INDEPENDENT REGULATORY REVIEW COMMISSION
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May 15, 1998

Honorable James M. Seif, Chairman
Environmental Quality Board
16th Floor, 400 Market Street
Harrisburg, PA 17105-2063

Re: IRRC Regulation #7-335 (#1922)
Environmental Quality Board
Radiological Health

Dear Chairman Seif:

The Independent Regulatory Review Commission (Commission) has enclosed comments on your proposed regulation #7-335. These comments outline areas of concern raised by the Commission. The comments also offer suggestions for your consideration when you prepare the final version of this regulation. These comments should not, however, be viewed as a formal approval or disapproval of the proposed version of this regulation.

If you or your staff have any questions on these comments or desire to meet to discuss them in greater detail, please contact James M. Smith at 783-5439 or John Jewett at 783-5475. They have been assigned to review this regulation.

Sincerely,

Robert E. Nyce
Executive Director

REN:kcg
Enclosure
cc: Sharon Freeman
Barbara Sexton
Office of General Counsel
Office of Attorney General
Pete Tartline

COMMENTS OF THE INDEPENDENT REGULATORY REVIEW COMMISSION

ON

ENVIRONMENTAL QUALITY BOARD REGULATION NO. 7-335

RADIOLOGICAL HEALTH

MAY 15, 1998

We have reviewed this proposed regulation from the Environmental Quality Board (EQB) and submit for your consideration the following objections and recommendations. Subsections 5.1(h) and 5.1(i) of the Regulatory Review Act specify the criteria the Commission must employ to determine whether a regulation is in the public interest. In applying these criteria, our Comments address issues that relate to economic impact, need, implementation procedures, reasonableness, and clarity. We recommend that these Comments be carefully considered as you prepare the final-form regulation.

1. Acquisition of Agreement State Status from the Nuclear Regulatory Commission. - Implementation procedures and Clarity.

The EQB states that the proposed amendments are needed for Pennsylvania to acquire Agreement State Status from the Nuclear Regulatory Commission (NRC). The NRC reviewed the EQB's proposed regulation in comparison to the equivalent NRC regulations in 10 CFR. As a result, the NRC submitted comments dated April 15, 1998, which identify 30 concerns with the proposed regulation. The NRC stated that they did not limit their review to provisions required for compatibility, and that some of their recommendations would not be necessary for purposes of compatibility.

We believe that all of the NRC's suggestions should be considered, regardless of whether they are needed for compatibility. The NRC's comments foster consistency between Pennsylvania, NRC, and other states' regulations, even on issues not needed for compatibility. Therefore, we recommend that the EQB consider all of the comments submitted by the NRC and make the appropriate amendments to the extent allowed under Pennsylvania statutes and the scope of this rulemaking.

We further question why it is necessary to duplicate the language of federal regulations in Pennsylvania's regulation. The NRC's concerns could be eliminated if the CFR was adopted by reference. The EQB used incorporation by reference in proposed rulemaking #7-328 titled "Comprehensive Hazardous Waste Amendments." The format of rulemaking #7-328 highlights the differences within Pennsylvania. Alternatively, a format which paraphrases the CFR with only a few variations within the bulk of the text makes it more difficult for the reader to find the differences within Pennsylvania. We recognize that there may be practical differences between the Environmental Protection Agency requirements for hazardous waste and the NRC requirements

for radiological health. However, we believe the possibility of adopting the CFR by reference should be explored. Therefore, we recommend that the EQB consider adopting the federal regulations by reference as it did in EQB rulemaking #7-328.

2. Section 215.2. Definitions. - Reasonableness and Clarity.

The proposed regulation would delete the definition of the term "misadministration" from Section 215.2 and move an updated version of the same definition to Section 224.2. One commentator, Krishnadas Banarjee, Ph.D., Radiation Safety Officer at St. Francis Medical Center in Pittsburgh, expresses opposition to this deletion. Another commentator, Peter Bloch, Ph.D., Department of Radiation Oncology at the University of Pennsylvania Medical Center, provided suggestions for clarifying certain subparagraphs in the existing definition of "misadministration" in Section 215.2.

The Department of Environmental Protection (DEP) is working with the Radiation Protection Advisory Committee to address these comments. A portion of the existing definition was removed from the updated definition in the amendments for Section 224.2. This portion is in Subparagraphs (vii) and (viii) of the existing definition. Although these two subparagraphs are not necessary for Agreement State Status with the NRC, DEP staff, and Advisory Committee members agree that they should be retained. If the EQB and DEP decide to retain these subparagraphs, we recommend that they use the suggestions offered by Dr. Bloch to clarify Subparagraphs (vii) and (viii).

