds the EQB's statutory authority, that section is effective "only to the extent authorized by law."

These subsections do not provide sufficient notice as to the requirements with which regulated parties must comply. Since noncompliance may result in penalties pursuant to Section 308 of the Radiation Protection Act (35 P.S.§ 7110.308) and Sections 504 and 505 of the Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.504 and 7130.505), regulated parties must have a clear understanding of which state or federal provisions apply to their activities. Therefore, there should be a citation to the specific provisions of Chapter 1 of Title 10 that are incorporated by reference. In the alternative, the EQB could provide that Title 10 is incorporated by reference with the exception of specific provisions that are not incorporated by reference. Additionally, the regulation should specifically reference the provisions of any other "laws of the Commonwealth" and any other provisions of the *Pennsylvania Code*, besides Article V, that apply.

A similar concern is discussed below for Section 217.131 relating to incorporation by reference.

2. Section 215.2. Definitions. – Clarity; Protection of Public Health and Safety.

Misadministration

Two commentators expressed concerns with this definition. There are five related issues.

First, the federal regulations contain a definition of "misadministration" at 10 CFR 35.2. The federal definition is substantively different from the definition proposed in this regulation. In response to this conflict, it is our understanding that the title of this proposed definition will be changed from "misadministration" to "medical event from x-ray producing machine." The regulation should also clarify whether the federal definition of "misadministration" is incorporated by reference.

Second, the provisions of the proposed definition identify the events that must be reported pursuant to Section 219.228 relating to reports of misadministration from x-ray. The proposed provisions are also substantive in nature. Hence, it would improve clarity to move the provisions of this definition to Section 219.228 in this regulation.

Third, the commentators suggested adding words such as "therapeutic" or "therapy" and "diagnosis" to the description of dose in Subparagraph (i). The types of doses covered by this definition of "misadministration" are unclear. Does this term apply to doses for both therapy and diagnosis?

Fourth, Subparagraph (ii) defines "misadministration" as a "dose that results in or is likely to result in functional damage to tissue." What is "functional damage" and how is it determined? Who determines whether "functional damage" has occurred? The subparagraph includes an exception for situations when damage is "an expected outcome of the prescribed procedure" or it "can not [sic] be avoided without compromising the efficacy of the procedure." Who makes the determination that these exceptions apply and when to file a report? The regulation should identify who is responsible for determining when an incident needs to be reported and who is responsible for the actual report.

Fifth, what is meant by the term "wrong site" in Subparagraph (iii)? Does it include partial misalignment or exposure to areas surrounding the treatment site?

3. Section 215.27. Vacating premises. – Clarity.

This section states "When deemed necessary by the Department, the licensee shall decontaminate the premises as the Department may specify." In what situations would the Department deem it necessary to decontaminate? The regulation should include the criteria that the Department will use in making its determination. If there are certain levels of radioactive contamination that trigger the need for decontamination, the regulation should include this standard.

4. Section 215.28. Deceptive exposure of a monitoring device. - Clarity.

This section states "*Exposure* of a personnel monitoring device or area monitoring device to deceptively indicate the dose delivered to an individual is prohibited [emphasis added]." This is unclear. Please explain the intent of this provision.

5. Section 217.131. Incorporation by reference. - Clarity.

Subsection (a)

Pursuant to this subsection, the requirements of 10 CFR Part 30 are incorporated by reference, except as provided in Subchapter B. For two reasons, this provision is vague. First, it does not provide sufficient notice to regulated parties as to the standards in Part 30 with which they must comply. Second, it does not specifically indicate when the requirements of Part 30 are superseded by the requirements of Subchapter B. A preferable approach would be to cite those sections of Part 30 that are incorporated by reference. In the alternative, the EQB could provide that Part 30 is incorporated by reference with the exception of specific provisions that are not incorporated by reference.

Subsection (b)

This subsection lists several sections of Part 30 that are not incorporated by reference, notwithstanding the requirements of Part 30 that are incorporated by reference. If specific provisions of Part 30 were incorporated by reference, this subsection would not be necessary.

The same concerns apply to Sections 217.141, 217.151, 217.161, 217.171, 217.181, 217.201, 219.5, 220.9, 225.2a, 226.4, 230.3, and 232.2.

6. Section 217.191. Transfer of material. – Clarity; Reasonableness.

Subsection (a)

Subsection (a)(3) refers to "[a] person exempt from this article to the extent permitted under the exemption." The regulation should indicate who would be exempt and how an exemption is granted.

Subsection (a)(4) refers to "a general license or its equivalent, or a specific license or equivalent licensing document." Are equivalent licenses issued by another jurisdiction? The final-form regulation should clarify what documents are equivalent to general or specific licenses.

Subsection (a)(5) refers to "[a] person otherwise authorized by the Department in writing." The regulation should specify who would fall into this category.

Subsection (c)

Subsection (c) lists the acceptable methods for verifying that the transferee's license authorizes receipt of the type, form and quantity of radioactive material to be transferred. Subsection (c)(3) refers to "oral certification." A definition of "oral certification" would improve clarity.

Subsection (c)(4) authorizes the transferor to "obtain other sources of information compiled by a reporting service from official records of the Department, the NRC, the licensing agency or an agreement state or a licensing state as to the identity of licensees and the scope and expiration dates of licenses."

