DRAFT Minutes of the Radiation Protection Advisory Committee (RPAC) Meeting
Virtual Meeting Via WebEx
July 9, 2020

Meeting called to order at 9:03 a.m.

Members in Attendance:

John Keklak
Todd Mobley
Kent Lambert
Shawn McNeeley
Steven King
Summer Kaplan
Aaron Fisher
Margaret Blackwood
Michael Sheetz
Anthony Montagnese
Nathaniel Burden
Joseph Och
Victor Rizzo

Members Absent:

Peter Smith
Chrysan Cronin

DEP Staff in Attendance:

David Allard
John Chippo
Kristina Hoffman
Stephanie Banning
Jennifer Noll
Dwight Shearer
Kate Cole
Bryan Werner
Roy Huhn
Robert Zaccano
Lisa Funk
Keith Salador
Bob Lewis
Barbara Bookser
Lisa Forney
Terry Derstine
Joshua Myers
Barbara Bookser
Dennis Ferguson

Guests in Attendance:

Kendall Berry
Karen Colucci

Introduction; Adoption of Agenda; Approval of Minutes:

The agenda for this meeting was adopted.

Introduction of new members took place for Dr. Summer Kaplan, Aaron Fisher, and Nathaniel Burden. Chrysan Cronin is also a new member but was unable to attend the meeting.

The minutes from the October 10, 2019, meeting were adopted with a correction to the date.

Open Floor:

Three of the four new members introduced themselves: Dr. Sumer Kaplan, Aaron Fisher, and Nate Burden.

One member brought up a concern about a database DEP has started using to check EIN numbers versus facilities. It was reported that the database has caused industry a vast amount of work and has cost some registrants a lot of man hours. One example issue with the database provided was some EINs are being matched to the wrong companies based on the names provided. In response, DEP staff explained that these issues are being caused by current limitations in DEP's eFacts database and are impacting all program areas throughout DEP. Fixing these issues is something the Department is actively working on.

A member also mentioned that the PA Department of Health (DOH) has been sitting on expensive equipment approvals (e.g., MRI, fluoro rooms, etc.) for over eight months. The equipment cannot be used until it is approved, and some patients may be denied treatments until approval is received. Dave Allard requested an email regarding this issue so he can assist in fixing this problem by escalating to the appropriate personnel.

Other members were interested in hearing about how the remote inspection process has gone so far and learning the reasons for the remote inspection process. Dave Allard explained that due to the Governor's emergency disaster declaration and based on advice from the PA DOH regarding the mitigation of the spread of Coronavirus, the Bureau of Radiation Protection (BRP) staff have limited ability to go into their offices. Regional inspectors have been performing virtual inspections so far, which have been going well. Nuclear Power Plant interface is still by remote contact. Bob Zaccano stated they are doing paperwork only since the beginning of the stay at home order in his region. Dwight Shearer stated that their inspectors are requesting as much documentation electronically as possible, in turn limiting the amount of being out at the facilities. Each is submitted for approval by regional management to do the inspection. They are looking at smaller facilities that seem less at risk in green counties and not large facilities, such as hospitals. MQSA has allowed inspections to resume with no virtual inspections permitted.

Program Updates:

Radiation Control: Permitting is going well, and everything is going ahead as usual with minimal delays.

Decommissioning/Environmental Surveillance: The Section Chief retired, but BRP was able to hire her back as an annuitant. Her old position has been posted and interviewed for. Permission was given to start up the environmental surveillance sampling again. There is no public contact with this.

Radon: The certification backlog is being worked through and is almost complete. Open positions are being moved forward.

Nuclear Safety: The Division Chief has retired, but he will be back as an annuitant. His position is posted. Several rehearsals were canceled, and others coming up will probably be reduced in size in order to be in line with COVID guidelines.

Discussion Items:

Election of Chair and Vice Chair: BRP thanked John and Peggy for being the Chair and Vice-Chair for the past several years. John Keklak nominated Peggy Blackwood for Chair and Mike Sheetz seconded. Peggy Blackwood accepted the nomination. The nomination was approved

by RPAC unanimously. Mike Sheetz nominated Steve King for Vice Chair and John Keklak seconded. The nomination was approved unanimously.

