PA RPAC Meeting of October 10, 2019

Summary for the DVC-AAPM, compiled by John Keklak, RPAC Chair

Most of the official agenda items consisted of:

(a) Regular reporting by the DEP-BRP central office (Dave Allard, John Chippo, Bryan Werner, etc) on happenings of note related to all areas of the Pa. Radiation Protection Program (Radiation Control, Decommissioning & Surveillance, Nuclear Safety, and Radon); and,

(b) Proposed (draft) revisions to regulations pertaining to radiation producing devices used for non-clinical purposes (e.g., cabinet x-ray units, electron microscopes, etc). For the most part these would not relate to clinical medical physicist duties unless job descriptions at a particular facility included radiation safety and survey responsibilities for these units. A number of items of concern about the wording and scope of these regulations were raised. A subcommittee (consisting essentially of all the current RPAC members) has been established and will begin having regular teleconference meetings to develop an improved draft.

Items of more direct interest to medical and medical health physicists included:

1. Re the CBCT regulations that became effective in January 2019, it is not always possible to measure field sizes, some units do not come with phantoms provided by the vendor, etc. These (and other questions) have been addressed in the “Frequently Asked Questions” that can be found by going to the Radiation Control section of the Pa. DEP (Bureau of Radiation Protection) website. [These are updated as new questions come in. Physicists are encouraged to check these FAQs regularly. Also, new questions can be submitted by anyone, and can be sent to the appropriate BRP division or section chief in Harrisburg; or you can send them to me and I will pass them along.]

2. The question of O-arms and whether the CT regulations applied also came up. Short answer, “no”, FDA and ACR classify O-arms as fluoro units, so that is how DEP considers them. [This is also addressed in one of the FAQs.]

3. The DEP summarized Medical Events (MEs), Medical Reportable Events (MREs), and other reportable events that occurred since the last time this information was provided to the RPAC. This prompted discussion of the following:

   a. The RPAC encouraged the DEP to look for ways to better inform licensees and registrants about these events, most importantly “lessons learned” and root causes, so that others could learn from and avoid similar events. It was noted that the summaries (“MRE” and “NMED” events) as written up for RPAC do appear with the RPAC meeting minutes and can be found on the DEP website (under “Public Participation/Advisory Committees). Physicists and others can review these items there. (Although root cause type information is often lacking or minimal.)

   b. It was mentioned that the wording of the current MRE definition (that became effective in January) leaves a large loophole for significant events that probably should be captured. All
criteria for what constitutes an MRE (deviation from prescribed by >20% total dose, >30% for weekly fraction total, or >50% for a single fraction) are all based on a “deviation from prescribed”. If an administration occurred without a prescription, it would not fall within these criteria since there would be no prescribed dose from which to calculate a deviation. *(This is one of a number of revised regulations that went into effect in January that are being listed for adjustment in a future “clean up” regulatory revision package.)*

c. Some of the reported events were based on 10 CFR 30.50 (incorporated by reference into Pennsylvania regulations and therefore applicable to accelerators and other devices.) [Physicists should be sure to be familiar with this regulation. You do not necessarily have to meet ME or MRE criteria for a safety device failure event to be reportable!]*

A key paragraph is copied here:

*(From 10 CFR 30.50)*

“2) An event in which equipment is disabled or fails to function as designed when:

(i) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(ii) The equipment is required to be available and operable when it is disabled or fails to function; and

(iii) No redundant equipment is available and operable to perform the required safety function.”

4. The AAPM position statement (supported by the HPS and ACR) on gonadal shielding was discussed with respect to the current wording in 25 Pa. Code Ch. 221.11(f):

“During diagnostic procedures in which the gonads are in the useful beam, gonad shielding of at least 0.5 millimeter lead equivalent shall be used for patients except for cases in which this would interfere with the diagnostic procedure.”

The takeaway from the discussion was that the caveat “…except for cases in which this would interfere with the diagnostic procedure” in the regulation as currently worded effectively provided a sufficient “out” that would allow Pennsylvania facilities to adopt shielding policies and procedures consistent with the AAPM position statement. *(This is another regulation designated for deletion or at least rewording in a future revision package.)*

Feel free to contact me with questions.

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