RADIOLOGICAL HEALTH AMENDMENTS
25 PA CODE CHS 215, 217, 219, 220, 224, 225, 226, 230 AND 232

ENVIRONMENTAL QUALITY BOARD REGULATION NO. 7-350

COMMENT AND RESPONSE DOCUMENT

COMMENT AND RESPONSES

Section 215.1 Purpose and Scope

1. Comment: "These subsections do not provide sufficient notice as to the requirements with which regulated parties must comply…there should be a citation to specific provisions of …Title 10 that are incorporated by reference. In the alternative…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". (6)

   Another commentator voiced a similar concern. "A clear and bolded statement regarding incorporation by reference should be included at the start of each chapter as appropriate." (5)

   Response: A list of each of the sections of the NRC regulations being incorporated by reference is impractical. Instead, the federal regulations are incorporated in their entirety and any sections not incorporated are listed. The language of incorporation by reference appears at the beginning of each Chapter or Subpart as necessary to identify the corresponding NRC regulations that are replacing or augmenting those Pennsylvania regulations. A suggestion to show a complete list of the incorporation of NRC regulations and exceptions at the beginning of Article V has been incorporated into the final rulemaking. Subsection 215.1(e) has been expanded to identify all of the exceptions to incorporation of 10 CFR. For convenience of the reader, the applicable NRC regulations and exceptions will continue to be identified at the beginning of the individual chapters or subparts of Article V.

   The equivalent Pennsylvania references to be universally substituted for words and phrases used throughout 10 CFR are identified in a new subsection (h).

   Existing references to other Commonwealth Laws and Pennsylvania Code described in 215.24, 221.11(a)(2), 226.51(d)(1) and 230.13(b) remain intact.

215.2 Definitions: Misadministration (medical event) from X-Ray

Three sets of comments were made regarding this definition. Two of the commentators expressed their position as isolated issues. (5,6) One commentator addressed the definition as a whole and provided a rewrite. (4) The individual issues are presented first.

2. Comment: "… the federal regulations contain a definition of misadministration… substantively different from the definition proposed… The regulation should also clarify whether the federal definition of misadministration is incorporated by reference." (6)

   Another commentator wrote "Replace the word Misadministration with Medical Event" (5)

   Response: To avoid confusion, "Misadministration (medical event) from X-Ray" has been renamed "Medical Reportable Event for Radiation Producing Machine Therapy" and moved to section 219.3 (relating to definitions). As such it is not connected to the definition of "Misadministration" in 10 CFR 35.2 (relating to definitions), which will be applicable only to administrations using radioactive material. These are separate definitions because the two modalities involved are similar but not identical. The 10 CFR 35.2 definition of misadministration is incorporated by reference through section 215.2 (relating to definitions) because of the need for compatibility with the NRC.

3. Comment: "… 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 … it would improve clarity to move the provisions of this definition to section 219.228..." (6)

   Response: The definition has been moved to section 219.3 (relating to definitions).

4. Comment: "… the commentators suggested adding words such as therapeutic or therapy and diagnosis to the description… The types of doses covered by this definition of misadministration are unclear. Does this term apply to doses for both therapy and diagnosis?" (6)

   Also, regarding subparagraph (i) another commentator offered "Either strike item (1) "An administration of a dose to the wrong individual" or change it to "An administration of a therapeutic dose to the wrong individual". (5)

Additionally, it was suggested that a minimum threshold dose be exceeded before applying the definition to situations involving delivery of a therapeutic exposure to the wrong individual. (4)

Response: The referral to dose under subparagraph (i) in the proposed definition has been clarified in the new definition to refer to "therapeutic radiation dose" in the final regulation. The mistaken exposure of the wrong individual to a therapeutic dose is too important to strike or ignore at any level. At the least, it suggests serious weakness in the licensee's or registrant radiation safety program.

