Minutes of the Radiation Protection Advisory Committee (RPAC) Meeting Room 105 Rachel Carson State Office Building, Harrisburg, PA February 14, 2019

Call to order - 9:03 a.m.

Members in Attendance:

John Keklak Margaret Blackwood Michael Sheetz Kent Lambert

Anthony Montagnese Shawn McNeely
Joseph Och Steven King
Marian Wolford Vincent Roding
Charles Chambers Janice Wirth

Members Absent:

Keith Salador Victor Rizzo
Eric Boeldt Victor Rizzo
Tiffany Whitcomb

Peter Smith

DEP Staff in Attendance:

David Allard Lisa Funk

John Chippo Stephanie Banning
Kristina Hoffman Dennis Ferguson
Dyran Altenburg Robert Zaccano
Terry Derstine Barbara Bookser
Roy Huhn Bryan Werner
Stefanie Muzic Joshua Myers
Dwight Shearer Jennifer Noll

Robert Schena

Guests in Attendance:

Kendall Berry Chandra Kota

Introduction; Adoption of Agenda; Approval of Minutes:

Introductions of members, guests and staff were made. The agenda for this meeting and minutes from the April 19, 2018 meeting were approved with one edit to the minutes. In Open Floor, replace Landauer with dosimetry, regarding badges.

The next RPAC meeting is scheduled for October 10, 2019 in the 14th floor conference room.

Open Floor:

BRP has created a Frequently Asked Questions (FAQ) document and published this on the website. This was done to clarify the new regulations as questions arose. This is a working document and more clarifications can be added to this document at any time.

In the new regulations, Chapter 223 applies to laboratory animals, however some of the equipment used is not diagnostic and cannot comply with these regulations (cabinet X-ray). An application for an exemption can be submitted to the Department. This will be added to the FAQ's.

There are shortfalls in the current definition for a medical reportable event for radiation-producing machine therapy including not capturing if a dose of radiation is given to a patient for whom it was not prescribed. These will be corrected with the next human use regulation package in the near future. A question was also posed about where medical events should be reported. Medical reportable events should be reported to Central Office. These are time sensitive as there are time deadlines for DEP to report events meeting certain criteria to the NRC.

RP Program Update:

<u>Nuclear Safety</u> – The recent news on TMI Unit 1 and Beaver Valley Power Station Units 1 & 2 on possible shut downs was briefly discussed. It is believed there is some action happening in the PA Legislature. However, action is not taken, Exelon will send the second, and final, letter to the NRC requesting to be shut down and TMI will start making the transition to a decommissioning phase in the Fall. DEP yearly power plant drills were discussed, with two to three FEMA graded exercises being performed every year. Also, every eight years a post plume ingestion exercise is required. This is a much larger undertaking lasting for a week. There will be an ingestion exercise in March 2019 at Beaver Valley.

<u>Radon</u> – The ongoing very high radon development below Allentown, PA was discussed including the ambient radon monitoring that has been going on for over a year now. Those results were discussed at a public meeting in that area recently to help make all homeowners more aware of the dangers. The Radon Division is also involved in a re-entrainment study. Its purpose is to determine if the output from the radon mitigation systems need to be above the roofline of the house, as currently required, or would a lower output be acceptable. The data will be reviewed once it is finished.

<u>Decommissioning/Environmental Surveillance</u> – Various decommissioning sites such as Safety Light, Shallow Land Disposal Area, and Westinghouse were discussed. Work is slowly progressing on all locations.

BRP is currently performing the required three-year fee review. This was due to be completed last year but was pushed back because of the delays with the last fee increase package. The required three-year review of nuclear power plant fees was finished in 2017 with no increase recommended.

A question was asked if DEP is locked into the same fee categories as the NRC? Can new categories be created for the large differences in licensees that have the same fee category (e.g., one site vs. many sites, but the same fee)? We will begin to look at the workload required in licensing and inspection for different license categories. DEP is also planning on reviewing the workload and fee relationship for registration of chiropractors due to a request from an RPAC member.

Radiation Control:

Final Rule and Guidance on "Medical Use of Byproduct Material – Medical Definitions, Training and Experience, and Clarifying Amendments" – This became final on January 14, 2019. The definitions on permanent implants written directive (brachytherapy) no longer requires a dose be specified, which possibly changes the medical event reporting requirements. The 10 CFR 35.300 modality has had considerable changes to becoming an authorized user, including now requiring board certification instead of allowing training and experience as an alternate pathway for 10 CFR 35.390 to name one. These changes were discussed at length, and it was noted that they are more difficult to understand, and it is more difficult to achieve authorized user status than before. Guidance will hopefully be issued by the NRC including new 313 forms that may help with the issues.

The ABR is still issuing certificates that say Authorized User eligible. However, ABR is doing recertification through their website and when these new certificates are printed, they don't denote the AU eligible notation required by the NRC and by incorporation the DEP. This may be an issue for the OAS to bring up. DEP has been using the letter mailed to the doctor that states the certificate name and also denotes they are AU eligible. The point was made that basically the regulations are still labyrinthian and quite cumbersome.

