

**DRAFT Minutes of the Radiation Protection Advisory Committee (RPAC) Meeting
14th Floor Conference Room
Rachel Carson State Office Building, Harrisburg, PA
July 23, 2015**

Call to order – 9:07 a.m.

Members in Attendance:

John Keklak	Margaret Blackwood
Eric Boeldt	Tiffany Whitcomb
Kent Lambert	Anthony Montagnese
Shawn McNeely	Michael Sheetz
Vincent Roding	Joseph Och
Victor Rizzo	

Members Absent:

Douglas Eggli	William Thorne
Charles Chambers	Janice Wirth
Charles Stoup	John Pammer
Richard Purse	Eric Miller
Michele Tate	Paul Houle

DEP Staff in Attendance:

David Allard	Dwight Shearer
Joseph Melnic	John Chipppo
Dyran Altenburg	Keith Salador
Bob Lewis	Joe Koshy

Guests in Attendance:

Jim Smith, IRRRC	Tim Difelice
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Introduction of Members and Staff:

Mr. Allard welcomed everyone, and introductions were made.

Adoption of Agenda:

Today's agenda was approved unanimously.

Approval of Minutes:

Meeting minutes from June 4, 2015, were approved unanimously.

Open Floor:

Pennsylvania Chiropractic Association representative, Dr. Victor Rizzo, requested to readdress the committee and submit a formal request to reduce the administrative fee for chiropractors having registered X-ray devices. He submitted a letter regarding his fee analysis (included with the minutes) and proposed suggestions to alleviate the high cost to chiropractors. One suggestion is lowering the fee for chiropractors and another suggestion is to move chiropractors into the dental, podiatry and veterinary fee category. Mr. Allard informed the committee that the latest fee analysis has already been submitted to the EQB and the proposed rulemaking

package is in process. He confirmed that the Department is not proposing any fee increase to X-ray registrants. Dr. Rizzo's suggestions will be considered as part of the next fee analysis to be conducted in 2018.

Another comment was provided on whether Increased Control licensees should have an increase to their fee since there are more security and safety issues of concern. This will also be included in the next fee analysis.

Mr. Koshy, a Southeast Regional inspector, addressed the committee promoting the idea of accreditation requirements for therapy machines (e.g., medical accelerators). He suggests either accreditation or an annual peer review be adopted by all medical accelerator facilities.

Superficial radiation therapy (SRT) devices were also discussed. The Department is proposing the following sentence be added in the electronic brachytherapy definition: "X-ray devices specifically designed and solely used to treat skin cancer lesions are not considered electronic brachytherapy devices under this definition and shall meet the applicable parts of Title 25 pertaining to registration and use." Some new SRT devices are being advertised as "electronic brachytherapy." The Department and the committee agree this is incorrect; regardless, SRT units do require additional regulation. Currently, the Department believes the regulations in §§ 221.71 – 221.76 for therapeutic X-ray systems with energies less than 1 MeV are sufficient for these devices. Nevertheless, the committee is concerned with these new devices, primarily with the absence of formal training requirements for dermatologists. The Department will reevaluate the need to license these devices or keep them as a registration with additional requirements added to the therapeutic X-ray systems section. The Conference of Radiation Control Program Directors (CRCPD) is forming a working group to address these concerns.

Regulatory Revisions

The following revisions to the draft proposed Radiological Health regulations package were suggested by committee members:

- Section 221.2
 - Definitions were added for "health physics" and "medical physics."
 - In the QMP definition, there is no need to define "certified" as it implies an individual is recognized by a nationally accrediting body. After "certifying body," add "recognized by the Department" in (i)(A) and check for other areas in the regulations where that statement may need to be added. Under (i) the definition states the QMP needs to be certified and have continuing education, but (ii) and (iii) says the QMP doesn't necessarily need to be certified. Under (ii) the QMP can be one who has a degree, "three years of documented relevant clinical training and experience...", and continuing education. And in (iii) it states "An individual who has been practicing as a QMP in one or more of the subfields of medical physics or health physics for at least 5 years...is exempt from the requirement of subparagraph (i) and (ii)." This may need to be revised later to require certification if expertise gets diluted by having this alternate pathway.

Under (iv) the regulations should be more specific regarding records. The Joint Commission has standards with language that may work better.

ACTION: Delete (iv) altogether as it is already in the registrant responsibilities section.