5. Comment: "… 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 cannot 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 accident needs to be reported and who is responsible for the actual report." (6)

Another commentator questioned the use of functional damage as a criteria. "Strike item (ii) – the statement is so subjective as to make it unlikely that any event would ever be reported." (5).

Response: Reference to "functional damage" whether due to therapeutic or diagnostic doses has been removed from the definition but retained as a reporting requirement under new section 219.229 (relating to other medical reports). This will flag therapeutic or diagnostic occurrences of excessive exposure that may produce demonstrable deleterious effects but do not qualify as Medical Reportable Events for Radiation Producing Machine Therapy. However, any functional damage to patient tissue that was an expected outcome when the causative procedure was prescribed is exempted.

The reporting requirement refers to information possessed by the licensee or registrant. It is unnecessary to specify who will determine that a report is required or who will report it. That is the responsibility of the registrant or licensee as well as compliance with all other regulations. Determination of functional damage to tissue and medical outcomes are clinical considerations that can only be under the purview of the treating physicians and medical physicists.

The Department does not agree that suspected functional damage is too subjective to ever be reported. Probability of causation and

likelihood of outcomes are routine considerations used in assessing clinical treatment.

6. Comment: "… what is meant by the term wrong site? Does it include partial misalignment or exposure to boundary areas of the treatment site?" (6)

Concern was echoed by other commentators that a definition of wrong site might be needed to differentiate the regulatory response between gross targeting errors outside the treatment volume and errors of precision in and overlapping the treatment volume. (4 , 5)

More flexible limits were also suggested. "If the wrong site is taken to include a partial misalignment then better wording for (iii)(b) is, [The result is an increase in the total expected dose that exceeds the larger of 20% of the expected dose or 2.5 Gy (250 rad) or is expected to cause functional damage]" (5)

Response: References to "wrong site", "wrong energy" etc. have been removed from the definition so the meaning of "wrong site" in Subparagraph (iii) will no longer be relevant. The objective is to prohibit unnecessarily damaging exposure to any area of a patient. The reason for the excessive exposure is not significant. Only the criteria for an unacceptable exposure level is retained as a bench mark for defining a Medical Reportable Event for Radiation Producing Machine Therapy. Even if an event occurs in which this level is not reached, it will still be reported under new section 219.229 (relating to other medical reports), if it causes injury to the patient.

7. Comment: "The definition for Medical Event from X-ray in Ch. 215.2 should be revised to read as follows:" (4)

"Medical Event from X-ray - The administration to a human being, except for administrations resulting from the direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:

(i) An administration of a dose for diagnosis or therapy to the wrong individual that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin.

(ii) An administration of a dose for diagnosis that results in or is likely to result in acute functional damage to tissue, unless the damage is an expected outcome of the prescribed procedure or

the damage can not be avoided without compromising the efficacy of the procedure.

(iii) An administration of a dose for therapy when one of the following applies:

(1) The total dose delivered to the intended treatment site identified in a written directive differs from the prescribed dose by more than 20%.

(2) The total weekly fractionated dose delivered to the intended treatment site identified in a written directive differs from the prescribed dose, for the number of fractions to be delivered in a week, by more than 50%.

(3) A dose is delivered to the wrong anatomical site from that which was specified in the written directive (this does not include positional errors of the treatment field targeting the intended treatment site).

(iv) An administration of a dose for therapy by the wrong treatment mode (photon versus electron), wrong effective energy, wrong applicator or wrong treatment geometry which results in a dose to the skin or an organ or tissue outside of the intended treatment site and causes clinically significant functional damage to the tissue."

"The purpose of number (1) is to include diagnostic errors which exceed a certain dose limit to the patient - consistent with NRC definition. Number (2) limits the type of damage which can occur from excessive interventional procedures only to acute effects to the skin, and does not include stochastic effects. For X-ray therapy, a tolerance level of 50% for one fraction is too restrictive. It is more appropriate, from a clinical standpoint, to control the total amount of radiation delivered over a week. The 50% tolerance level on a single fraction of dose incorporated in the new 10 CFR 35 regulations is intended for HDR brachytherapy and Gamma Knife radiosurgery where the doses per fraction are in excess of 500 rads. Typical doses for external beam therapy are 150 to 250 rads per fraction.

