

Radiation-generating Equipment Committee (REC)
February 13, 2009
Minutes

MEMBERS PRESENT

Lawrence Osher, Chair
Sally Baden
Thomas Hangartner
Jack Dukes
Mary Ann Hargrove
Chuck Wissuchek
Nina Kowalczyk
Brenda Johnson
Teresa Yates

VISITORS

Rick Sites, OHA
Jill Paessun, Mt. Carmel
Susan Suchan, Mt. Carmel

MEMBERS ABSENT

Ruth Hackworth
Richard Dehner
Kerry Krugh

ODH ATTENDEES

Robert Owen
James Castle
David Lipp
Stephen Helmer
Margie Wanchick

The Radiation-generating Equipment Committee (REC) meeting was called to order by the chairperson, Larry Osher, at 10:10 a.m. The meeting was held at the Ohio Department of Health (ODH) in the Basement Boiler Room at 246 N. High Street, Columbus, Ohio. The Sign-in Sheet serves as the Roll Call and official record of attendance.

Past Minutes: The committee reviewed the October 3, 2008 minutes. Jack Dukes made a motion to accept the minutes with the noted edits identified during this meeting; Brenda Johnson seconded it, and the committee unanimously approved the motion.

Old Business:

All Rules Status - Margie Wanchick distributed an updated "X-ray Rule Status Log" (dated 2/13/09) and explained the latest progress of the rules being revised. The Quality Assurance rule 66-04 was passed and became effective on 12/22/08. A copy of this rule was distributed to the members to keep in their rule notebook. Margie noted that all the final rules are posted on the ODH website and can be printed out. A public hearing was held for the six other rules (Dental, Fluoroscopy, Mammography, CT, BD and Industrial Radiography) sent to the Public Health Council (PHC). In addition to a written testimony of support from Larry Osher and Kerry Krugh, there were two testimonies given regarding the fluoroscopy rule from Paul Johnson and Rick Sites, and one testimony regarding the dental (handheld) rule from Doug Harding. The final vote for approval to adopt will be held at the PHC meeting on March 26, 2009. Margie noted that, following the review of the Definitions and General Administration (GA) rule, the bureau plans to initiate the plan of separating out the Industrial and Therapy rules into separate chapters in the Administrative Code. This will allow each user group (i.e., medical, industrial and therapy) to have their own set of Definitions and will make it easier for these types of users to identify and reference their applicable rules.

Subcommittee to address specialty CT units – Margie reported that the subcommittee has not formed yet. The original plan was to bring the group together to make recommendations to the new CT rule. The new CT rule is not scheduled for approval until the PHC March 26 meeting. Therefore, the subcommittee will be formed after the new CT rule goes into effect.

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New Business:

Review Inspection Rule 3701:1-38-04 - Robert Owen explained the rationale for the fee increases being presented for review. This 20% fee increase is in line with the governor's plan to increase just about all state fees across the board. The Department is trying to have these fees take effect as close as possible to July 1, 2009 which is the date that the fees in statute will go into effect because some fees, such as medical practitioners, can be changed only through the state's biennial budget bill. Regardless of the governor's plan driving the fee increase amounts, the Department still wants the fees in the rules to follow the usual process, starting at the REC for recommendations, going through a public comment period, and requesting approval from RAC. Then, the rules would proceed to PHC and JCARR for adoption.

Margie Wanchick passed out a copy of the Inspection rule that only included changes to increase the fee amounts and to include the unregistered handler and review of shielding plans fees into Appendix B, of which the latter were not previously listed, but should have been. The committee had a long discussion about the impact of the fee increases on the registered facilities, considering that most facilities do not have the same option of increasing their fees for services, especially those that are driven by the healthcare industry. There were questions of concern about: 1) whether the operating costs for the program have truly gone up by 20% since the last fee increase in 2003 to justify the increase; and 2) would the increased revenue be guaranteed to stay within the Department and be used only to fund the x-ray inspection program. Overall, the committee was concerned that the mission of the program could be compromised if the fees were not increased. With these questions and concerns, the committee requested that the bureau provide the radiation advisory members with budget information to include revenue and expenses up through the next biennium. They requested that this data be available to them to review at the March 17 meeting. Margie explained that the Department was prepared to put the rule out on the ODH website today for a 30-day public comment, with the comment period shortened to meet the deadlines for the PHC and JCARR timelines. The Department is trying to have the rule ready for PHC to approve as close to July 1, 2009 as possible since the state budget bill will be in effect on that day. Sally Baden made a motion to accept the edited Inspection rule as is and put it out for public comment; Chuck Wissuchek seconded the motion. The committee passed the motion unanimously.

