DRAFT Minutes of the Radiation Protection Advisory Committee (RPAC) Meeting
14th Floor Conference Room
Rachel Carson State Office Building, Harrisburg, PA
October 11, 2019

Call to order – 9:03 a.m.

Members in Attendance:
John Keklak
Todd Mobley
Kent Lambert
Shawn McNeeley
Steven King
Marian Wolford
Margaret Blackwood
Michael Sheetz
Anthony Montagnese
Janice Wirth
Joseph Och

Members Absent:
Victor Rizzo
Peter Smith

DEP Staff in Attendance:
David Allard
John Chippo
Kristina Hoffman
Stephanie Banning
Neil Shader
Kate Cole
Bryan Werner
Roy Huhn
Robert Zaccano
Lisa Funk
Keith Salador
Bob Lewis
Bobby Schena
Dwight Shearer
Joshua Myers
Barbara Bookser
Dennis Ferguson

Guests in Attendance:
Kendall Berry

Introduction; Adoption of Agenda; Approval of Minutes:

Introductions of members, guests and staff were made.

The agenda for this meeting was approved.

The minutes from the February 14, 2019 meeting were approved with edits to the last paragraph prior to RP program updates. The definition of a medical reportable event for radiation-producing machine therapy was discussed. The way it is written in the minutes is very confusing and potentially misleading to the public. The discussion was, effective as of January, the definition of a medical reportable event was changed, and outside of using the wrong treatment plan for a patient it comes down to more than 20% from the total dose, more than 30% from the weekly sum or more than 50% for a single fraction is a medical event. The question is 50%, 40%, 30% of what? If the dose isn't prescribed, then you don't have a medical event by the

current definition. These, along with some items in the radon chapter will be cleaned up in a future regulatory action. The minutes were then contingently approved.

Open Floor:

A question regarding PA Code 221.32a, collimation for radiographic machines, was asked. We allow for a +/- 2% with other imaging but not when using positive beam limitation (PBL). In PBL the regulation notes no larger than the film size. Why is it +/- 2% for everything else but when using PBL it is limited? The reason for this is for customization, and to allow the operator to size smaller, only when positive beam limitation is used. Currently, it can't be larger than the cassette. The regulation should be corrected to include the +/- 2%. This will be addressed in the update.

What is DEP going to do regarding the regulation of mobile O-arms? Are they being treated like mobile fluoroscopes? Since the FDA views them as fluoroscopes, DEP will be inspecting them against the fluoroscopy regulations. This answer is in the FAQ's currently posted on the website.

Is there a requirement for a QA program for both the CT and fluoroscopy ability of an O-arm? Has anyone been able to use phantoms provided to survey them as required for their CT ability? Since they are inspected against the fluoroscopy regulations, this isn't necessary.

A section of the regulations indicates the people who can use fluoroscopic equipment must have direct supervision. Radiology residents being included in this is causing concern. They must be trained and competent before they complete their residency. This in in the FAQs and will be updated and corrected to clarify.

When using the ACR digital QA manual, a condition notes repeat rate analysis is now optional. An inspector stated DEP was going to revert to the QA section of the regulations and still require that for mammography. DEP noted the way the FDA regulations are written, they note to follow the manual you were provided from the manufacturer. DEP is following the FDA on this and will defer to their regulations for the MQSA inspections. However, if the FDA contract ever disappears, the units would revert to being inspected against § 221.11.

In 25 Pa Code § 223.1, research animals were added, making the regulations applicable to research animals. Often a cabinet X-ray unit is used on these animals and you cannot comply with that regulation with a cabinet X-ray unit. A member requested an exemption for this, and it was denied. The denial letter was given to the Committee for review. The intent was meant for operators who attempt to use an overhead system on a dog, a pig or a laboratory animal and that this operator needs to be protected. This is a cabinet vs. open beam conflict. This will be looked at in the updates to the current package. The scope of the chapter will be specifically looked at for this.

RP Program Update:

Radiation Control:

DEP performed a fee review and presented the report for the EQB on June 18, 2019. Fees are required to be reviewed every three years. Our review showed no increase is necessary at this

time. Nuclear power plant fees are hardwired into the statute and action would need to be taken by the Legislature and signed by the Governor. That fee review will be completed next year.

The "Radioactivity at Solid Waste Processing and Disposal Facilities" (DEP ID: 250-3100-001) Solid Waste Radiation Monitoring Technical Guidance will be published in the PA Bulletin on October 19. The requirements for the solid waste facilities fall under this. DEP's Oil and Gas regulations Chapter 78a point to this guidance because of their generation of TENORM, so the guidance was also updated. It will be published for comment in the PA Bulletin.

Decommissioning:

Decommissioning is still doing various cleanups around the state and also license termination work. The Safety Light site clean-up in Bloomsburg was estimated at $100,000,000. Over $40,000,000 has been spent so far. The Decommissioning section has been supporting EPA Region 3 here. The soil is still contaminated, and an end game is still trying to be figured out. It most likely will be a restricted site for a long time.

TENORM study follow up: There are a number of sewage treatment plants that are contaminated with radium from oil and gas waste. The media has shown a large interest in this contamination and DEP is currently involved in options for clean-up.

