Radiation-Generating Equipment Committee (REC)
September 21, 2018
Meeting Minutes

MEMBERS PRESENT	MEMBERS ABSENT	ODH ATTENDEES
Fisher, Douglas	Kathryn Gardner	James Castle
Jonathan Fortkamp	Ruth Hackworth	Chad Lehman
Bob Friedman	Linnea Hopewell	Caitlin Wuerthner
Paul Geis	Verma Sadhna	Mahjabeen Qadir
John Grecula		Gene Phillips
Paul Johnson		Rebecca Fugitt
Kerry Krugh, Vice Chair		
Christopher Mitchell		
Bryan Murray		
Lawrence Osher, Chair		
Mike Strongosky		
Susan Suchan		
Chuck Wissuchek		

GUESTS
Mike C. Fair, Radiation Advisory Council
Kevin Wunderle, Cleveland Clinic
David Hintenlong, Ohio State University
Kevin Little, Ohio State University
Michael Evans, Cleveland Clinic
Sven Gallo, Promedica
Priya Rayqdurgam, Cleveland Clinic
Frank Dong, Cleveland Clinic
Dramane Konate, Ohio State University
Jacob Burlingame, Ohio State University
Trisha Coffman, Mount Carmel Health System

The Radiation-Generating Equipment Committee (REC) meeting was called to order by chairperson, Lawrence Osher at 10:05am. The meeting was held at the Ohio Department of Health (ODH), Basement Training Room A, 35 E. Chestnut Street, Columbus, Ohio 43215. The sign-in sheet serves as the official record of attendance.

Past Minutes:
The committee reviewed the November 3, 2017 meeting minutes. Chuck Wissuchek made a motion to accept the minutes as written. Kerry Krugh seconded the motion; the members present unanimously approved the minutes.

Current Business:
Five-year review status update:

- General Radiation Protection Standards for Sources of Radiation, Ohio Administrative Code (O.A.C.) Chapter 3701:1-38 is due for five-year review by ODH and REC beginning January 2019.

- Therapy Radiation-Generating Equipment, O.A.C. Chapter 3701:1-67 is due for five-year review by ODH and REC beginning May 2019.

- Non-Medical Radiation-Generating Equipment, O.A.C. Chapter 3701:1-68 is due for five-year review by ODH and REC beginning February 2021.

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Suggested State Regulations (SSRs)

- Explanation to members and public stakeholders at the meeting:
  - The Ohio Revised Code (O.R.C.) requires the Ohio Department of Health (Department) to be as stringent as the SSRs.
  - The Department is committed to talking through the items of concern to see if the rules can be modified to provide alternative methods to meet the SSRs.

- REC and stakeholder comments at the meeting:
  - Kevin Wunderle stakeholder – the O.R.C language to be as stringent as the SSRs defeats the purpose of having this committee and open forum to discuss revision to the rules. The task groups are made up of a small number of individuals. The SSRs are not open to public comment. The O.R.C. language ties the hands of the Director from varying from a SSR requirement when needed. Many of the stakeholders' present echoed the same concerns.
  - Chuck Wissuchek REC member – I have been wanting to get the language changed for around 20 years. Medical physicists are not that involved with the SSR Tasks groups. Bryon Murray interjected stating that he believes medical physicists are consulted on the SSR Task Groups. After the interjection, Chuck stated, that he did not mean that medical physicists were not involved but the CRCPD doesn't spend nearly as much time and effort writing the SSR's as REC does writing the rules.

O.A.C. 3701:1-38-04, Radiation-Generating Equipment Inspection Schedule and Fees:

- No public comments received. This was a no change rule.

- Bryon Murray made a motion to approve O.A.C. rule 3701:1-38-04 to move forward to the Radiation Advisory Committee (RAC). Paul Johnson seconded the motion; the REC members present unanimously approved the draft rule to move forward to RAC.

O.A.C. Chapter 3701:1-66 public comment review and discussion with REC and the stakeholders present at the meeting - Blue text identifies rule change:

- **O.A.C. 3701:1-66-01:**
  - REC no change. The "or" in definition is a rule writing convention.

  - Old (B)(4) "Annual" - REC ok and voted to use the definition of 'annual' as defined in rule Chapter 3701:1-38-01 to align with definition in the Code of Federal Regulations and Nuclear Regulatory Commission.

  - Old (B)(27) – REC ok to remove definition of handler from rule 3701:1-66-01. The definition of "handler" is already defined in O.A.C. 3701:1-38-01.

