

Radiation-generating Equipment Committee (REC)

February 5, 2010

Minutes

MEMBERS PRESENT

Lawrence Osher, Chair
Kerry Krugh, Vice Chair
Chuck Wissuchek
Thomas Hangartner
Ruth Hackworth
Jack Dukes

MEMBERS ABSENT

Mary Ann Accorinti
Nina Mayr
Kathryn Gardner
Brenda Johnson
Teresa Yates
Nina Kowalczyk

GUESTS

Thavendra Rajah, Mt Carmel

ODH ATTENDEES

Margie Wanchick
James Castle
Jean Hardy

The Radiation-generating Equipment Committee (REC) meeting was called to order by chairperson, Larry Osher at 10:30 a.m. The meeting was held at the Ohio Department of Health (ODH) in the 7th Floor Conference Room B 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 January 8, 2010 minutes. Tom Hangartner made a motion to accept the minutes as written; Larry Osher seconded it, and the members present unanimously approved the motion.

Old Business:

Status of Rules

Margie Wanchick distributed a February 2010 version of the X-ray Rule Status Log for the new Chapter 3701:1-67 therapy rules. The superficial therapy draft rule 67-05 is currently under REC review and should be finished today. The higher energy therapy rule (Draft rule 67-06) is ready to be started at today's meeting. The Definitions draft rule 67-01 is still under construction and will be ready for the next meeting. Draft rules 67-01 to -09 and 67-12 rules are expected to be posted on the website to elicit public comment in April. 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.

Follow-up on recommendation for nuclear medicine QA regulations

Larry Osher reported that a discussion regarding this subject took place at the January 15 RAC meeting. The RAC members did not propose to take any action on the matter. The REC members reiterated the rationale for pursuing QA requirements for nuclear medicine. Larry agreed to contact the Radioactive Material Committee (RMC) chairperson, Susan Hiatt, and ask her to have the topic addressed in more detail to the RMC members. Larry will compile the documentation for the rationale from the REC members and forward it on to Susan.

Follow-up on several rule issues Margie researched

Margie distributed a handout containing several rule discussion points that she researched which contained the Bureau of Radiation Protection's recommendation. REC accepted the following changes:

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67-03(F) If the results of the surveys required by paragraphs (A) to (D) of this rule indicate any radiation levels in excess of the respective limits, the handler shall lock the control in the "OFF" position and not use the unit for patient care:

(1) Except as may be necessary to repair, replace, or test the therapy equipment, the therapy equipment shielding, or the treatment room shielding; or

(2) Until the handler has received a specific exemption from the department.

[Noted: REC did not prefer the term "lock" in this paragraph because lock implies a key is needed and not all therapy equipment has a key]

67-08 (B) As of the effective date of this rule, facility design information for the first installation of therapy equipment, or other installations of therapy equipment of higher energy into the same room at the facility, shall be conducted by a qualified medical physicist and submitted to the Department prior to actual installation of the therapy equipment. The minimum facility design information that must be submitted is contained in the appendix to this rule.

67-08(C) Delete this paragraph since paragraph (A) of this rule requires that rules 38-12 and 38-13 be met which considers any factors that change regarding survey requirements

67-08 Appendix A

I. C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

67-09

(A) Quality assurance tests for a conventional or virtual simulator shall be conducted by, or under the supervision and in the presence of, a qualified medical physicist.

(B) A quality assurance program shall be developed by the qualified medical physicist and shall include specific measurements to be performed, frequency of the measurements, and the acceptable tolerance for each parameter measured. The qualified medical physicist shall use the "American Association of Physicists in Medicine" reports as listed within this rule as the basis for the quality assurance program. Any variation from the testing procedure, frequency, or accepted tolerance for each parameter measured shall be based upon the therapy equipment performance, and shall be documented in the quality assurance manual. The quality assurance program shall be reviewed annually by the designated qualified medical physicist. This annual review and any changes made to the quality assurance program shall be documented and submitted to the facility's IRRP or the facility's administration if the designated IRRP is the facility's qualified medical physicist, or to the facility's QA committee if it is a hospital.

C) Quality assurance tests as required by paragraph (A) of this rule shall:

(1) Include acceptance testing and periodic verification of system performance; and

(1) Be performed in accordance with "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group No.40: AAPM Report No. 46" for a conventional simulator; or

(2) Be performed in accordance with "Quality assurance for computed tomography simulators and the computed tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66: AAPM Report No. 83" for a virtual simulator.

67-12 (A) Other than misadministrations that result from intervention by a patient or human research subject, a handler shall report any event in which the administration of radiation from therapy equipment involves the wrong patient, wrong treatment, or wrong treatment site; or any one of the following:

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- (1) The calculated weekly administered dose differs from the weekly prescribed dose as prescribed in the treatment plan by more than thirty per cent;
- (2) The calculated total administered dose differs from the total prescribed dose as prescribed in the treatment plan by more than twenty per cent of the total prescribed dose;
- (3) The calculated total administered dose differs from the total prescribed dose in the treatment plan by more than ten per cent of the total prescribed dose for treatments consisting of three or fewer fractions; or
- (4) The calculated total administered dose to critical organs differs from the prescribed dose in the treatment plan by a significant amount as determined by the prescribing physician.