3. Section 217.58. Financial assurance arrangements for reclaiming sites. - Need and Clarity.

In the Preamble the EQB states Section 217.58 is a new section and is compatible with the CFR. However, Subsections (h) and (i) are requirements in addition to those in 10 CFR Section 30.35. It is not clear why Subsections (h) and (i) are needed in Pennsylvania. The NRC also expressed concerns with the clarity of Subsections (h) and (i) because they create conflicts with other subsections. We recommend that the EQB explain the need for these provisions, and, if they are needed, amend the provisions to eliminate conflicts which affect the clarity of the regulation.

4. Section 219.51. Dose limits for individual members of the public. - Implementation; Need; and Economic impact.

The EQB proposes to delete the exemption which allows a total effective dose up to five mSv. The regulation, as amended, would only allow a total effective dose up to one mSv. One commentator supports the one mSv limit, but recommends that the EQB allow a grandfather clause for existing facilities at the current five mSv limit. We recommend that the EQB consider adding a grandfather clause as long as this provides sufficient protection to the public.

Additionally, if it is acceptable to grandfather existing facilities, we further question the need to impose a one mSv limit on new equipment and what the associated costs on the regulated community will be. Therefore, we recommend that the EQB explain the need to impose a one

mSv limit on new equipment and how that need justifies the associated costs imposed on the regulated community.

5. Section 224.151. Use of radiopharmaceuticals for uptake dilution and excretion studies. - Need; Possible exemption; and Clarity.

In Section 224.151, Merck & Company is concerned with the distinction between radiopharmaceutical drugs and byproduct materials added to compounds to research the human absorption, distribution, metabolism, and excretion of the compounds. Merck & Company is concerned that the proposed amendments may require additional licensing of researchers whose intent is not to manufacture and distribute radiopharmaceuticals. Merck & Company suggests language to address their concern.

The Preamble description of Section 224.151 describes the use of radiopharmaceuticals for diagnosis and therapy. The Preamble does not directly express an intent to expand licensing to include research. The language of proposed Section 224.151 also does not specifically address byproduct material added to other compounds for research. Therefore, we recommend that the EQB explain the intent of the proposed amendments to Section 224.151 to clarify whether the activities described by Merck and Company will require licensing. If the intent is to license these activities, we recommend that the EQB explain the need to license what are described as incidental dosages that present a minimal radiological risk and why it is not feasible to exempt these activities. If the intent is not to license these activities, we recommend that the EQB clarify that intent in the regulation.

6. Chapter 225. Radiation safety requirements for industrial radiographic operations. - Protection of the public health; Reasonableness; and Need.

The regulation will require the licensee or registrant to maintain records for five years or longer for inspection by the Department. We recognize the Department's mandate to protect citizens from unnecessary and harmful exposure to radiation. We see value in requiring the registrant or licensee to do regular inspections and to keep a record of the results. However, we question how a Department inspection of records that are up to five years old will effectively protect citizens from excessive exposure to radiation.

Another concern is that there is a cost imposed upon the registrants and licensees by requiring them to maintain records for five years. The five-year requirement appears in Sections 225.73, 225.105, 225.152, 225.153, 225.154, 225.201, 225.204, 225.205, 225.206, 225.255, 225.256, 225.257, 225.258, and 225.259. Additionally the requirement in Section 225.153(d) requires report retention until termination of the license or until disposition is authorized for inaccuracy. We note that similar provisions in Chapter 226 were reduced from five years to three years. While all of these requirements will not apply to one facility, in most instances, a registrant or licensee will typically fall under several of the requirements.

We recommend reducing the length of time records must be maintained, and using that time period consistently throughout the radiological health regulations. If the EQB does not reduce the requirements, we request an explanation of the following:

- The value of requiring maintenance of records for five years or more;
- Why it would not be equally as effective to maintain records for a shorter period, such as two or three years; and
- Why maintaining the most recent record would not be sufficient.