The definition of wrong treatment site needs to be defined to address both anatomical errors (right lung versus left lung) and positional or setup errors (deviation of the treatment field orientation from that intended, but still targeting the treatment site). The former clearly qualifies as a medical event from one fraction. However, with the later, is very difficult to set a rational threshold for these types of

deviations due to the subjective nature of defining appropriate treatment fields. Therefore, such errors should only be considered a medical event if it results in clinically significant damage." (4)

Response: This commentator's wording in subparagraph (i) introduces the concept of a threshold level for reporting. However, since the new proposed definition will not include diagnostic exposures it is not expected that any exposure to the wrong individual from therapy will be small or insignificant. Therefore no minimum value is stated in final form.

In final-form, the condition for functional damage is moved to new section 219.229 (relating to other medical reports). The wording of subparagraph (ii) is similar but adds the restriction of acuteness. Long term damage is also a legitimate concern and it is also included in the final-form of the regulation.

The comment on subparagraph (iii)(2) regarding error limits for therapy fractions suggests using a weekly error limit rather than an individual fraction error limit. The Department agrees with the use of a weekly limit; however, 30% not 50% is the value traditionally associated with teletherapy. The individual fraction limit will be replaced by a weekly error limit of 30% in the final-form regulation.

The comment on subparagraph (iv) would make certain errors of energy, geometry or mode applicable only if they result in "significant functional damage." Any error under the licensee or registrant's control that results in a deleterious effect is significant. The regulation in final-form addresses that concern.

In summary to the comments regarding the definition, the regulation in final-form replaces the functionality of the existing requirements for misadministration for x-ray therapy. It defines a medical reportable event for radiation producing machine therapy only. However, the reporting requirements in the proposed regulation for therapeutic and diagnostic events of interest that did not meet the definition of "Medical Reportable Event" have also been captured by retaining the trigger of functional damage, but specifying it as a separate reporting requirement under section 219.229 (relating to other medical reports). Using the concept of functional damage makes the regulation outcome-based without locking in numbers for threshold values. The Department believes that these changes simplify the final regulation. Reference to an individual dose fraction has been deleted as unnecessarily restrictive. However, existing language pertaining to the constraints placed on weekly dose and total treatment dose are retained as they are generally accepted nationally. There are no longer separate standards for energies below 1 mev and above 1 mev or separate categories of dose fractions. The source of errors (wrong beam energy, wedge factor, etc.) is no longer specified, the trigger is the outcome

of increasing dose by more than 20 percent. The previous difficulty in reconciling wrong treatment site with alignment accuracy versus gross positional errors no longer exists.

Section 215.27. Vacating premises.

8. Comment: A commentator suggested the regulation should include criteria and standards for decontamination. (6)

   Response: No change is necessary. The situations requiring decontamination are identified in 10 CFR 30.36. The standards are incorporated by reference in 10 CFR Part 20 Subpart E. The language "When deemed necessary by the Department, the licensee shall decontaminate the premises as the Department may specify" reflects the caveat that, though there are decontamination standards, the standards are maximum limits that are also subject to the criteria of "ALARA" (as low as reasonably achievable). ALARA may vary with circumstances and is in the judgment of the Department.

   However, to add clarity as suggested to issues regarding decontamination, a new Section 219.7 (relating to incorporation of 10 CFR 20.1403 "*Criteria for license termination under restricted conditions*") has been added to clarify the process of obtaining a license termination under restricted release conditions.

Section 215.28. Deceptive exposure of a monitoring device.

9. Comment: A commentator indicated that section 215.28 is unclear, and asked that its intent be clarified. (6)

   Response: The Department agrees and has clarified this section in the final rulemaking.