A commentator noted that using the type of service referenced in Subsection (c)(4) would not allow the transferor to know if the quantity to be transferred falls within the transferee's license limits. This is because there is no way of knowing how much radioactive material is already at the licensee's facility. Therefore, the only way to know if the amount transferred is permissible under the license is to contact the licensee. We request the EQB explain how verification through the method identified in Subsection (c)(4) would be sufficient to determine that the quantity to be transferred falls within the licensee's limits.

The same concern applies to Subsection (c)(1), which provides that the transferor may have a copy of the transferee's license to verify that the transferee is authorized to receive the radioactive material. Without contacting the licensee directly, how would the transferor know that the amount of material to be delivered would not result in the transferee exceeding the limits in the license?

7. Section 225.71. Definitions. - Clarity.

RSO – Radiation Safety Officer

The last sentence of this definition is substantive. Further, the information in this sentence is included in Section 255.72. For these reasons, the last sentence should be deleted from the definition.

8. Section 225.74. Training and testing. - Public health, safety and welfare; Clarity.

Subsection (a)(3) requires a radiographer to receive "instruction covering regulatory requirements, operating and emergency procedures and the use of radiation-producing machines...." How many hours of instruction are required? The minimum number of hours of required training should be specified in the final-form regulation.

Subsection (a)(4) provides that a registrant may not permit an individual to act as a radiographer until that individual has: "demonstrated competency and understanding of the information in this subsection to the satisfaction of the registrant or licensee as evidenced by the successful completion of a written test and a field examination." Are there industry standards to determine competency? Since each licensee drafts its own tests for radiographers, what protections exist in the regulation for public health, safety and welfare without the assurances of standardized testing?

9. Section 225.76. Reporting requirements. - Clarity.

Subsection (c) provides for reports of overexposures and excessive exposures. It is not clear if these reports are subject to the same 30-day requirement provided in Subsection (a). Reporting requirements in Subsection (c) should be clarified in the final-form regulation.

10. Section 225.82. Operating requirements. - Clarity.

Subsection (b)(4) and Subsection 225.84(5) refer to a "pocket dosimeter" in quotes. The quotes should be removed in the final-form regulation. Further, if "pocket dosimeter" has a specific meaning, it should be included in Section 215.2 relating to definitions.

Additionally, Subsection (b)(4) characterizes, a pocket dosimeter as "an operable, calibrated pocket ionization chamber." It is characterized in Subsection 225.84(5) as a "direct reading personnel monitoring device." Subsection 225.83(5) refers to a "daily pocket ionization chamber." Subsection 225.93(a) refers to "a direct reading pocket dosimeter" while Subsection 225.93(d)(1) refers to an "electronic personal dosimeter." The references to a "pocket dosimeter" should be consistent in the final-form regulation.

11. Section 225.83. Records required at temporary job sites. - Clarity.

This section provides for the maintenance and availability for inspection of records or documents at the temporary job site. This section does not address how these records are supposed to be handled after they are removed from the temporary job site. Does the record keeping requirement in Section 225.93 apply? If so, Section 225.93 should be referenced in Section 225.83 in the final-form regulation.

12. Section 225.85. Surveys and survey records. - Clarity.

Subsection (b) provides "if the survey has been used to determine an individual's exposure, the records of the survey shall be maintained until the Department authorizes their disposition." The final-form regulation should include a timetable for the retention of the surveys and records.

13. Section 225.93. Personnel monitoring control. - Clarity.

Subsection (d)(1) requires dosimeters to be recharged "at least daily or at the start of each work shift." If the minimum requirement is for the start of each work shift then why is it necessary to include the option for "at least daily"? Consideration should be given to deleting the phrase "at least daily."

Subsection (d)(1) also permits "electronic personal dosimeters" to be used in place of direct reading pocket dosimeters. Is the term "personal" appropriate for the term "electronic dosimeters"? If not, then it should be deleted from the final regulation. Further, this requirement is not easily discerned from this subsection and should be moved to Subsection (a) so that the information is readily apparent to licensees.

14. Section 225.101. Cabinet X-ray systems and baggage/package X-ray systems. - Clarity.

The first sentence in Subsection (b) does not appear to be a requirement. Is it? If so, the EQB should explain the intent for this provision and rephrase the sentence to make it clear.

15. Section 225.104. X-ray detection systems for explosives, weapons and illegal items. - Clarity.

Subsection (f)(2) requires safety or warning devices to be repaired "in a timely manner." This requirement is not clear. In the final-form regulation, a specific time frame should be added.

16. Section 230.13. Transportation of licensed material. - Clarity.

This section references the regulations of the NRC, Pennsylvania Department of Transportation, and U.S. Department of Transportation (USDOT). However, the section does not contain specific citations to the applicable regulations of the USDOT. In the *Pennsylvania Bulletin*, the amendment to this section changes it to one long sentence. The end of this sentence reads:

> ... the licensee shall conform to the standards and requirements of those **regulations** to the same extent as if the shipment was subject to the **regulations** [emphasis added].

The intent of this section is unclear. To which rules and standards, is the term "regulations" referring? The provision should be clarified in the final-form regulation.