Review Definitions Rule 3701:1-66-01 - Margie Wanchick provided a copy of the existing rule and the bureau's recommendations. Each item was discussed and determined whether to accept, not accept, or accept with modification. A copy of the bureau recommendations and the REC's decisions will remain an attachment to these minutes as a permanent part of the record.

Future Meeting Dates: Margie Wanchick requested that the committee set up future meeting dates in line with the timelines necessary to review the public comments from the rules reviewed. The following were agreed to be the best dates from the majority of members present.

March 17, 2009 - Special meeting, if necessary, to review public comments on the Inspection rule fee changes is scheduled from 10:00- 12:00 noon preceding the afternoon RAC meeting.

May 1, 2009 – to finish review of the Definitions and GA rules

July 10, 2009 – to review public comments for the Definitions and GA rules

Adjourn: The meeting was adjourned at approximately 2:45 p.m.

Recommendations for Definitions rule amendments (3701:1-66-01)

Prepared for REC meeting on February 13, 2009

Red text added following the 2/13/09 REC meeting

Add New Definitions

“**Air Kerma Rate or (AKR)**” means the air kerma per unit time.

Rationale: Taken from the new version of the SSR (also see new definition for “kerma.” below)

REC Decision: **Accepted**

“**Annual**” means at least once a year not to exceed fourteen months.

Rationale: Discussed during 2008 REC rule reviews.

REC decision: **Accepted**

“**Dose**” means a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed effective dose equivalent, or total effective dose equivalent as defined in rule 3701:1-38-01 of the Administrative Code.

Rationale: Discussed during 2008 REC rule reviews; to be defined the same as 3701:1- 38-01(A)(50)

REC decision: **Not accepted; the definition in Ch. 38 will remain applicable to Ch 66.**

“**Fluoroscopic irradiation time**” means the cumulative duration ~~of during an examination, or procedure of operator applied continuous pressure to the device, enabling~~ x-ray tube activation in any fluoroscopic mode of operation.

Rationale: Taken from the new SSR.

REC decision: **Accepted with edits as shown above.**

“**Hand-held radiation-generating equipment**” means x-ray equipment that is **specifically** designed to be ~~hand-held~~ **held in the hand** during operation.

Rationale: Taken from new SSR.

REC decision: **Accepted with edits as shown above.**

“**Image Receptor**” means any device, ~~such as fluorescent screen, radiographic film, x ray image intensifier tube, solid state detector or gaseous detector which~~ **that** transforms incident x-ray photons ~~either into~~ **into either** a visible image or ~~into~~ another form ~~which that~~ can be made into a visible image by further transformation. In those cases, where means are provided to preselect a portion of the image receptor, the term “image receptor” ~~shall~~ **means** the preselected portion of the device.

Rationale: Taken from new SSR.

REC decision: **Accepted with edits as shown above.**

“**Interventional procedure**” means **an invasive procedure that utilizes radiation-generating equipment for diagnostic or therapeutic purposes.**

Rationale: Stuart Kline from CCF recommended that we define this term (from his public comment while reviewing the fluoroscopy rule).

REC decision: **This definition was developed by REC.**

“**Kerma**” means the quantity defined by the “International Commission on Radiation Units and Measurements” where kerma (K) is the quotient of dE_{tr} by dm, where DE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm

Recommendations for Definitions rule amendments (3701:1-66-01)

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of material; thus $K=dE_{tr}/dm$, in units of J/kg, where the special name for the unit of kerma is gray(Gy). When the material is air, the quantity is referred to as “air kerma”.”