Patient Gonadal Shielding: Presently, there is an issue with the use of gonadal shielding and interfering with images that can cause higher exposure to patients. The American Association of Physicists in Medicine (AAPM) came out with a position statement on this issue. The American Society of Radiological Technologists (ASRT) has not endorsed the AAPM position statement on this, which is a sticking point because the radiology technicians (RTs) are the ones dealing with the patients and families. They were taught shielding and are examined on it. This is being reevaluated and could be removed from their exams, but this change is not endorsed by ASRT yet.

The way Pennsylvania's regulations related to this are currently written allows RTs to not use gonadal shielding. However, due to the language under § 221.11(f), "…except for cases in which this would interfere with the diagnostic procedure," the argument could be made that it is actually required almost anytime. This language in Chapter 221 needs to be revised, because the overall implication of the statement is that gonadal shielding should be used. The exception is not in the RTs purview. It should be revised to say that shielding is not recommended given current data and possibly include a clause for use for comfort. There are two reasons to stop shielding: (1) the idea that it could interfere and increase the dose to more sensitive organs; and (2) the ICRP weighting factors have decreased over the past 40 years and the gonads are weighted less sensitive. Numerically it does not make sense and could be harmful.

Joe Och stated that the facility had to address this in their policies and procedures. If a facility does that it would take the weight of the decision off the technologist. The problem with this is that the facilities are looking to the RPAC for answers. DEP will get an FAQ and/or a fact sheet on the DEP website to make facilities are more comfortable with the policies that do not require absolute use of gonadal shielding. The managers and inspectors that look at facilities also won't cite them for not using gonadal shielding. If needed this regulation will be updated.

Members asked if there were any updates on HB 1811. DEP staff shared that there had been no updates on HB 1811, which seeks to establish a radiation and therapy board.

Review of Nuclear Material Events Database (NMED) and Medical Reportable Events: There were 12 NMED events since the last RPAC meeting. Three were lost, stolen, or missing material events; four were medical events; and five were equipment failures to perform as designed. There were five medical reportable events using machine-produced radiation submitted for this time period. Two were inaccurate isocenter shifts; one was a superficial single dose delivered to the wrong site; one was an incorrect treatment; and one was where the patient was set up for the CT Sim markings as opposed to treatment markings.

Discussion of Proposed Chapter 225, 227a, and 228 Regulations on Analytical X-Ray Equipment for Radiation-Producing Devices:

Department staff explained that anything in brackets is moved or deleted from the section. A lot of the Chapter 225 deletions are primarily being moved to the new Chapter 227a.

All that follows are questions and comments that were addressed for the final draft of the proposed regulations, which will be provided to the Environmental Quality Board:

Discussion on Chapter 225:

- On page 7 of Chapter 225: Change subchapter heading from “machines” to “devices” for consistency.
- On page 9, § 225.103— Items c and d were added. (c) says about an operator having a calibrated instrument, but then (d) says an alarming dose rate meter may be used. Is that used to satisfy the requirement in (c) above? It was suggested that the word “dose” should be removed from item (d). That may need to be looked at a little more carefully. This would be for a standard electronic meter. It implies it is connected to item (c) somehow. The meter may be worn if it is in place. We have a survey meter upon each approach. Per Part 34, there is both. Change “may” to “shall.”
- Is there a difference between radiographer, radiographer assistant and radiographer trainee? The difference is in the hours of training. To mimic Part 34, the radiographer has to have 40 hours of training and so many hours of operations, and the assistant is expected to know the procedure. There is an exam for X-ray if we want to put it in our rule. If they are working in a shielded room then Part 34 does not require an alarm rate meter. There are exceptions to working inside a shielded room. Shielded room is taken out of Chapter 225 and relocated to Chapter 227a.

Discussion on Chapter 227a:

- It was asked if cabinet X-rays were considered non-healing arts. Cabinet X-rays are considered non-healing arts because they are non-human and is now located in Chapter 227a.
- The subcommittee started at this point after Thanksgiving, and we have covered all of the edits that were presented. A lot of was taken out of Chapter 225. Old Chapter 227 is being reserved and creating Chapter 227a, which is a rewrite of Suggested State Regulations (SSR) Part H. It was decided to be the cleanest way to do this.
- § 227a.10 - In the next to last sentence, we should add “analytical” if the title has analytical in it. That is very narrow. Should it be made more general radiation protection vs. radiographic operations? This will be under review.
- §227a.18(b) - Under bypassing (1), “An individual may not bypass a safety device or interlock, and may not remove shielding, unless the individual has obtained approval of the radiation safety officer.” Shouldn’t it be written approval? It is written approval; it is stated in (a). Is it labeled on the device? There is a lock out, tag out? This is in subsection (2).
- In § 227a.52, (5) is a duplicate of (4). Need to correct the labeling dose numbers in (5) and change from microrem to millirem.
- For the equipment evaluation in (2)(iii), how is unintended damage different than intended damage? The language does not match up to the ANSI standard. The word unintended should be removed. Also, the annual review does not need to be done on image quality. This will be highlighted and looked at by the Department. Put “per manufacturer’s specification” at the end. We could also use “by the recommendation of the national standard.” For the quality assurance (QA) test runs that are done, do we need to specify qualified expert? Could it be an operator following QA procedures? Why would you do optimization of the radiation dose? You want to optimize the image quality; you don’t want a dose so low there is no significant information. Also, it is a strict timeline on this, can it be changed to 14 months? The Department explained that everything else in the chapter is 12 months, and we need to keep consistency. A request for extra time could be done and would be reviewed. There’s a limited supply of

