

**Radiation-generating Equipment Committee (REC)**

**March 5, 2010**

**Minutes**

**MEMBERS PRESENT**

Lawrence Osher, Chair  
Mary Ann Accorinti  
Chuck Wissuchek  
Thomas Hangartner  
Ruth Hackworth  
Jack Dukes  
Nina Kowalczyk

**ODH ATTENDEES**

Margie Wanchick  
David Lipp  
Pam Hintz

**MEMBERS ABSENT**

Kerry Krugh, Vice Chair  
Nina Mayr  
Kathryn Gardner  
Brenda Johnson  
Teresa Yates

**GUESTS**

Thavendra Rajah, Mt Carmel  
Susan Suchan, Mt. Carmel  
Rick Sites, OHA  
Jamie Berringer

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The Radiation-generating Equipment Committee (REC) meeting was called to order by chairperson, Larry Osher at 10:25 a.m. The meeting was held at the Ohio Department of Health (ODH) in the Basement Training Room A at 35 Chestnut Street, Columbus, Ohio. The Sign-in Sheet serves as the Roll Call and official record of attendance.

**Past Minutes:** The committee reviewed the February 5, 2010 minutes. Jack Dukes made a motion to accept the minutes as written; Tom Hangartner seconded it, and the members present unanimously approved the motion to accept the minutes without change.

**Old Business:**

The subject of Quality Assurance (QA) regulations in Nuclear Medicine was added to the agenda and discussed as the first order of business. Chuck Wissuchek asked for an update of the subject. As discussed in the February REC meeting, Larry plans to collect data from Chuck Wissuchek and Kerry Krugh to support making a recommendation to consider regulations relating to QA in nuclear medicine. To date, Larry has not received the supporting documentation he needs to write a position paper. Thavendra Rajah added that poor image quality, including artifacts, could indirectly affect the treatment plan for radiation therapy via improper diagnosis of the nuclear medicine images, thus affecting overall patient safety. Once Larry has the information and position paper, he will pass it on to the Department through Margie.

Status of Rules - Margie Wanchick distributed a March 2010 version of the X-ray Rule Status Log for the new Chapter 3701:1-67 therapy rules. The four rules updated from the last meeting were given a draft date of 2/22/10 and were made available to the committee for their binders. The finished version of rule 67-05 (Superficial Therapy RGE) is dated 2/24/10 and is ready for public comment. The only remaining rules to finish, before the Chapter 67 drafts are put out to public comment, are the higher energy rule 67-06 and definitions rule 67-01. The Department is planning to post the draft rules (67-01 to -09 and 67-12) on the ODH website to elicit public comment during April and May. Incoming public comments are expected to be reviewed in a May REC meeting. The final therapy rule drafts need to be presented for approval to the Radiation Advisory Council (RAC) at their June 25, 2010 meeting in order to meet the state mandate for its five year review.

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Draft Rule 67-06 - The committee continued to review and edit draft therapy rule 67-06 for the **Technical Requirements for the Therapy Equipment Operating above 500 kV and Electron Systems Above 500 keV**.

During the February meeting, there was discussion about the need for “leakage radiation” requirements. Margie contacted the chairperson of the CRCPD Part X committee and verified that the requirement for leakage radiation was not intended to be a part of an annual calibration or a recurring measurement. Rather, the intent was to require the registrant to assure adequate shielding design, and to verify that the leakage radiation was measured upon commissioning and accepting the unit. Another measurement may be required when major changes of the unit are made as warranted and determined by the qualified medical physicist. The committee voted on whether to maintain the draft language in paragraph (B) and (C); the majority decided to maintain the language as currently drafted.

The committee had a lengthy discussion regarding the filters and wedges requirement in paragraph (D) and decided to recommend only using the term “wedges” and not the term “filter.”

Paragraph (E) was reviewed which led to a discussion about the referenced IEC document. Since the document is not readily available on line and is only available in hard copy, Larry Osher offered to purchase it and provide a detailed analysis of the applicable items that pertain to the safe operation of therapy units. The committee thought that it might be better to list out the IEC requirements rather than have the registrants have to purchase the document themselves to identify the items necessary to meet compliance. Margie noted that she checked about federal requirements, and found out that the FDA does not provide regulations for therapy units as it does with diagnostic RGE.

Paragraph (F) was reviewed with several decisions made: 1) use the term “dose rate” instead of “dose monitor unit rate” in the opening statement; 2) delete the second subparagraph since this requirement does not exist in our current therapy rules since adding it in would be making the new rule less stringent; and 3) deleting subparagraph (3)(a) since it is not applicable.

As the meeting time was ending, the committee ended the review of this rule. Chuck Wissuchek made a recommendation to move shielding and room design paragraphs (N) and (O) of rule 67-05 and paragraph (Q) of 67-06 into the Appendix of rule 67-08 and to organize the requirements by energy levels. It was also recommended that all QA requirements listed in rule 67-05 and 67-06 be moved into rule 67-09. Specifically, paragraphs (P) & (Q) from 67-05, and paragraphs (R), (T), (U) & (V) should be moved from 67-06 to encompass all quality assurance requirements for all simulation & therapy equipment into 67-09.

**New Business:** There was no new business.

**Future Meeting Dates:** The next meeting will be held on April 9, 2010 to finish review of the 67-06 and 67-01 rules. The members decided to work on the review of the new drafts which will incorporate moving the shielding and quality assurance requirements to draft rules 67-08 and 67-09 in between the next meeting to assure that immediately following that meeting the rules can be put out for public comment. Plus, Larry offered to review the IEC 60601-2-1 document and determine what standards are applicable to the 67-05 and 67-06 rules.

Tentative dates for reviewing the public comments were set for Monday May 24, 2010 and Friday June 4, 2010.

**Adjourn:** The meeting was adjourned at approximately 3:00 p.m.