

DRAFT Minutes of the Radiation Protection Advisory Committee Meeting
12th Floor Conference Room
Rachel Carson State Office Building, Harrisburg, PA
March 6, 2014

Call to order – 9:03 a.m.

Members in Attendance:

Mr. John Keklak, Ms. Margaret Blackwood, Mr. Michael Sheetz, Mr. Anthony Montagnese, Mr. Vincent Roding, Mr. Joseph Och, Dr. Paul Houle, Mr. Kent Lambert, Mr. Eric Boeldt, Dr. Peter Smith, Ms. Janice Wirth

Members Absent:

Dr. Douglas Eggli, Dr. Charles Chambers, Dr. Charles Stoup, Ms. Jean Gresick-Schugsta, Dr. Richard Purse, Dr. William Thorne, Ms. Michele Tate, Dr. John Pammer

Personnel Representing DEP:

Mr. David Allard, Director, Bureau of Radiation Protection (BRP); Mr. E. Christopher Abruzzo, Secretary, DEP, Mr. Vincent Brisini, Deputy Secretary, WARR, Mr. Joseph Melnic, Chief, Division of Radiation Control; Mr. Dwight Shearer, SW Regional RP Manager; Mr. Ben Seiber, RP Program Analyst; Mr. John Chipppo, Chief, RAM Licensing; Ms. Sandra Martin, Chief, X-Ray & Accelerator Licensing; Ms. Kim Childe, RP Counsel; Ms. Sharon Trostle, DEP Executive Assistant; Ms. Laura Henry, DEP Policy Office; Ms. Kristina Hoffman, RP Program Analyst; Ms. Dyrán Altenburg, Management Technician; Mr. Robert Lewis, Chief, Division of Radon; Mr. Robert Maiers, Chief, Division of Decommissioning and Environmental Surveillance; Mr. John Winston, SWR Inspector

Members of the General Public in Attendance:

N/A

Introduction of Members and Staff:

Mr. Melnic welcomed DEP Secretary Chris Abruzzo and Deputy Secretary Vince Brisini.

Adoption of Agenda:

Today's agenda was approved unanimously.

Comments from the Secretary:

Secretary Abruzzo expressed his appreciation for the fine job the bureau does in protecting and safeguarding the citizens of the Commonwealth from unwanted radiation. He complimented the bureau's response to the Fukushima accident and how he and the Governor stayed informed by BRP's briefings. He stated his purpose for attending today's meeting was to formally thank the RPAC members for taking time away from their busy schedules to serve on the committee. The RPAC members responded by noting the good relationship they have with the bureau. They also wished to express their concern regarding hiring and the importance of training quality staff for the BRP. Secretary Abruzzo acknowledged this concern, and Deputy Secretary Brisini noted he is working diligently in helping to resolve these issues.

Approval of Minutes:

Minor clarifying revisions were made to pp. 6 and 7 of the December minutes after which the minutes were unanimously approved as amended.

Radiation Protection Program Update:

Integrated Materials Performance Evaluation Program (IMPEP): The IMPEP audit occurred the week of January 13-17, 2014. This audit occurs every four years and allows the Nuclear Regulatory Commission (NRC) to verify the Department's agreement to oversee the safe and secure use of radioactive materials. Similar to the last IMPEP, all performance indicators resulted in a "Satisfactory" rating (the highest rating that can be achieved). One recommendation was issued to continue to improve the notification and evaluation process for incidents and allegations.

Frank Costello, Southeast Region Health Physicist, was elected to represent the Organization of Agreement States for the NRC's Advisory Committee for the Medical Use of Isotopes (ACMUI). The ACMUI comments on changes to NRC regulations and guidance, among other things.

Regulatory Revisions (Radon):

Before breaking out to a separate Chapter 240 Subcommittee meeting, Bob Lewis expressed his thanks to Dr. Houle for his work on the subcommittee. Dr. Houle pointed out that comments received so far are focused and identify only a few minor areas in need of clarification. The additions to the regulations are procedures and protocols that are already occurring in the industry and should not have much of an impact from normal business.

Review of Comments from the December meeting:

- Revision to § 215.22 was accepted.
- Revision to § 216.2 was partially accepted, however, the subsection regarding mobile registrants was recommended to include: "must provide an accurate schedule upon request and readily available" which should include the date and location where services are to be performed, rather than to "notify the department..."
- A concern was discussed regarding mobile devices showing up at a facility without appropriate notification to the responsible individual. The committee concurred this concern should be handled internally within the facility.
- Revisions to §§ 219.3, 221.25, 221.38a, and 221.64 were accepted, with a note that the definition for "medical reportable event" still needs clarification and further discussion.