  - (A)(6) "Bone densitometry equipment" - REC ok to change the word from "intended" to "used" to be consistent with the other definitions in the Chapter.
    - "Bone densitometry equipment" means radiation-generating equipment ~~intended~~ used for the medical purpose of quantifying bone density and mineral content by x-ray measurements through the bone and adjacent tissues.

  - (A)(20) "Digital Radiography" – REC remove the last sentence containing flat panel from the definition to remove confusion.
    - "Digital radiography" or "(DR)" means an x-ray imaging method which produces a digital rather than analog image. ~~DR includes both computed radiography and flat-panel based image receptors.~~

- (A)(27) REC proposed to remove the wording "at a medical facility" and "direct."
  - "Full time training in medical physics" means having been engaged in the practice of clinical medical physics for a minimum of eighteen hundred hours within twelve consecutive months ~~at a medical facility~~, under the ~~direct~~ supervision of a board-certified medical physicist.

- (A)(28) "Full time work experience" – REC no change, Keep current definition.

- (A)(29) "Fluoroscopically-guided interventional (FGI) procedures" - REC no change keep definition but reorganize alphabetically.

- (A) (35) "Image intensifier" – REC no change. Keep current definition.

- (A)(46) "Medical Event" – REC keep current term "skin dose" not 'peak skin dose' as it is too detailed for the intent of the rule.
  - Remove unnecessary wording "five times the facility's established protocol" in rule (b)(i) and (ii). The language adds confusion. Removing it does not change anything as the word "and" is used for dose, and dose is what matters anyway. Also add "greater than, equal to sign" to (c)(ii).
    - (b) Unintended dose other than skin dose in a single procedure greater than:
      - (i) ~~Five times the facility's established protocol, and >~~ 0.5 Gy (50 rad) to any organ; or
      - (ii) ~~Five times the facility's established protocol, and >~~ 0.05 Sv (5 rem) effective dose;
    - (c) Wrong patient or wrong site for entire procedure when the resultant dose is:
      (ii) Effective dose greater than or equal to 0.05 Sv (5 rem).
  - Add definition for "unintended" using SSRs language but remove the word "human" and just use "error" as it captures any error. New definition: "Unintended Dose" or "Unintended Skin Dose" – means a patient radiation dose resulting from an error or equipment malfunction during procedure.

- (51) Phantom definition – REC remove the general definition of phantom as it is not necessary because where phantom is used in rule, the description of the phantom is provided. Otherwise, change the general definition to mean a volume of material or test object useful for evaluating an imaging system. Removed general definition.

- (54) Protective Apron – REC keep definition with no change. This is a standard protection term in the profession.

- **O.A.C. 3701:1-66-02:**
  - (C)(3)(a) – REC no change. A clear breakout of knowledgeable individuals instead of assuming a category covers them possesses no issue. Ohio licensed Physicians, radiologists and oncologists can operate radiation-generating equipment under O.R.C. 4773.

  - (H)(1)(b)(iii) - REC move the re-calculation paragraph to its own paragraph for this case prior is not applicable, the re-calculation just needs to be done when workload changes.
    - New paragraph (H)(1)(c): Use a radiation expert to perform a re-calculation of area radiation survey results after any increase in clinical workload that exceeds the assumptions used in the existing radiation survey.

- (H)(5) REC remove the words 'facility design for' as it is not necessary, and the protective barrier requirements of paragraph (H) already address it.
  - Assure the ~~facility design for~~ stationary CT and mobile CT radiation-generating equipment used in a fixed location provides for two-way aural communications between the human patient and operator.

- (I) REC no change - reinstallation of the same, is clear and does not need to be further defined.

- (J)(10)(c) REC no change. REC believes there will be an increase in tracking but only for cassettes that are not used on a weekly basis. If computed radiography plates are used frequently enough, they do not need to be tracked for erasing weekly. If computed radiography plates are used less than weekly, the quality assurance program must assure the plates get erased before use.

- (J)(10)(d) Rule summary: Facilities other than dental, podiatric, and veterinary, using computed and digital radiography imaging systems shall have quarterly phantom image evaluations using a phantom approved by a radiation expert or system manufacturer. The analysis at a minimum shall include artifacts, spatial resolution, contrast/noise, work station monitors, and exposure indicator constancy.
  - REC - Many believe this highly descriptive quarterly image testing is unnecessary and only adds to costs, when daily system and image checks already catch and fix problems. The current annual descriptive image evaluation tests by a radiation expert is sufficient.
  - AAPM Report No. 93, Task Group 10 recommends quarterly test (technologist) QC phantom analysis, including resolution, contrast/noise, laser jitter, and exposure indicator accuracy.
  - There was a supporting public comment for this rule.
  - Bryon Murry pointed out that the AAPM's public comment did not include an issue with this quarterly imaging testing.