Section 217.131. Incorporation by reference.

10. Comment: A commentator suggested that the specific regulations of 10 CFR Part 30 that are incorporated by reference, and when they are superceded, is vague. Subsection (b) would be unnecessary if each applicable section of Part 30 was specified. The same concerns apply to Sections 217.141, 217.151, 217.161, 217.171, 217.181, 217.201, 219.5, 220.9, 224.10, 225.2a, 226.4, 230.3, and 232.2. (6)

    Response: As noted in the Department's response to comment #1, specification of each applicable section of 10 CFR Part 30 is impractical. The scope of incorporation has been defined in the alternative by listing the exclusions to incorporation in entirety. For clarity, subsection

217.13(b) lists all the sections of 10 CFR not incorporated by reference.

Section 217.191 Transfer of Material.

11. Comment: Two commentators requested deletion of Subsection 217.191(c)(4) and Subsection 217.191(c)(1) that allow verification using other sources of information compiled from official records or from information presented by personally examining a copy of the transferee's current license. The reason was that only direct contact with the licensee could ensure that the quantity of material to be transferred would not exceed the recipient's authorized license limits when added to existing inventory (a quantity that would only be unknown by the licensee). (3,6)

Response: The comments appear to misinterpret what a transferor is required to verify in regards to the quantity of material authorized by the recipient's license. The transferor is not required to consider or verify the quantity that the recipient has already. (The recipient is responsible for controlling their inventory. The recipient, not the transferor, will be held responsible if the license possession limits are exceeded.) The transferor must verify that the material transferred does not exceed the quantity limits listed in the license document. This is why a copy of the recipient's license or an official record describing the license are listed as acceptable forms of verification. It is agreed that if the recipient has a poor procurement system, it may under certain circumstances lead to a technical violation of possession limits. The low probability of a possession limit violation and the minimal safety impact do not warrant deleting the regulation or imposing impractical burdens upon the transferor.

The Department is also not aware of whether the provision for utilizing reporting services has ever been exercised. In the history of the regulation, no one has approached the agency for access to compile this data. If a third party reporting mechanism were proposed, it would require approval by the Department.

These are not new, but existing regulations formerly located in section 217.101. Since they are a requirement for compatibility with the NRC, these provisions and those of section 217.191(c)(4) have been retained. However, the text of Subchapter I has been replaced with language incorporating 10 CFR 30.41 by reference in the final rulemaking.

12. Comment: [Regarding subsection 217.191(a)(3)], "The regulation should indicate who would be exempt [from Article V] and how an exemption is granted" (6)

Response: In the regulations, exemptions are granted without petition to certain persons meeting the specifications described in the regulations. For example, section 215.32 cites federal agencies in general and subsection 217.13(a) allows transfer of exempt quantities not for commercial distribution. Section 215.31 also permits the Department to grant exemptions by petition or by fiat such as a license condition. It is not practical to list all possible exemptions with any section. That would invite the same for all other sections of the regulations. The format has been to list exemptions of general applicability in Chapter 215. Other exemptions appear in the chapters that most closely regulate the provisions addressed by the exemption.

13. Comment: [Regarding subsection 217.191(a)(4)], “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.” (6)

Response: Document naming conventions may vary among different regulatory agencies. The equivalent of a general license in these regulations may be called a registration certificate in another state. A specific license may be a permit elsewhere. In any case the licensing requirements are not necessarily identical in all jurisdictions. A regulated activity that requires a specific license in one jurisdiction may be allowed under a general license in another jurisdiction. Equivalent documents cannot be specified in advance. It is the responsibility of the transferor to ascertain whether the authorization of the transferee meets the requirements of the regulation.

