AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE

September 7, 2018

James Castle
Office of the General Counsel
Ohio Department of Health
246 N. High St.
Columbus, Ohio 43215

Via: ODHRules@odh.ohio.gov

RE: Comment to Proposed Amendments to "Proposed Regulations: Draft Radiation-Generating Equipment Rules"

Dear Mr. Castle:

The American Association of Physicists in Medicine (AAPM)[1] is pleased to submit comments to the Ohio Department of Health (ODH) regarding its Draft Radiation-Generating Equipment Rules. The AAPM commends the ODH on its work in updating quality assurance and safety requirements for safety to the operator, patient and other members of the public. The AAPM, however, believes that some provisions of the draft rules are ambiguous, and AAPM provides the following comments and recommendations for your consideration:

Discussion

3701:1-66-01 (Definitions)

[1] The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography, CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to ensure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various state regulatory agencies. AAPM represents over 8700 members.

Annual

In the draft rules, the definition of "annual" has been deleted and replaced by a reference to the definition in 3701:1-38-01. While the new definition is consistent with other OAC sections, we believe the definition needs greater clarity. The revised definition of "annual' provides *two* options for the definition ("at intervals not to exceed one year" or "once per year, at about the same time each year, plus or minus one month"). The first is ambiguous because one year could mean 365 days or 366 days in the case of a leap year. The second is contradictory ("at about the same time each year" is different than "not to exceed 365 days" if that is the first definition) and adds additional ambiguity.

The AAPM recommends that ODH keep the current definition and augment it to state: "'Annual' means at least once a year, at intervals not to exceed 395 days." By using days, instead of months for the "allowance," ambiguity is eliminated. This would clarify that there is an allowance of 30 days past 365 days to get an annual requirement done. Use of the terms "months" is suboptimal as it raises the question that if a survey was performed on June 15 in one year, is a survey performed on July 16 of the next year within one month afterward? (It is within the following month and 31 days later (most months are 31 days long), but is one day after the same day in the month following the previous survey). By using *days* for the allowance, ambiguity is completely eliminated, leading to fewer inquiries of and by the regulatory staff, and a higher likelihood of compliance.

Full Time Training in Medical Physics

The proposed rules add a definition of "full time training in medical physics," which includes the requirement that the trainee have "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." The AAPM finds this definition to be confusing and potentially unattainable for consulting diagnostic medical physicists. The term "at a medical facility" implies that the 1,800 hours of training would all have to be done while the trainee was physically located in a medical facility. For consulting physicists, however, much of the training (e.g., reading, preparing reports, researching issues on the internet, classroom training, etc.) as well as much of the clinical practice (e.g., reviewing images on a DICOM reader, scoring said images, etc.) does

not occur within the walls of a medical facility. It occurs in an office setting or a remote work setting. Only those activities that *need* to be taught and performed in the medical facility are actually done on site (e.g., performing the image collection and measurement portions of an equipment performance evaluation, interacting with medical personnel, etc.). We recommend that "at a medical facility" be deleted because the term "in the practice of clinical medical physics" makes it sufficiently clear that the trainee would have to be performing training/work in a medical facility at appropriate points in their training.

In addition, we believe "under the direct supervision of a board-certified medical physicist" is confusing and potentially problematic. "Direct supervision" refers specifically to supervision where the trainer is at the same physical site (but not necessarily in the same room) as the trainee, and quickly available to be present if needed. The AAPM believes that on-site measurements made on the equipment need to be under direct supervision of a board-certified medical physicist. However, while this level of supervision (or an even greater level of supervision, i.e., personal supervision) may be appropriate for the actual equipment performance survey portion of the training, many training activities are done independently – again, research, reading, online didactic courses, preparing reports, etc. – and this clause implies that the board-certified medical physicist needs to be physically present in the same office during all 1,800 hours. We recommend that this provision be clarified to require "direct supervision" for hands-on equipment training, but allow "general supervision" for those other learning activities.