- (J)(11) REC voted to change language. The evaluation can be a documented visual check, and if warranted a radiation exposure check. Paul Johnson pointed out that Joint Commission is already requiring this.
  - Old language - Annual evaluation of the integrity of all protective gloves, aprons, and thyroid collars, if any.
  - New language - Annual evaluation of the integrity of all required protective apparel.

- (K) - REC no change. Keep consistent medical event reporting with Radiation Therapy and Nuclear Regulatory Commission.

- **O.A.C. 3701:1-66-04:**
  - (B)(15) - REC no change. The word "human" is used to clarify that the rule does not apply to veterinary facilities.

  - (B)(16) - REC no change. Keep policies for verifying human patient identity and exam to be performed, including identification of the appropriate body part. Having radiation safety policies protects patients, operators, and owners of facilities.

  - (B)(17) – REC no change. A policy regarding who can order x-ray examinations must be in the written quality assurance program.

  - (C)(5)(d) – REC change. Correct spelling typo "performance."
    - ~~Peformance~~Performance evaluation summaries for radiation-generating equipment including a description of any issues found; and

- (D) - REC change the committee name from "radiation protocol committee" to "radiation dose review committee" to remove confusion of what is meant by protocol. With this change, there is no need to define protocol for rule (D) through (D)(6). Explicitly exempt veterinarian equipment from this rule.
  - In addition to the requirements of paragraphs (A) and (B) of this rule, the quality assurance program of registrants performing fluoroscopically-guided interventional other than veterinary procedures, and computed tomography (CT) other than veterinary and cone beam CT procedures shall establish a radiation ~~protocol~~ dose review committee in accordance with the following:
  - (D)(3) The radiation ~~protocol~~ dose review committee shall include at least the following members:
  - (D)(4) A quorum of the radiation ~~protocol~~ dose review committee shall meet as often as necessary to carry out its duties, but at least annually. To establish a quorum at least one-half of the committee's membership must be present either in person or by telecommunication means, and must include the individual responsible for radiation protection. A record of each meeting shall be maintained and include the following:
  - (D)(5) The radiation ~~protocol~~ dose review committee for fluoroscopically-guided interventional procedures shall establish and implement written protocols that include but are not limited to the following:

- (D)(3)(b) - REC no change. In Ohio there are different credentialing requirements for radiation experts. The qualification requirements for a diagnostic radiation expert is in 3701:1-66-03(D).

- (D)(3)(c) - REC remove the word "supervising" as a physician that performs fluoroscopically-guided interventional and/or computed tomography procedures is capable to serve and conduct business to meet the intent of this committee.
  - As applicable, a ~~supervising~~ physician that performs fluoroscopically-guided interventional and/or computed tomography procedures; and

- (D)(3)(d) - REC remove the word "lead" in the rule, as any technologist that performs fluoroscopically-guided interventional and/or computed tomography procedures is capable to serve and conduct business to meet the intent of this committee.
  - As applicable, a ~~lead~~ technologist that performs fluoroscopically-guided interventional and/or computed tomography procedures;

- (D)(6)(e) - REC no change. No need to distinguish adult chest from adult chest smokers for this rule.

- (E)(1) - REC no change. The retention period for data and tests results of evaluations and calibrations of x-ray equipment considers the longest inspection period of 5 years (Dental facilities). One retention period holds all facilities to the same standard.

- (E)(2) - REC no change. Data and test results of evaluations of shielding and surroundings is kept until registration is terminated. Shielding surveys can assist in litigation cases for the facility and the survey can be used if another unit of the same output and orientation is installed in the room. This reduces costs.

- (E)(3) - REC no change. The retention period for maintenance logs of x-ray equipment considers the longest inspection period of 5 years (Dental facilities). One retention period holds all facilities to the same standard.
- (E)(5) - REC no change. Rule (E)(5) uses "current" as the time frame.

- (E)(6) - REC reword paragraph and include time frame.
  - Biennial calibration certificates or cross calibration documentation for all instruments used to perform area radiation surveys, calibrations and evaluations for five years.

- **O.A.C. 3701:1-66-05:**
  - One public comment supporting changes.

- **O.A.C. 3701:1-66-06:**
  - (D) REC no change, as licensing for operators of dental x-ray licensing is governed by the Ohio Dental Board. The operator only needs to be evaluated/observed annually on the criteria in the rule. Documentation of the annual evaluation will serve as evidence at the inspections
    - Ohio Dental Board or Ohio Dental Association did not comment on this rule. Chris Moore at the Ohio Dental Association had no issue with this proposed rule during a prior phone conversation.