14. Comment: [Regarding subsection 217.191(a)(5)], “Subsection (a)(5) refers to a person otherwise authorized by the Department in writing. The regulation should specify who would fall into this category." (6)

Response: This rule is intended for flexibility. There is no way to anticipate every person who might fall into this category. An example is Section 217.22 that requires a licensee to obtain Department approval before a license can be transferred to another entity such as expected during a corporate merger.

15. Comment: [Regarding subsection 217.191(c)(3)], "Subsection (c)(3) refers to oral certification. A definition of "oral certification" would improve clarity." (6)

Response: The Department believes the meaning of "oral certification" to be ordinary language and sufficiently obvious. The formality of an "oath" is not implied. The recipient transmits and attests verbally to such

information contained in the license document that the transferor is required to verify in the manner specified by the subsection. The certification is not all oral as it must be completed by a written confirmation within 10 days.

Section 220.2(a)(3) Posting of notices to workers.

16. Comment: "Although this [section 220.2(a)(3) *posting of notices to workers*] is not a change from the current regulations, posting comprehensive operating procedures for a research and development organization does not seem possible. Posting operating procedures for radioactive devices or X-ray machines… is a reasonable and useful requirement. Trying to post procedures for wet chemistry work would just be confusing… Please revise §220.2(a)(3) to [read '*The operating procedures applicable to activities under the registration*."]. (3)

Response: The Department disagrees. The requirement applies to activities involving licensed radiation sources as well registered sources and unsealed radioactive material as well sealed sources and devices emitting radiation. The comment appears to be based upon a misunderstanding of the requirement. The procedures relative to the regulated activity are the procedures for implementing the radiation safety program. Rather than technical procedures that the commentator alludes to, these are things such as the general radiation safety manual and any specific safety procedures relevant to the posted area. It would address concerns like "personnel monitoring required beyond this point" or "verify the target room is unoccupied before energizing" etc. In any case, where a complete posting is impractical because safety concerns in the local work area are more complicated than a few simple admonitions like, "do not pipette by mouth", section 220.2(b) only requires that the posting contain a reference to the location of the pertinent documents.

Chapter 224 Medical use of radioactive material

17. Comment: There is a general objection to incorporation by reference of 10 CFR Part 35. The commentator believes the NRC regulations of Part 35 are inconsistent, contradictory and not right in general. The formation of a task force to develop independent regulations that can be crafted to eliminate perceived problems is recommended. (2)

Response: Radiation-producing machine therapy is handled separately from Chapter 224 and 10 CFR Part 35. Only those licensees who are already subject to Part 35 are affected. For them, no change is proposed at this time. It is common knowledge that the NRC has had much friction with the medical community over the years and the NRC

is currently working on a comprehensive revision to Part 35. Amendments to Chapter 224 will not be contemplated until it is apparent how the new Part 35 will look.

Section 225.71. Definitions: RSO – Radiation Safety Officer

18. Comment: "The last sentence of this definition [radiation safety officer] is substantive. Furthermore the information in this sentence is included in [Section 225.72 (relating to duties of personnel)]…For these reasons the last sentence should be deleted from the definition." (6)

Response: The Department agrees and the sentence has been deleted.

Section 225.74. Training and testing.

19. Comment: Regarding subsection (a)(3), a commentator questioned how many hours of safety instruction are required and suggested that a minimum number of hours should be specified. (6)

Regarding subsection (a) (4) the commentator also noted that each licensee / registrant may conduct their own testing and certification. Is there adequate assurance of safety without requiring standardized testing. (6)

Response: With respect to subsection (a)(3), no set time or minimum time will be established because this is a performance based requirement which is satisfied by passing a written test and field examination. The degree of effort is variable depending upon the individual.

With respect to subsection (a)(4), non-destruct testing radiography with radiation producing machines is inherently safer than with radiographic exposure devices using radioactive material. The relative relaxation in the regulations reflects this. The majority of programs utilize sources in completely shielded cabinets or rooms. Except in the case of accelerators, an evaluation of the program for safety training does not occur prior to the routine site inspections conducted by the Department. For accelerators, prior review of training is conducted as part of the licensing process. (Note: non-accelerator x-ray is an activity registered after the fact, not a licensed activity regulated before the fact.)