The AAPM strongly supports the requirement that the trainer be a board-certified medical physicist but asks ODH to clarify that the board certification needs to be one that is applicable to the training (i.e., diagnostic radiological physics, therapy medical physics, etc.). A boarded diagnostic medical physicist is not qualified to supervise the training of a therapy physicist and vice versa.

Full Time Work Experience

The draft amendments define "full time work experience" but do not specify that the required experience be supervised in any way. We believe that a common interpretation of this definition would be that the experience be under the general supervision of a board-

certified medical physicist (in the appropriate specialty). The AAPM recommends that ODH consider inclusion of that additional stipulation.

Medical Events

The draft rules add a definition for diagnostic radiation-generating equipment "Medical Events" to align with the Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations (SSRs). We believe the language used to define a medical event is vague. In particular, the use of "unintended" dose is difficult to interpret for dynamic procedures such as interventional and cardiac catheterization procedures where the length of the procedure and dose depend on many variables as the exam proceeds.

The reference of doses relative to the "facility's established protocol" is also problematic because there is no guidance given regarding what the established protocol is intended to consist of, or how it is determined or defined. The SSRs define protocol as: "Protocol" means a collection of settings and parameters that fully describe an examination. This would encompass many more parameters than simply a dose metric.

Phantom

Draft provision 1-66-01(A)(51) added a definition for "phantom," which we believe is a very limiting definition of phantom. Phantoms may be useful for evaluation of many aspects of radiation-generating equipment. The AAPM suggests that definition of phantom be modified to allow the radiation expert to consider whether a particular phantom is appropriate to provide meaningful image quality, attenuation, or scattering data.

3701:1-66-02 General administration requirements for medical radiation-generating equipment:

Individual Responsible for Radiation Protection (IRRP)

The AAPM supports the draft rules' provision of qualifications for the individual responsible for radiation protection (IRRP). We note, however, that the listed qualifications are highly varied in terms of their level of education and training, and some qualifications listed may in fact not exist. For example, a Certified Health Physicist (CHP) as noted in sub-section (f) has vastly greater education, experience and training than an individual with an associate degree

in radiologic science. We believe that (e) suffices as a requirement for both (f) and (g) based on the requirements to be considered a radiation expert as defined in 3701:1-66-01. Also, we believe that (d) is actually a component of (a) – anyone licensed to operate radiation-generating equipment in Ohio has to possess those certifications, so this redundancy can be eliminated. Also, we do not believe there are any institutions granting associate degrees in health physics or nuclear engineering.

Moreover, we believe that non-medical utilization is not represented in this section, and we recommend that it be addressed, inasmuch as we assume that some non-medical registrants may currently have no qualified radiation-trained person on staff to manage dosimetry, events, etc. Accordingly, we recommend that ODH consider the appropriate qualifications list in greater detail and revise it to clearly state appropriate minimum qualifications for the responsibilities for the IRRP.

Reinstallation

Section (I) addressing "reinstallation" is ambiguous because "reinstallation" and "operating parameters" are not well-defined. It is therefore unclear what actions may be exempted from radiation surveys by this section. We recommend that this section be re-written to avoid ambiguity. We believe a radiation expert should be charged with determining whether the change in question could change the radiation scatter, or if the existing radiation survey remains applicable. If a radiation expert determines that the prior radiation survey is no longer applicable, then the radiation survey should be redone. We believe that pointing to the core issue versus trying to refer to all of the possible changes that would create an exemption, is more efficient and robust as an approach to this section.

3701:1-66-04 Quality assurance program for medical radiation-generating equipment:

Diagnostic Radiation Expert

In Section (D)(3)(b), it is unclear what a "diagnostic radiation expert" is. While "radiation expert" is elsewhere defined, adding "diagnostic" without qualification adds ambiguity here. We believe to conduct properly CT protocol optimization requires perhaps the most education, training and experience of all activities in the medical physics sphere. The AAPM recommends that this section be re-worded to require a board-certified diagnostic medical

physicist specifically boarded in diagnostic radiation physics for this very complex activity. We believe that requiring a Certified Radiation Expert (CRE) for this role would be a logical way of addressing this issue.