The above rules will be updated and distributed at the next meeting.

New Business:

State e-notification system for rules

The state of Ohio has instituted a web-based application for notifying interested parties in view and commenting on rules for all agencies.

Draft Rule 67-05

The committee continued to review and edit draft rule **67-05 Technical Requirements for Therapy Equipment Operating at Less than 500 kV** starting with paragraph (P) where they left off during the last meeting. The edited version will become a permanent part of these minutes.

Draft Rule 67-06

The committee started 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**. There was question and discussion about the need for “leakage radiation” requirements. Margie offered to research why there was a requirement to measure leakage radiation (i.e., the absorbed dose due to leakage radiation (except neutrons) outside the maximum useful beam and through beam limiting devices).

Future Meeting Dates: April 9, 2010

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

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3701:1-67-05 Therapy equipment operating at less than five hundred kilovoltage.

As used in this rule, “therapy equipment” means therapeutic radiation-generating equipment operating below five hundred kilovoltage. In addition to the applicable rules adopted pursuant to Chapter 3701:1-38 and this chapter of the Administrative Code, handlers of therapy equipment shall comply with the following:

- (A) When the x-ray tube is operated at its maximum rated tube current for the maximum kilovoltage (kV), the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapy equipment:
 - (1) For five kV to fifty kV systems, the leakage air kerma rate measured at any position five centimeters from the tube housing assembly shall not exceed one milligray (one hundred millirad) in any one hour.
 - (2) For greater than fifty kV and less than five hundred kV systems, the leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed one centigray (one rad) in any one hour. This air kerma rate measurement may be averaged over areas no larger than one hundred square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed thirty centigray (thirty rad) per hour.
 - (3) For each piece of therapy equipment, the handler shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in paragraphs (A)(1) and (A)(2) of this rule for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the department.
- (B) Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.
- (C) Requirements for adjustable or removable beam limiting devices include:
 - (1) All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than five per cent of the useful beam for the most penetrating beam used; and
 - (2) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

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- (D) The filter system shall be so designed that:
- (1) Filters can not be accidentally displaced at any possible tube orientation;
 - (2) An interlock system prevents irradiation if the proper filter is not in place;
 - (3) The air kerma rate escaping from the filter slot shall not exceed one centigray (one rad) per hour at one meter under any operating conditions; and
 - (4) Each filter shall be marked as to its material of construction and its thickness.
- (E) Requirements for tube immobilization include:
- (1) The x-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and
 - (2) The tube housing assembly shall be capable of being immobilized for stationary portal treatments.
- (F) The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.
- (G) Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at one hundred kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.
- (H) A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.
- (1) A timer with a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator;
 - (2) The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

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- (3) The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;
 - (4) The timer shall permit accurate pre-setting and determination of exposure times as short as one second;
 - (5) The timer shall not permit an exposure if set at zero;
 - (6) The timer shall not activate until the shutter is opened if irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and
 - (7) The timer shall be accurate to within one per cent of the selected value or one second, whichever is greater.
- (I) The control panel, in addition to the displays required by other provisions in this rule, shall have:
- (1) An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
 - (2) An indication of whether x-rays are being produced;
 - (3) A means for indicating x-ray tube potential and current;
 - (4) The means for terminating an exposure at any time;
 - (5) A locking device which will prevent unauthorized use of the therapeutic radiation machine; and
 - (6) A positive display of specific filter(s) in the beam.
- (J) When a control panel may energize more than one x-ray tube:
- (1) It shall be possible to activate only one x-ray tube at any time;
 - (2) There shall be an indication at the control panel identifying which x-ray tube is activated; and
 - (3) There shall be an indication at the tube housing assembly when that tube is energized.
- (K) There shall be a means of determining the central axis target-to-skin distance (TSD) to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

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- (L) Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.
- (M) Therapy equipment having a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high
- (N) In addition to having shielding adequate to meet requirements of rule 3701:1-67-08 of the Administrative Code, the treatment room design shall provide for:
 - (1) Continuous two-way aural communication between the patient and the operator at the control panel; and
 - (2) Permit continuous observation of the patient during irradiation. This viewing system shall be so located that the operator can observe the patient from the control panel. Therapy equipment shall not be used for patient irradiation unless at least one viewing system is operational.
- (O) Treatment rooms that contain therapy equipment capable of operating above one hundred fifty kV shall meet the following additional requirements:
 - (1) All protective barriers shall be fixed except for entrance doors or beam interceptors;
 - (2) The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room; and
 - (3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
- (P) Requirements for full calibration of therapy equipment subject to this rule include:
 - (1) Full calibration of therapy equipment shall be performed by, or under the supervision and in the presence of, a qualified medical physicist:

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- (a) Before the first medical use following installation or reinstallation;
 - (b) At intervals not exceeding one year; and
 - (c) Before medical use under the following conditions:
 - (i) Whenever quality assurance check measurements indicate that the radiation output differs by more than five per cent from the value obtained at the last full calibration and the difference cannot be reconciled; and
 - (ii) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.
 - (d) Notwithstanding the requirements of paragraph (P)(1)(c) of this rule:
 - (i) Full calibration of therapy equipment with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and
 - (ii) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in paragraph (P)(1)(c)(i) of this rule.
 - (iii) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam, the appropriate part of the full calibration shall be performed prior to irradiation of a patient.
- (2) To satisfy the requirement of paragraph (P)(1) of this rule, a quality assurance program shall be developed by the qualified medical physicist and shall include specific measurements to be performed, frequency of the measurements, and the acceptable tolerance for each parameter measured. The qualified medical physicist shall use the “National Council of Radiation Protection (NCRP) report 69, Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV (1981),” as listed within this rule as the basis for the quality assurance program. Any variation from the

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NCRP report 69 testing procedure, frequency, or accepted tolerance for each parameter measured shall be based upon the therapy equipment performance, and shall be documented in the quality assurance manual. The quality assurance program shall be reviewed annually by the designated qualified medical physicist. This annual review and any changes made to the quality assurance program shall be documented and submitted to the facility's IRRP or the facility's administration if the designated IRRP is the facility's qualified medical physicist, or to the facility's QA committee if it is a hospital.

- (3) The handler shall maintain a record of each calibration for the duration of the registration. The record shall include:
- (a) The date of the calibration;
 - (b) The manufacturer's name, model number, and serial number for both the therapy equipment and the x-ray tube;
 - (c) The model numbers and serial numbers of the instruments used to calibrate the therapy equipment; and
 - (d) The signature of the qualified medical physicist responsible for performing the calibration.

(Q) Requirements for periodic quality assurance checks include:

- (1) Periodic quality assurance checks shall be performed on therapy equipment subject to this rule;
- (2) To satisfy the requirements of paragraph (Q)(1) of this rule, quality assurance checks shall meet the following requirements:
 - (a) The registrant shall perform quality assurance checks in accordance with written procedures established by the qualified medical physicist; and
 - (b) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in paragraph of (P)(1) of this rule. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in paragraph of (P)(1) of this rule, shall be stated;

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- (3) The cause for a parameter exceeding a tolerance set by the qualified medical physicist shall be investigated and corrected before the system is used for patient irradiation;
- (4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the qualified medical physicist's quality assurance check procedures, the system shall be recalibrated as required in paragraph of (P)(1) of this rule;
- (5) The handler shall use the dosimetry system described in paragraph (I) of rule 3701:1-67-03 of the Administrative Code. to make the quality assurance check required in paragraph (Q)(2) of this rule;
- (6) The handler shall have the qualified medical physicist review and sign the results of each radiation output quality assurance check within thirty days of the date that the check was performed;
- (7) The handler shall ensure that safety quality assurance checks of therapy equipment subject to this rule are performed at intervals not to exceed thirty days or prior to use if not used monthly;
- (8) To satisfy the requirement of paragraph (Q)(7) of this rule, safety quality assurance checks shall ensure proper operation of:
 - (a) Electrical interlocks at each external beam radiation therapy room entrance;
 - (b) The "BEAM-ON" and termination switches;
 - (c) Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room; and
 - (d) If applicable, electrically operated treatment room doors from inside and outside the treatment room; and
- (9) The handler shall maintain a record of each quality assurance check required by paragraphs (Q)(1) and (Q)(7) of this rule for three years. The record shall include:
 - (a) The date of the quality assurance check;
 - (b) The manufacturer's name, model number, and serial number of the therapy equipment;

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- (c) The manufacturer's name, model numbers and serial numbers for the instrument(s) used to measure the radiation output of the therapy equipment; and
 - (d) The signature of the individual who performed the periodic quality assurance check.
- (R) Requirements for operating procedures include:
- (1) The therapy equipment shall not be used for irradiation of patients unless the requirements of paragraphs (P) and (Q) of this rule have been met;
 - (2) Therapy equipment shall not be left unattended unless secured pursuant to paragraph (I)(5) of this rule;
 - (3) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;
 - (4) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed fifty kV. In such cases, the holder shall wear protective gloves and an apron of not less than 0.5 millimeters lead equivalency at one hundred kV;
 - (5) A copy of the current operating and emergency procedures shall be maintained at the therapy equipment control console; and
 - (6) No individual other than the patient shall be in the treatment room during exposures from therapy equipment operating above one hundred fifty kV. At energies less than or equal to one hundred fifty kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of rule 3701:1-38-12 of the Administrative Code.
- (S) Each facility location authorized to use therapy equipment in accordance with this rule shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range ten microsieverts (one millirem) per hour to ten millisievert (one thousand millirem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with rule 3701:1-67-07 of the Administrative Code.