qualified experts. It was noted that a qualified expert is a broad definition and broader than a qualified medical physicist. They aren't necessarily the same.

- The training requirements for the radiation safety person has some inconsistency. This section only mentions a radiation safety officer (RSO). Could they have a choice of a radiation safety officer or person in charge of radiation protection? One member noted that overall, eight hours of training of an RSO is excessive. There is a concern for mass screening, and in other professions and the expertise is there. DEP wanted to have someone at the facility with a little more training because of variations. DEP also wanted more training for these remote locations with these remote types of devices. Doctors' offices have radiation training. These facilities (prisons) don't have that level of expertise. These RSOs can go to several prisons. The operators' that are screening these prisoners should have some level of knowledge of this. Eight hours is an incredible amount of time to talk about these topics. Maybe a specific training needs to be done for that. The question is how many hours are adequate. Four hours may be a compromise. The Department will review this.
- There are areas of training in Appendix A that do not apply to the training for these devices. Perhaps put "as applicable" in there or list the topics. There are training recommendations from the ANSI standards and the NCRP Report. Some of those could be incorporated into this. The Department will review this.
- In § 227a.52 (8), minors and declared pregnant individuals should not be prohibited since the doses are very low. We are keeping it consistent with the other regulations. They can request an exemption. Can the word prohibited be changed to discouraged? Or put prohibited without department approval? "Prohibited without department approval" will be added. We don't give permission to put outside people through the screening and another viewpoint is these facilities do have signoff sheets for females asking they are pregnant or not. Alternative means need to be used if they cannot be screened. A record is maintained of all the scans.

Discussion on Chapter 228:

- In Chapter 228, the definition of accelerator was in conflict with the definition the NRC uses. This was changed to match the NRC definition. It needs to be the same, as we incorporate by reference.

Following this discussion, Tony Montagnese motioned to concur with the Department's recommendation to proceed with taking the proposed rulemaking to the EQB for consideration once the Department has incorporated the modifications agreed upon during the Committee's discussion. Steve King seconded the motion. The motion passed unanimously. The Committee also was informed they can submit a letter to be included in the rulemaking package further explaining their approval of the proposed rulemaking.

Open Floor:

For the radon program, Nate Burden had two questions. His first question was about certified testers and mitigators up for recertification. Specifically, he wanted to know what is the status of the radon certification program for someone wanting to recertify or putting in a new application considering the Department's physical office closures. The Department explained that applications are still being approved and moved. His second question concerned the Region III Stakeholders Meeting. He wondered what the status was of the Radon Stakeholders Meeting. Dave Allard explained that these meetings are being canceled until the following year, and that the meeting once held may be a virtual meeting.

In § 221.65, where it notes other CT systems, Joe Och states they recently added two CT's. One is a dedicated biopsy CT unit, and the other is a hybrid with interventional fluoroscopy unit. He believes the exceptions granted in this regulation need to be expanded to encompass a wider range of units and uses. Neither unit can be used for routine diagnostic work, because they are both used in a sterile environment. Joe will send an email to Lisa Funk Dave Allard, and John Chippo regarding that.

As was noted during the member renewals, this committee expired years ago. It will be handled at the next meeting by rewriting the bylaws.

Tony Montagnese raised a question wondering if PARAP is still viable. Dave Allard replied that it is, and he made a note to discuss with PEMA. He suggested that perhaps a virtual meeting can be set up to inform all parties involved.

The meeting was adjourned at 1:19 p.m.

The RPAC's next meeting will be held October 29, 2020, and will be planned as another virtual meeting.