Section 225.76. Reporting requirements.

20. Comment: A commentator suggested that it is not clear whether notification of excessive exposure under subsection (c) is required to be followed up

by a report within 30 days as is required by the events in subsection (a) (6).

Response: Thirty-day reports under subsection (c) are required. Subsection (c) references 10 CFR 20.2203, which proscribes the thirty-day reporting requirement for events covered by 10 CFR 20.2202 and 20.2203. However, the Department agrees that references to thirty-day reporting requirements should be further clarified. Subsection (a) now references sections 219.221 and 219.222 specifically. Section 219.222 has been renamed *"Notification of Incidents and Reportable Events"* since it represents both Parts 20.2202 and 20.2203. The general reference to 10 CFR Part 20 in 219.222 has been replaced by specific references to Parts 20.2202 and 20.2203 and notes the written thirty-day reporting requirement. In regards to subsection 225.76(c), the reference to include the information in subsection 225.76 (b) will read "to the extent known". Complete information referenced in subsection 225.76 (b) may not be immediately available and will not be mandatory until the thirty-day report is due. Subsection (b) also references licensees in addition to registrants for clarity.

Section 225.82. Operating requirements.

21. Comment: A commentator asked that the terminology used throughout Subchapter B be consistent. Subsection 225.82(c)(4) and 225.84(5) refer to "pocket dosimeter" in quotes. The quotes should be removed and the term should be included in definitions. Elsewhere, it is also referred to as a "pocket ionization chamber," "direct reading personnel monitoring device," "direct reading pocket dosimeter" and a substitute for "electronic personal dosimeter". (6)

Response: This various usage of these terms mimics that employed by the NRC. There has been no confusion in the regulated community interchanging these commonly-used terms. However, for clarity, the references have been reduced to two standards. Since Subchapter B deals with radiation-producing machines and not NRC-regulated material, the two standard definitions, "direct reading dosimeter" and "personnel dosimeter" have been added to Section 225.71. For the purposes of Chapter 225, "personnel dosimeter" means any subset of "individual monitoring devices" (see 10 CFR 20.1003 *Definitions*) that must be processed and evaluated to generate a permanent record of an individual's dose. This also includes Film Badge, TLD and OSLD. "Direct reading dosimeter (DRD)" means an individual monitoring device that does not require additional processing to measure an individual's dose. This also includes direct reading personnel (individual) monitoring devices like pocket dosimeter, pocket

ionization chamber and electronic personal dosimeter. The appropriate substitutions have been made to terms in Subchapter B.

Section 225.83. Records required at temporary job sites.

22. Comment: "This section provides for the maintenance and availability for inspection of records or documents at the temporary job site. This section does 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." (6)

Response: Other than to specify retention periods, it is not necessary to describe how records are to be handled after they are removed from a temporary job site. Pursuant to subsection 215.12(a), all records required under this article must be maintained and available for inspection. How this is accomplished is at the discretion of the licensee / registrant. With regard to the record keeping requirement in section 225.93, it applies to all of Chapter 225. A section of Chapter 225 is applicable to the entire chapter unless otherwise indicated such as through the use of phrases like "except for…" or "otherwise exempt from all other provisions of this chapter…". It is unnecessary to change the text of section 225.83.

Section 225.85. Surveys and survey records.

23. Comment: A commentator believes that a timetable should be specified for retention of surveys and records used to determine an individual's exposure. (6)

Response: The Department agrees. The final-form regulation has been changed to indicate the retention periods. The periods are consistent with similar regulations of the NRC. Surveys must be maintained for a period of three years unless they are used to determine personnel exposure. Then they must be maintained until termination of the registration or license.

Section 225.93. Personnel monitoring control.