- Include a definition for “General Supervision.” The NRC defines it as “able to be contacted by the technologist.”
- Section 221.11
 - Recommend revising “could exceed skin dose” to “likely to exceed skin dose” in (b)(1). Also, it was suggested that the “200 rads (2 Gy)” become 500 rads. Department staff stated that the 200 rads requirement will be retained because it is more conservative and was adopted from the National Council on Radiation Protection (NCRP) and the Council of Radiation Control Program Directors’ (CRCPD) Suggested State Regulations. The RPAC, if it wishes to do so, may suggest 500 rads as a formal comment.
 - Recommend deleting (b)(2) continuing education requirements from this section since it is already addressed in § 221.16.
 - Under (l) in the third sentence where it states what the program will address at a minimum, image quality and artifacts need to be added before “...and maintenance and modifications to the quality assurance program.” The fourth, fifth and sixth sentences should be consolidated into the following sentence: “The registrant shall take corrective actions as necessary for any findings.” The next sentence states that records will be maintained by the registrant for three years; this is being changed to five years.
- Section 221.16
 - (a)(2) – In the sentence “All individuals... is registered...”, “is” will be changed to “are” for grammatical correctness.
- Section 221.61
 - The first sentence in (a) should be revised to “Fluoroscopic systems used solely for radiation therapy simulations need only comply...” instead of “...shall comply...”
- Section 221.64
 - (a)(5) – Add “In addition to the requirements of § 221.16...” to the beginning of the sentence. It should read “In addition to the requirements of § 221.16, the CBCT X-ray system shall only be operated by an individual who has been specifically trained in its operation.”
- Section 221.65
 - There’s a concern that X-ray attenuation systems may not cover all kinds of modalities. For example, gross anatomy and disease staging are also considered types of attenuation systems. Also noted was that certain attenuation

systems may be classified as 'diagnostic' only for reimbursement/billing processing.

- Section 221.201
 - Move the new “Alert value” definition from the general definitions in § 221.2 to this section.
 - Under the “CT number” definition, correct the spelling of Hounsfield (not Houndsfield).
- Section 221.202
 - In (h)(4), and throughout, abbreviate qualified medical physicist as QMP.
- Section 221.204
 - (a)(1) – delete “...who is physically present at the facility during testing.”
 - (a)(3) – delete “...and within 30 days after any change or replacement of components which, in the opinion of the QMP, could cause a change in the radiation output or image quality.” This part about change or replacement of components should be moved to its own paragraph (5) and should read “Thirty days after any change or replacement of components which, in the opinion of the QMP, could cause a change in the radiation output or image quality. The QMP shall perform tests to determine performance and image quality.” Renumber former (5) to (6).
 - (a)(4)(xi) – the subparagraph referenced in this section should be changed to (x), not (xi).
 - (a)(4)(xiii) – there are two changes needed to this sentence. One is adding “Review the process...” and the other is changing “method” to “policy or procedure.” This sentence should read “Review the process determining who has access and authority to make changes to the protocol management systems, including a policy or procedure to prevent inadvertent or unauthorized modifications to a CT protocol.”
- Section 221.205
 - (a) – add “In addition to the training requirements in § 221.16, a CT X-ray system shall be...”
 - (b)(1) – add “and reporting deviations in protocols” to the first sentence so that it reads “Instructions on the use of the CT phantoms and reporting deviations in protocols including a schedule of routine QC appropriate for the system...”
 - (b)(2) – delete “and the process for reporting deviations in protocols” at the end of the sentence, since it’s been moved to (b)(1).

- Section 223.10
 - (d)(2) – this should be changed to “Individuals shall be positioned so that no part of the body will be struck by the useful beam unless protected by at least 0.5 millimeter lead equivalent material. The lead equivalent of the material is to be determined at 60 kV.”
 - (e)(1) – delete the word “appropriate” so the sentence will read “Mechanical holding devices or chemical restraint shall be used when the technique permits.”
 - (e)(2) and (3) – Reverse subsections (2) and (3).
 - (h) – Delete “including CBCT systems” from the sentence.

The members voted unanimously to move the regulatory package forward after addressing the items discussed in today’s meeting.

Other Business:

Members once again expressed concerns regarding conflicting laws between the Department of Health (DOH) and DEP. The Radiation Protection Act 147, Section 306, specifically states:

“Ordinances, resolutions or regulations now or hereafter in effect of the governing body of any agency or political subdivision of this Commonwealth relating to radiation or radiation sources shall be superseded by this act if such ordinances or regulations are not in substantial conformity with this act and any rules and regulations issued hereunder.”

It is recommended that RPAC formally submit a comment referencing the Radiation Protection Act, and requesting DOH concurrence. The comment should contain examples of conflicting rules and how it affects health care facilities.

BRP will begin development of a new regulatory revision package in the near future. This package will address weaknesses in the non-medical radiation generating devices.

With the approval of the radiological health package, the September meeting was cancelled. The 2016 meeting dates will be addressed via email.

When the radiological health fees package gets through the regulatory review and approval process and is ready for publication as a final rulemaking, the effective date of implementation will be provided to all licensees through an information notice.

Adjournment – 3:04 p.m.