  - (J) REC Ok to remove nominal kVp and use the current SSR language that does not allow dental units to be operated below 51 kVp.
    - (J) ~~Dental equipment with a nominal fixed kVp of less than fifty shall not be used to make diagnostic dental radiographs of human beings~~. Dental equipment shall not be operated at less than a measured fifty-one kVp.

- **O.A.C. 3701:1-66-07:**
  - (C)(2)(d) - REC no change. Keep wording "low contrast resolution evaluations" not "low contrast detectability."

  - (C)(2)(e) - REC annual evaluation of five-minute timer is ok if it can be verified during normal procedures. Otherwise it is over burdensome. Handle with guidance identifying that this can be verified during normal equipment operation while performing a procedure.

  - (C)(2)(f) - REC no change. Evaluation of the accuracy of technique indicators and integrated radiation dose displays. This can be accomplished through normal radiation output test for timer and kVp accuracy and evaluating the service engineer's mA tests.

  - (C)(4)(c) – REC no change. Keep the time frame for the radiation experts documented approval of designee's test results.

  - (F) and (H) Changing from 2 hours to 4 hours general fluoroscopy equipment training. Added 8 hours of fluoroscopy training for fluoroscopically-guided interventional procedures.
    - Explanation and options for compliance:
      - There is a two-year compliance period to update to the additional training hours.

- The number of individuals required to be trained has been reduced see bullet below.
- The fluoroscopy training is required for only the supervising physician and operator of the x-ray equipment. These individuals are responsible for ensuring radiation protection to all individuals in the room. Ancillary staff are required to have general radiation safety training in accordance with rule 3701:1-66-04(B)(13).
- The designated radiation expert oversees and approves all aspects of the fluoroscopy training.
- The designated radiation expert can approve training from another entity that covers all the topics if there is documented proof of the training.
- Subject to approval by the radiation expert, certified ARRT radiographers, licensed radiologists, licensed radiation oncologists and licensed physicians may use documented fluoroscopy training from their educational and training curriculum to meet the training requirements.
- Licensed physicians not demonstrating documented fluoroscopy training must receive fluoroscopy training.
- Retraining applies to the operator and supervising physician in the room.
- Method to meet CE requirements. Both radiographers and physicians are required to complete CE's to renew their license. If two of the hours are related to fluoroscopy, this satisfies the CE requirements of rule 3701:1-66-07(H).

▪ REC:
- In the explanation - add the word "radiation" in front of oncologist for clarity and cardiologists to the guidance list. Cardiologist residency training needs further review.
- Kerry Krugh stated that there is no evidence that the current two hours of fluoroscopy training is not sufficient for Ohio. Changing the hours because the Suggested State Regulations now identifies a number of hours is just not a good enough reason.
- Kevin Little, public stakeholder, stated the amount of training and tracking may be reduced with the new requirement.
- REC voted to not change the rule and keep the current two hours of fluoroscopy training. The committee agreed with Kerry Krugh's statement that there is no evidence that the current two hours of fluoroscopy training is not sufficient for Ohio. Changing the hours because the Suggested State Regulations now identifies a number of hours is just not a good enough reason.

▪ REC clarify in rule that previous fluoroscopy training applies:
- 3701:1-66-07(G) The training required by paragraph (F) of this rule shall be approved by the registrant's designated radiation expert, and be specific to the type of fluoroscopic equipment used. Previous documented fluoroscopy training approved by the registrant's designated radiation expert may be used to meet the training requirements of paragraph (F)(1)(a) and (F)(1)(b) of this rule. Documentation of receiving the training required by paragraph (F) of this rule shall be retained by the registrant and be available for review upon inspection. At a minimum, training topics shall include, but not be limited to:

- **O.A.C. 3701:1-66-08:**
  - 3701:1-66-08 - REC no change. In accordance with rule 3701:1-66-08(F) shielding requirement of 3701:1-66-02(H)(2) and (H)(3) do apply to sampling units.

  - 3701:1-66-08 - REC no change. The handler is still required to follow the safe operating procedures and operator training requirements of rule 3701:1-66-04(B)(4) and (B)(5) for sample tissue units. Based on most business operation, the operators of these units are usually licensed radiographers, but a license is not required if the exposure is not on human beings.

  - (C)(2)(d) - REC no change. As this rule adds initial qualifications to the license requirement, whereas the language in rule 3701:1-66-10 and 3701:1-66-11 is redundant to the license language already addressed in 3701:1-66-02.