24. Comment: A commentator noted that subsection (d)(1) requires dosimeters to be recharged at least daily or at the start of each work shift. Consideration should be given to deleting the phrase "at least daily". The commentator also questioned whether the term electronic "personal" dosimeter in subsection (d) is appropriate and whether the requirement should be moved to subsection (a).(6)

Response: The Department agrees with the change in subsection (d)(1). The phrase has been deleted. Also “recharged” has been changed to read “re-zeroed.” The term electronic "personal" dosimeters is correct. However, the specific references to electronic personal dosimeter have been removed from subsection (d)(1)-(4) because the definition of "direct reading dosimeter" in the final rulemaking includes this term. The accuracy of DRDs in subsection (d)(3) has also been changed to 20% to conform with generally accepted standards and parallel regulations of the NRC for Industrial Radiography using radioactive sources.

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

25. Comment: A commentator believes that subsection (b) is not written as a requirement and should be rephrased for clarity. (6)

Response: Subsection (b) is a requirement and the Department has revised the first sentence accordingly. In addition, reference to 10 CFR 20.1301 rather than 10 CFR 20.1201 has been made in subsections (b) and (d).

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

26. Comment: A commentator objects to the wording of subsection (f)(2) that requires safety or warning devices to be repaired “in a timely manner.” A specific time frame should be added. (6)

Response: The Department disagrees. Specifying a specific time frame such as 30 days would be unnecessarily prescriptive. It is not possible to determine the time needed to correct a malfunction that is not yet defined. More importantly, individuals operating equipment under this section do so potentially at grave risk from dangers far greater than the hazards associated with radiation from this equipment. In recognition of such overriding risks, and putting radiation risks in perspective, it is the intent of this section to apply more flexible requirements for radiation safety than are normally used for activities involving less risk.

Section 230.13. Transportation of licensed material.

27. Comment: "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 the 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?" (6)

Response: The Department agrees that the reference to "regulations" is unclear. Section 230.2 (relating to definitions) was deleted. The regulations of the U.S.DOT and PA DOT had been defined therein. The text of section 230.13 in final-form has been clarified to show the applicable references within the U.S. DOT and PA DOT regulations.

GENERAL COMMENTS

28: Comment: "At a minimum a copy of the definitions contained in 10CFR should be made available by the State to licensees and registrants who do not also hold NRC licenses. This might be accomplished by inclusion on the State's web site." (5)

Response: 215.1(g) lists hard bound sources of the incorporated regulations which includes definitions. The Department also plans to establish links in its web site to the document pages of the NRC's web site.

29. Comment: A commentator expressed general support for future Agreement State status. (1)

Response: The Department acknowledges this support. Compatible regulations are a requirement for acquiring Agreement State status.

Proposed Rulemaking (#7-350): Article V , Radiological Health, 25 PA Code Chapters 215, 217, 219, 220, 224, 225, 226, 230 and 232

This is a list of corporations, 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	John A. Labrecque Michael J. Nanney II-VI Incorporated 375 Saxonburg Blvd. Saxonburg, PA	16056			
2	Michael A. Vince, Ph.D. Chief Medical Physicist & Radiation Safety Officer Altoona Hospital Center for Cancer Care 620 Howard Avenue Altoona, PA	16601-4899			
3	Eric Boeldt Radiation Safety Oficer Penn State University 6 Eisenhower Parking Deck University Park, PA	16802			
4	Michael Sheetz, M.S. CHP Senior Health Physicist Niversity of Pittsburgh G-7 Parran Hall Pittsburgh, PA	15261			
5	Jerry Rosen University of Pittsburgh Graduate School of Public Health Rm. G7 Pittsburgh, PA	15261			

ID	Name/Address	Zip	Submitted 1 pg Summary	Provided Testimony	Req Final Rulemaking
6	Robert E. Nyce Executive Director Independent Regulatory Review Commission 14th Floor, Harristown #2 333 Market Street Harrisburg, PA	17120			