

Radiation-generating Equipment Committee (REC)

June 4, 2010

Approved Minutes

MEMBERS PRESENT

Lawrence Osher, Chair
Kerry Krugh, Vice Chair
Jack Dukes
Chuck Wissuchek
Nina Mayr
Ruth Hackworth

MEMBERS ABSENT

Mary Ann Accorinti
Thomas Hangartner
Nina Kowalczyk
Kathryn Gardner
Brenda Johnson
Teresa Yates

GUESTS

Rick Sites, OHA
Ron Droege, MRP, Inc.

ODH ATTENDEES

David Lipp
Margie Wanchick

The Radiation-generating Equipment Committee (REC) meeting was called to order by chairperson, Larry Osher at 10:10 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 official record of attendance.

Past Minutes: The committee reviewed the April 9, 2010 minutes. Jack Dukes made a motion to accept the minutes with one typo correction; Nina Mayr and Chuck Wissuchek seconded it, and the members present unanimously approved the motion.

Old Business:

Status of Rules: Chapter 66 & 67

Margie Wanchick distributed an April 2010 version of the X-ray Rule Status Log for the new Chapter 3701:1-67 therapy rules and the Chapter 3701:1-66 rules. She explained that the only remaining rules to finish for Chapter 67 were Electronic Brachytherapy (67-10) and the Other Uses of Electronically-produced Radiation rules which are emerging technology and currently do not exist in the current x-ray therapy rules 3701:1-66-14 & 15. Also, several rules in Chapter 3701:1-66 need to begin the 5-year rule review process soon as they must be in Public Health Council by January 2011. These include Certified Radiation Expert (66-03), General Radiographic Equipment (66-05), Industrial Analytical RGE (66-13), and Industrial Particle Accelerator (66-17).

Review of Public Comments for Chapter 3701:1-67 Therapy Rules

The committee began its review of the public comments. Ron Droege presented his own comments since he attended the meeting. There was a long discussion about his general comments relating to “manufacturing standards” and required testing of these standards. The committee members explained that the tests for certain equipment standards, such as leakage, need to be met, but not necessarily tested by the qualified medical physicist. The committee recommended that paragraph (E)(3)(b) of rule 67-09 be changed to delete “acceptance testing and” from the first sentence. The following changes were recommended based on Ron Droege’s comments:

- Modify 3701:1-67-02(I)(4) – Signature of ~~person~~ qualified medical physicist or authorized individual as delineated in the facility’s quality assurance manual authorizing the return of the

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therapy equipment to clinical use after any service or intervention that affects patient treatment, or after repair or upgrade.

- Add new subparagraph (2) into 3701:1-67-03 (F) — Until implementation of any administrative control to reduce the radiation levels below the respective limits.
- Change subparagraph (a) in 3701:1-67-04(C)(3) to read – ~~Checking both primary and secondary dose calculations~~ the parameters and the results of the primary dose calculation with a secondary method to verify.....
- Add to paragraph (D)(1) of rule 3701:1-67-07 – If not calibrated by the ADCL, a description...
- Change paragraph (E)(8) of rule 3701:1-67-09 to read – Therapy equipment subject to the requirements of this rule shall have applicable safety quality assurance checks as listed in the AAPM report 46 performed at intervals ~~not to exceed one week~~ as prescribed in the QA manual.
- Delete paragraph (B)(4) of rule 3701:1-67-12.
- Change paragraph (C) of 3701:1-67-12 to be like the SSR language, except for retaining the term “treatment plan” instead of “written directive” – Any unintended deviations from the treatment plan is identified, evaluated and appropriate action is taken.

The following changes were recommended based on Patrick Diltz’s comments:

- Change paragraph (B) of rule 3701:1-67-08 – ~~As~~ After six months of the effective date ...

The following changes were recommended based on Chris Deibel’s comments:

- The committee was not sure about what did not make sense about paragraph (D)(5) of rule 67-02. Margie thought that maybe the word “hold” before “certification” was missing. Or was the requirement redundant? ODH will research and clarify the language.
- Add exemption to paragraph (C)(1) of rule 3701:1-67-08 - No individual, other than the patient, shall be in the treatment room..... purposes except as provided in paragraph (R)(6) of rule 3701:1-67-05.
- Replace “at intervals not exceeding one year” to “annually in paragraph (D)(1)(b) in rule 3701:1-67-09 and 67-05(P). Any other rules containing the term “one year” will also be changed
- Change paragraph (E)(8) of rule 3701:1-67-09 to read – Therapy equipment performed at intervals ~~not to exceed one week~~ as prescribed in the quality assurance manual.

The following changes were recommended based on Valdir Colussi’s comments:

- Definition for “conventional simulator” and “simulator” will be consolidated into one definition
- Add “name and” before “signature” in paragraph (P)(3)(d) of rule 3701:1-67-05 and any other rule requiring a signature.
- Typo in paragraph (B) of rule 3701:1-67-09 – “tot” should be “to
- Delete paragraph (B)(4) in rule 3701:1-67-12 – ~~The calculated dose administered to critical organs differs from the prescribed dose.....as determined by the prescribing physician.~~

Margie explained that the bureau conducted their internal review of the rule drafts during the public comment period also. This resulted in: 1) finding several spelling typos and rule reference errors which need to be corrected; 2) including the addition of omitted standards found in current rules 66-14 & 15, (i.e., requiring a warning label on all therapy equipment, being able to use interview and use observation to determine that the handler assures competency and adequate safe operating instructions to the therapists, ; 3) finding that existing 66-14 & 15 therapy rules permitted the medical physicist to vary the

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testing procedure and frequency for quality assurance tests, but not for the accepted tolerances; therefore, “accepted tolerances” in the 3rd sentence in paragraphs (B) and (D)(2) of draft rule 67-09 will be deleted; 4) the Department reserving the right to organize the final paragraphs of the rules, and depending on the organization of that, change rule titles as they deem necessary and appropriate. David Lipp is waiting for a response from the IEC regarding whether ODH can use specific IEC language (i.e., is it legally permitted?). If not, the Department may be forced to just use the reference in the same manner as used in the SSR Part X.

New Business:

Distribution of Draft Therapy Rules:

Margie distributed the last two drafts of new therapy rules 67-10 Electronic Brachytherapy and 67-11 Other Uses of Electronic Therapy.

Future Meeting Dates: August 6, 2010 and tentatively September 10, 2010

Adjourn: The meeting was adjourned at 5:30 p.m.