Badging Responsibility – 10 CFR Part 20 is incorporated by reference in our regulations. This applies to all radioactive materials licensees, accelerator licensees, and X-ray registrants. It is referenced in Chapter 219 and 221. BRP may issue a Fact Sheet regarding this. The Department believes badging is the responsibility of the employer. However, this is not explicitly captured in the regulations and can be an issue with external personnel such as sales reps or vendors. BRP's attorney will look into this matter. DEP does have authority to inspect the company under the Statute to make sure it is providing dosimetry badges to employees.

Review of Medical Reportable Events (MRE) and Nuclear Material Event Database (NMED):

Josh Myers provided a verbal summary of nine NMED events from the period from March 2018 to September 2018. The NMED events at the next meeting in October will encompass the period from September 2018 until September 2019 to catch us up. Discussed were three leaking sources, one exceeding occupational dose limit, two lost or stolen devices, one shutter malfunction, and two contamination events. Lisa Funk noted there was one MRE submitted for this period, which was a wrong treatment site.

Information Notices:

Two Information Notices (IN) were sent out. IN 2018-3 – National Security Advisory for Licensees that Possess, Use, Ship, or Receive Risk-Significant Radioactive Materials. Two threat levels were developed to replace the antiquated color system and the NRC believes that Category 1 and 2 licensees should maintain awareness of these alert levels. IN 2018-4 Regulatory Requirements for Transfer of Control of Specific Radioactive Materials Licenses. This requested that DEP receives a 90-day prior notice of a change of ownership for radioactive materials license and detailed the process to complete this action.

Extremity Dosimetry:

The current issue is the NRC and DEP require dosimetry badges, whereas hospital infection control policies do not allow it. This question was posed to the CRCPD and the NRC, and both note that the regulations are required. A paper is being drafted on this issue by some members of the RPAC. We are waiting on this paper. Until then it's still an open question. The point of the previous RPAC presentation was there are processes in place for eye doses and there are various sources to use to prove that the factor they developed is reasonable, and using precedence, this should be reasonable also.

Current Chapter 227 Regulations on Analytical X-ray Equipment and CRCPD Model State Regulations SSR Part H for Radiation Generating Devices:

There is an updated suggested model state regulation from the CRCPD, SSR Part H that became final in July 2016. SSR Part H coincides with Pa Code Title 25. Chapter 227, which is currently titled "Analytical X-ray Equipment" and will become "Radiation Generating Devices." SSR Part H will cover a broad range of industrial and research devices including the whole-body X-ray security scanners currently being incorporated into the state prison system to find internal body contraband. Currently, there is one sentence in our regulations that states if you apply Xrays for nonmedical uses you need DEP approval. All state prisons have applied for these scanners, and even one drug rehab facility. BRP is using the ANSI standard N43.17-2009 for its review with the bottom line being scanned individuals will not exceed more than 25 mrem whole body exposure annually. We are also requiring operator training by the manufacturer, 8hour RSO training, and the ability to track individual dose. SSR Part H is considered guidance for us, however, BRP will be looking through all this to revise our regulations for Chapter 227. In Chapter 228, regarding accelerators, our definition conflicts with NRC's definition in 10 CFR 30.4. BRP plans to revise our current definition. There are also some cabinet X-ray items in Chapter 225 that will be reviewed and ensure any changes do not affect the industrial radiography regulations. One approach is Chapter 227 could be deleted and a Chapter 227a could replace it. BRP's will work on a review of Part H and Chapter 227 to look for consistencies and for formatting purposes. Part H will also be reviewed for provisions that may be more stringent than the current regulations. Also, examples were presented that are standard in the human use world, now being used for non-medical uses that may not meet these requirements. The goal is for the RPAC to have something to review for this at the next meeting in October, pending DEP's internal review.

Possible Future Regulatory Updates

CRCPD Model State Regulation Part S is in the works for Category 1 and 2, and possibly Category 3 radioactive sources. BRP will also be reviewing financial assurance regulations to possibly attach them to sealed sources.

Open Floor:

The current accelerator amendment form, upon completion, ends up as two pages and since the signature is on a page alone, it is not being accepted by certain individuals. The form will be corrected. One change will be made to the form allowing for signature to be acceptable as two pages.

Any comments RPAC has regarding the new regulations should be written down and submitted to BRP for review and possible clarification in the FAQs that are on the website.

Some questions have come up on the requirement to use phantoms. Some CR/DR units don't have a phantom and are following the manufacturer's QA program. QC must be done. This should be written and submitted to BRP for inclusion in the FAQ's.

There was an answer on a previous question about why a licensee needs a security plan to secure a source they no longer have - the NRC's answer is the plan must be kept for three years.

There is another push for licensure of medical physicists again in the State Legislature. The Department has no comment on this.

There was another request for the Department to intervene with the Department of Health regulations and inspectors as they are misinforming the regulated community regarding proper regulation of radioactive material. A request was made for RPAC to draft an email to Dave Allard for him to take to upper management regarding issues with the Department of Health.

A licensee asked whether using NCRP 122 and a single dosimetry badge for fluoroscopy procedures is acceptable. The NRC has a Regulatory Information Summary (RIS) on this. It will be reviewed and should be acceptable as this is a universally accepted method.

The Delaware Valley Society for Radiation Safety will hold its next meeting on March 6, 2019, at the Einstein Medical Center in Philadelphia.

Next meeting is October 10, 2019, on the RCSOB 14th floor.

Adjournment – 1:30 p.m.