Regulatory Revisions (Chapters 216-221):

Joe Melnic walked the Committee through amendments to each of the chapters.

Chapter 216

- § 216.2b - Service providers are required to be in compliance with Chapter 219, particularly monitoring their employees when needed.
- § 216.3 - Exempt electronic brachytherapy (eBx) from registration, since licensure is required.

Chapter 217

- Delete the transitional "until agreement state status is in effect" language from §§ 217.132-217.133, 217.142, 217.152, 217.162, 217.172, 217.182, and 217.202.
- Add three isotopes for gauge devices in § 217.143.

Chapter 218

- Codify eBx licensing fee in §§ 218.1 and 218.11.

Chapter 219

- § 219.3 - The committee believes the new definition for medical reportable event (MRE) for radiation-producing diagnostic or interventional machines should have a higher-than-2 Gray (Gy) reporting criteria. It was pointed out that NCRP 168 indicates that anything greater than 15 Gy must be reviewed as a sentinel event as required by The Joint Commission. It was decided to wait for peer review of the CRCPD's Suggested Regulations Part F (SR-F). A definition for "unintended dose" should be added to § 221.2. Subsection (iv) should be deleted since it is covered by the previous subsections.
- § 219.3 - For therapeutic MRE, subparagraph (i) should include "wrong treatment plan" along with wrong modality. If adding "plan," then subparagraph (v) can be deleted. Subparagraph (iv) should use the term "exceeds" rather than "differs." If a dose is too low, an additional fraction (boost) can be ordered.
- § 219.229 - Delete "therapeutic" since this is addressed in § 219.228, and leave the statement "and any functional damage to a patient organ..." because procedures may have at times an expected functional damage. RPAC recommended waiting for input from Mr. McNeely, who represents therapists in The American Association of Physicists in Medicine (AAPM).

Chapter 220

- Delete the transitional "until agreement state status is in effect" language from § 220.10.

Chapter 221

- § 221.2 - Accept all revisions to the definitions; however, include "ionizing" radiation in the IORT definition.
- § 221.11 - The committee noted that technique charts are not inclusive and obsolete and recommended replacing "chart" with "protocol information."

The remainder of Chapter 221 and Chapters 223-230 will be discussed at the next RPAC meeting. It was noted that March 2016 is the required implementation date for Agreement States to adopt the NRC security regulations codified as Part 37. In order to continue with the regulation package, the bureau will need to submit a draft to the EQB by December 2014. A summer meeting may be necessary to complete the package. If revisions to the regulations cannot be completed, the Part 37 amendments will need to be submitted separately. If so, the department will seek to move the package directly to final rulemaking, negating a public comment period, given that the amendments are strictly incorporation by reference.

Mr. Och addressed the committee on behalf of Ms. Gresick-Schugsta, chair of the CT subcommittee, noting and complimenting the revised § 221.202a. This revision requires CT systems to be accredited by an accrediting organization recognized by the Department. Mr. Och further stated that this proposed regulation is analogous to the MQSA regulation in § 221.13(c). It addresses phantom image quality standards, QA requirements, and quality clinical images. With this one regulation, nothing else is needed. A handout was distributed to the committee (see attached JOch.pdf). Mr. Winston pointed out that the MQSA regulations are thoroughly addressed by the FDA. The Department must do the same regarding CT

regulations. Mr. Och is concerned DEP regulations may become obsolete and the whole process of revising regulations would need to be repeated, whereas the American College of Radiology (ACR) can be updated faster. He continued by stating “HVL” and “table tilt” are examples that are not necessary to be included in regulation. Mr. Winston noted that dosimetry is also out of date and will be updated in the SR-F. Mr. Allard asked if any of the members anticipate pushback from physicians/facilities if the Department was to require accreditation. All agreed that no pushback is likely. The bottom line is if reimbursements are based on accreditation, then everyone will comply.

Other Business:

Mr. Lambert asked for guidance regarding DEXA scanners and how they fit in our regulations. Are they considered the same as radiographic units? Do they need to meet filter specifications the same as radiographic units? Are there operator training requirements? These units have a fraction of the dose compared to other radiographic devices. Mr. Keklak pointed out there are other similar devices and should be exempt from certain regulations. Mr. Allard noted that DEP approached the Department of State to accept the International Society of Clinical Densitometry (ISCD) criteria for operating densitometers and was successful in allowing ISCD qualified operators.

There are other parts of the regulation revision package that require further discussion. Criteria for all devices should be addressed. For example, analytical X-ray devices will be based on CRCPD’s Suggested Regulations Part H.

The next RPAC meeting is scheduled for April 24, 2014.

NOTE: Rescheduled to June 12, 2014.

Adjournment – 3:07 p.m.