Lead Technologist

In Section (D)(3)(d), we recommend elimination of the word "lead" from "lead technologist" because not all facilities would have such a position. We recommend the addition of language such as "a person holding an Ohio license to operate CT and/or fluoroscopically-guided interventional equipment, as appropriate" to ensure the person is appropriately qualified.

Substantial Radiation Dose Level Values

In Section (D)(5)(d), the draft amendments add a new requirement to determine a "substantial radiation dose level." The draft amendments refer to "substantial radiation dose level values following nationally recognized standards." We believe that term is unclear. The context would suggest that these dose levels can be selected by the site (essentially Diagnostic Reference Levels—DRLs), but if so, that should be stated.

It is unclear whether ODH is referring to dose notification levels, as in the previous subsection. If the committee is supposed to set dose "trigger" levels that trigger actions, that should be clearly stated. The AAPM recommends that the draft rules correctly clarify the distinction between alert level, notification level, and diagnostic reference level. In addition, we believe that (d) and (e) could be combined and reworded to use simpler and more direct language to clarify the state's expectations for what should be in the written protocol. We are also concerned that there is a focus on dose in this section, but not on image quality.

In Section (D)(6), we recommend that ODH employ the same language and approach (i.e., parallel structure) as for the FGI RPC. We note that these two sections seem to be structured in two different ways and use different language even where identical language would be appropriate.

Protocols

In (D)(5)(f), there is a new requirement to review "protocols" annually. This appears to apply to the written protocols as specified by (5)(a) through (f). The definition and use of "protocol" in that section appears to be substantially different than that used by other accreditation agencies, particularly in reference to CT, as well as (D)(6) which addresses the techniques used during image acquisition.

The CRCPD SSR definition of protocols is: "Protocol" means a collection of settings and parameters that fully describe an examination. We believe that if the intended use of "protocol" in this section is to review examination acquisition techniques, it will be very difficult to define and establish specific protocols for fluoroscopy-guided interventional procedures since the procedures are dynamic and highly variable to achieve the desired clinical outcomes. It should also be noted that The Joint Commission, which originally proposed that facilities establish fluoroscopy imaging protocols in their proposed standards, removed those provisions following public comment from the final standards (PC.01.03.01 25) published in June 2018.

3701:1-66-06 Dental radiation-generating equipment:

Section (D) provides that a dental operator must have an annual "evaluation." The AAPM believes this requirement should instead be "training."

3701:1-66-08 Mammography radiation-generating equipment:

The AAPM is concerned in this section that the proposed regulations exempt sample units from shielding requirements. We believe ODH should consider whether barrier requirements for operators of these sample units should be left completely unaddressed, or if there is a need to have some appropriate requirements. We request ODH to address this issue. Also, the rule exempts sample units from possessing a warning label. We do not feel that any radiation producing machine should be exempt from warning an operator that the unit produces radiation as required in 3701:1-66-02(E).

3701:1-66-10 Medical computed tomography radiation-generating equipment:

The AAPM believes that fluoroscopic cone beam computed tomography (CBCT) units should not be excluded from the requirements in this section. We request ODH to provide the rationale for this exclusion based on the radiation dose and image quality factors applicable to each. Also, The proposed regulations refer to protective curtains for "mobile" CT in Section (B)(4). The AAPM recommends that "portable" be used instead of "mobile," because "mobile" typically implies there is a self-contained trailer (with installed operator shielding and a separate control area) while "portable" typically refers to those units that can be wheeled around or moved within a facility and that do not have separate fixed control rooms.

In summary, the AAPM hopes that the ODH will consider AAPM's comments and adopt AAPM's recommendations when crafting the final rules.

Thank you for the opportunity to comment. If you have any questions or require additional information, please contact Richard J. Martin, JD, Government Relations Project Manager, at 571-298-1227 or Richard@aapm.org

Sincerely,

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President, AAPM