7. Section 226.17. Design and performance criteria for sealed sources. - Reasonableness; Consistency; and Clarity.

In the *Federal Register* on July 25, 1989, the NRC published a notice of exemption for well logging licensees from the requirement to use only sealed sources that meet the prototype testing rule specified in federal regulations at 10 CFR Section 39.41(a)(3). According to recent NRC documents and DEP staff, this exemption is still in effect. Craig B. Clemmens, Radiation Safety Officer for Appalachian Geophysical Surveys, submitted comments expressing the concern that this exemption was not included in Section 226.17 of the proposed regulation.

Specifically, Clemmens noted language in Section 226.17 that in its application would be more stringent than federal requirements unless the DEP and EQB recognize the exemption published by the NRC. Section 226.17 is similar to the NRC's provisions at 10 CFR Section 39.41(a). Hence it is necessary for State Agreement Status. In 1989, the NRC stated that it could implement this exemption under 10 CFR Sections 30.11 and 39.91 which allow the NRC, on its own initiative, to grant exemptions from the requirements of Part 39. DEP has a similar provision in existing statute at Section 303(b) of the Radiation Protection Act (Act) (35 P.S. Section 7110.303) which reads:

> The department [DEP] shall be exempt from the licensing and registration requirements of this act and is authorized to exempt certain radiation sources and users from this act provided the department determines that such action will constitute an insignificant risk to the health and safety of the public and to persons exposed to radiation sources.

This section authorizes the DEP to exempt certain radiation sources and users from the Act provided that it determines that the exemption will constitute an insignificant risk to public health and safety. Similar language is also found in existing regulations at 25 Pa. Code Section 215.31. Therefore, we recommend that the EQB and DEP evaluate the risk to the public health and safety posed by exempting well logging licensees as the NRC did in its notice on July 25, 1989, and indicate their findings in the preamble or comment and response document for the final-form regulation submittal. If the EQB and DEP concur with the NRC, we recommend that they either incorporate the exemption into Section 226.17 or exercise DEP's authority via Section 215.31 by publishing notice that DEP is granting the exemption.

8. Other Clarity Recommendations.

a) The format for units is not consistent throughout the regulation. For example, Section 219.21(f) uses "10 *rem* (0.1 *mSv*)" whereas Section 219.51(a)(2) uses the opposite format of "0.02 *mSv* (0.002 *rem*)." Another example of the inconsistency is that only one type of unit,

microcuries, is used in Section 224.61(a)(1)(iv) and one portion of Section 224.104(1) uses only millicuries. However, the existing portion of Section 224.104(1) uses both millicuries and "mBq." We recommend that the EQB review the regulation and make the necessary changes to use units consistently.

b) The first "sentence," after the italicized title of Section 217.58(f)(2), is not a sentence. It appears that there is a typographical error. We recommend that the proposed italicized title and the first sentence be combined to form the title of this paragraph.

c) In Section 217.58(f)(2), the first reference to Appendix F states "relating to...*official* tests...." We recommend amending this phrase to state "relating to ...*financial* tests...." to be consistent with the title of Appendix F.

d) The subsection/paragraph designations in Section 217.65 are inconsistent as published in the *Pennsylvania Bulletin*. We recommend correction for the final-form regulation.

e) The paragraph designations in Chapter 217, Appendix F, Parts II.c., and III are not consistent and need to be corrected.

f) In Chapter 217, Appendix F, Part III.c. states "...financial as assurance...." We recommend deleting the word "as" from this phrase.

g) The deletion of "Radiation Survey Instruments and Loss" shows deletion of "225.31 - 225.23." We recommend correction of this deletion to cover "225.31 - 225.33."

h) Section 225.108(5) has a typographical error in the phrase "...if of an ionization chamber...." We recommend deleting the word "of."

i) In Section 225.207(c) it appears the word "an" should be "and." We recommend this correction for the final-form regulation.

j) Section 225.253(a) begins with the phrase "A license...." We recommend correction to state "A licensee...."

k) Under the definition of "surface contaminated object" in Section 230.2 on pages 920 to 921 in the *Pennsylvania Bulletin*, the style of lettering is inconsistent in the designation of subparagraphs under two subsections labeled as "(i) SCO-1" and "(ii) SCO-2." The lettering switches back and forth between lower case and upper case. This needs to be corrected in the final-form regulation.

INDEPENDENT REGULATORY REVIEW COMMISSION

To: Shirley Hartman
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From: Kristine M. Shomper, Executive Assistant
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Date: May 15, 1998
# of Pages: 7

Comments: We are submitting the Independent Regulatory Review Commission's comments on the Environmental Quality Board's regulation #7-335. 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 Hartman **Date:** 5/15/98