  - (G) – REC correct the title of the document by changing "Guideline" to "Parameter" and "Stereotactically Guided" to "Stereotactic-Guided." Keep the current document that references the Stereotactic QC Manual (1999).
    - Quality control testing by a medical physicist shall be conducted on mammography radiation-generating equipment used for invasive localization or having stereotactically-guided breast biopsy capability. Quality control testing for stereotactically-guided breast biopsy equipment shall follow the "American College of Radiology (ACR) Practice ~~Guideline~~Parameter for the Performance of ~~Stereotactically Guided~~ Stereotactic-Guided Breast Interventional Procedures" (as revised in 2016). This document is available from the "American College of Radiology, 1891 Preston White Drive, Reston, Virginia 20191, telephone (703) 648-8900."

- **O.A.C. 3701:1-66-10:**
  - Opening paragraph – REC maintain the exemption for fluoroscopy with CT capability. Based on the equipment design and functionality, and that dose testing is covered in the fluoroscopy mode testing. Also, the word "mobile" was maintained as it is defined in 3701:1-66-01 as x-ray equipment permanently mounted on a base with wheels or castors for moving while completely assembled and is not used in a fixed location.

  - (B)(4) – REC add language for clarity.
    - Mobile CT radiation-generating equipment, except for stationary CT radiation-generating equipment installed in a van, trailer, or mobile vehicle and operator behind a protective control booth, shall be provided with protective curtains of not less than 0.25millimeter lead equivalent that completely surrounds the gantry bore during exposures, unless the protective curtains interfere with the sterile field of a surgical procedure.

  - (C)(1)(a)(ii) – REC no change. The term medical use and patient is applied the same in this sentence and was changed to be consistent throughout the rules. Yes, equipment standards apply to equipment used for medical research.

  - (C)(1)(c) – REC combine the first sentence of (C)(1)(c) with (C)(1)(e) to clarify testing to be done by CT technologist. Combine second sentence of (C)(1)(c) with (C)(1)(d) to clarify annual image testing to be done by the radiation expert.

- Researched into national standard documents: SSRs, ACR and AAPM. Removed and replaced "image thickness" test with "radiation beam width" test. Added CT number uniformity, artifact and table travel accuracy to testing. Identify that a water equivalent phantom can be used for weekly testing.
    - New (C)(1)(c) Perform evaluations of image quality at least annually using a CT phantom which has the capability of providing an indication of CT number accuracy for at least three materials. The evaluation of image quality shall include CT number accuracy and uniformity, noise, artifacts, radiation beam width, resolution for low and high contrast, alignment light accuracy, and table travel accuracy;
    - New (C)(1)(d) Develop the written quality control program conducted by the CT technologist appropriate for the evaluation of the CT system that includes the tests and allowable tolerance limits. The quality control evaluation for image quality shall include the use of a water equivalent phantom, and at a minimum, the evaluation of artifacts, noise, CT number accuracy and uniformity. The evaluation of image quality shall not exceed intervals of one week;

- **O.A.C. 3701:1-66-11:**
    - One public comment supporting changes.

- **O.A.C. 3701:1-66-16:**
    - REC no change. Keep rule 3701:1-66-16 in the Chapter. Due to the unique use of Security Screening Systems, it was debated at the time, to which O.A.C. Chapter should the Security Screening Systems be placed in. Since the Security Screening Systems are used to intentionally irradiate human beings, it was decided to put Security Screening Systems in Chapter 3701:1-66 to easily address the exception of irradiating human beings for a purpose other than medical.

    - (A)(1) & (D)(5) REC no change. The format of the ANSI title is a rule writing convention.

    - (F) – REC no change. The words "a qualified individual designated by the radiation expert" addresses the concern by putting the responsibility on the radiation expert to make sure they are qualified.

    - (H) - REC no change. Error on explanation sheet. The rule was removed because it is already covered in rule 3701:1-66-02.

- **O.A.C. 3701:1-66-17:**
    - No public comments received.

The REC recommendations and proposed rule changes to address stakeholder concerns will be reviewed by the Department. The results of the review and proposed rule changes will be emailed to the REC members. The requested rule changes are substantive and will have to be posted for a second public comment period.

New Business:
Next REC meeting review public comments to the second posting of the proposed revision to Medical Radiation-Generating Equipment, O.A.C. Chapter 3701:1-66.

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Open Forum:
No topics provided.

Future Meeting Date(s):
To be announced.

Adjourn:
The meeting adjourned at 5:12pm.