Rationale: Taken from new SSR.

REC decision: Not accepted; only the term “air kerma” is used in the rules and there is a definition for that. REC also believes that the radiation experts know the standard formula.

“Lateral fluoroscope” means ~~the portion of a biplane system consisting of an x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral~~ **an image receptor that are fixed in position to produce a horizontal x-ray beam.** ~~relative to the table with the x-ray beam axis parallel to the plane of the field.~~

Rationale: Taken from the new SSR.

REC decision: Accepted as shown above.

Delete Existing Definitions

~~“Industrial irradiation devices” means radiation-generating equipment used to alter the chemical, biological, or physical properties of materials or to sterilize materials.~~

Rationale: Redundant; already defined in rule 3701:1-66-12, and planning to move Industrial rules to another OAC chapter.

REC decision: Accepted

~~“Industrial radiation-generating equipment” means x-ray machines used to produce ionizing radiation for purposes other than dental, veterinary, medical or therapeutic uses on patients.~~

Rationale: Redundant; already defined in rule 3701:1-66-12, and planning to move Industrial rules to another OAC chapter.

REC decision: Accepted

Modify Existing Definitions 66-01(B)

(6) “Coefficient of variation”

Proposed Change: replace “ a sample” with “population” ... ”

Rationale: New SSR wording

REC decision: Accepted a change in the definition as follows: “Coefficient of variation” means the ratio of the standard deviation to the mean value of the observations.

(9) “Computed Tomography,” or “CT”

Proposed Change: Delete quotations around CT and replace with parentheses (CT)

Rationale: Recommendation made from REC reviewing CT rule last year.

REC decision: Accepted

(19) “Executive Administration”

Proposed Change:

“Executive administration” means individuals who belong to the two highest levels of authority within the hospital as listed on the hospital’s organizational chart. The highest level may include

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~~the president, chief executive officer, or hospital administrator. The second level may include vice president, chief financial officer, or an administrative director of hospital services groups employed at the highest levels of a hospital's administration and having the authority to expend capital funds, approve personnel actions, and implement changes to hospital policy and procedure. Executive administration may includes the president, chief executive officer, vice president, chief financial officer, and administrative director of hospital services. Executive administration may~~ **does** not include department heads and managers.

Rationale: As discussed by REC during the 2008 review of the QA rule, paragraphs (C)(3) &(4), the definition should better clarify and match the role of the hospital administrator to keep the authority of the position on the QA committee at the proper level.

REC decision: **Accepted as edited above.**

(21) Half-Value Layer, or "HVL"

Proposed Change: "Half-Value Layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate AKR is reduced by one-half of its original value. ~~The contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.~~

Rationale: As written in the new SSR.

REC decision: **Accepted as edited above.**

(25) Individual responsible for radiation protection (IRRP)

Proposed Change: Put the acronym in parentheses rather than in quotes. Specify specifics for qualifying to be an IRRP in preparation for new therapy, industrial chapters, and for general diagnostic in rule 66-02.

Rationale: The Industrial and Therapy rules will be put into their own chapters. The IRRP currently has no restrictions or qualifications for acting in this role.

REC decision: **Accepted a change in the definition be more in line with the RSO for Nuclear Materials, as follows: "Individual responsible for radiation protection (IRRP)" means an individual designated by the registrant who has the knowledge and responsibility for overall radiation safety and the quality assurance program at the facility, to include daily radiation safety operations and compliance with the rules.**

(40) Mobile

Proposed Change: "Mobile radiation-generating equipment" means x-ray equipment **permanently** mounted on a ~~permanent~~ base with wheels or ~~installed in a van, trailer, or mobile vehicle~~ castors for moving while completely assembled and is not used in a fixed location.

Rationale: In line with SSR; differentiates the mobile "RGE" from the mobile "type" of facility.

REC decision: **Accepted as edited above.**

(44) Patient

Proposed Change: "Patient" means an individual or animal subjected to radiation for the purposes of a radiographic ~~diagnosis, or examination, or therapy~~ **treatments**.

Rationale: Clarification.

REC decision: **Accepted as edited above.**