Environmental Surveillance:

DEP is doing more environmental surveillance and splitting samples on the TMI site. Unit 2 is grossly contaminated and Unit 1's fuel has been offloaded into the spent fuel pool. They'll be moving all this fuel into dry cast storage eventually. Many plants around the country are dealing with this issue.

The US DOT Maritime Administration contacted us regarding the merchant ship NS Savannah docked in Philadelphia harbor undergoing decommissioning. It needs to be defueled. The contractor needs to drydock the ship to remove three large pumps. Under federal authority it is regulated under the NRC and Maritime Administration to ensure independent radiological surveillance. The work should be done in a couple of months. When the work is finished up the ship will go back to Baltimore.

Nuclear Safety

Plume phase exercises occur every year, sometimes two or three depending on the cycle of the five power plants in the Commonwealth. Every eight years an ingestion exercise is performed. This exercise is a Chernobyl or Fukushima type scenario where the plant is extensively compromised, and radioactivity is released into the environment. The response then has to figure out how to recover from this. DEP performed very well.

DEP had a low-level waste advisory committee meeting last week. DEP manages a compact commission with Delaware, Maryland and West Virginia with Pennsylvania being the host site, however the site process has been put on hold since the 90's. As long as there is access for class A, B, C waste elsewhere we are ok to remain on hold. DEP will continue to monitor the disposal in Utah and Texas, as over 95% of the volume of class A waste goes to Utah.

TMI Unit 1 is now shut down. The plant has three options for decommissioning. Entombing, defueling, or safe storage. They have a 60-year window for the activation products to decay

and to finish decommissioning. Another option is to start decommissioning now, with this being a common method. Energy*Solutions* which runs the low-level waste site in Utah is interested in taking over the license for TMI Unit 1 and maybe TMI Unit 2. Beaver Valley may also be shutting down in a year or so.

Radon

More homes continue to be discovered in the high radon area below Allentown. Because of the high levels of radon in the soil and in rocks, DEP wants to require testing of homes in real estate transactions involving apartment buildings, schools, day care centers, and also to require new homes be built with radon-resistant new construction. There are legislative initiatives going on to try and make this a regulation.

Discussion Items

- Mr. Keklak stated that he expects to step down as chairman by the end of next year. A new Chairman will need to be elected by the next fall meeting. We are currently renewing terms for next year. Renewals from organizations are being figured out. We need to start thinking about succession in the advisory committee. According to bylaws the election would be open ballot at the beginning of the next meeting. The bylaws as written expired in 2006 and need to be renewed. We will need a volunteer to step up as chairperson for the spring meeting to step forward.
- The Compliance and Enforcement Guidance will be in the PA Bulletin and available for comment as soon as possible. This document is a basic overview on regulations. It was noted that this document does not talk much about licensee / registrant right to appeal the Notice of Violation (NOV). Mr. Schena stated that the NOV is not a final action and is not considered as appealable. An NOV identifies potential violations that we could take further action on. An order is a final action that can be appealed. The hope of the NOV is that there is communication between licensee and DEP to resolve. Mr. Schena believes the confusion is on the word appeal. It was requested that a licensee/registrant can challenge an NOV. DEP anticipates a conversation with the issuance of an NOV and will review any justification that may be returned and if the NOV situation is justified then the NOV will be retracted and the situation resolved.
- There were 17 NMED events from October 2018 through August 2019. These events range from simple industrial events involving stuck shutters on gauges to medical events involving cancer therapy on patients. NMED event reports capture a description of the event and the root cause of it. The NMED database is also public and searchable. It was suggested that Informational Notices should be sent out when issues occur or reoccur and that NMED does not have many details that were included in the licensee report. The answer is that the actual NMED reports are written by DEP and then Idaho National Laboratory (INL) rewrites them for NMED.
- It was noted that there are so many events regarding industrial gauges, how much effort is DEP spending on this area when these keep popping up? NRC has classified them as low risk and they are inspected every five years. The gauges are very robust and are inherently safe even when damaged severely. The actual event numbers are small relative to the very large number of the gauges in the field.
- There were four Medical Reportable Events involving machine therapy from October 2018 through October 2019. One was superficial radiation therapy for skin cancer. Two were due to table shifts before treatments, and the remaining one was due to

improper isocenter alignment. All of the radioactive material and X-Ray events will be included with the minutes.

- The recommendation from the RPAC over the next several months is to do a clean-up of the new Chapter 221 regulations. This should be a new action item.
- A question was raised regarding NRC's general capability. Under 10 CFR Part 30, there is a requirement to report a malfunction of a safety mechanism. Is there follow-up with manufactures, distributors, etc. to ensure they are addressing those malfunctions? If the NRC sees an increase with the incidence of this problem, they will follow up with the manufacturers. If the incident is not common, they do not follow up. The NRC looks for trends in the NMED data base and does respond to manufacturers for corrections if necessary.

Recent AAPM Position on Patient Gonadal Shielding

- It was noted that the basic physician statement is that gonadal shielding in the routine performance of X-ray imaging is a waste of time and is likely to add an increased dose or degraded imaging. Pennsylvania's § 221.11(f) states: "During diagnostic procedures in which the gonads are in a useful beam, gonadal 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". This should be interpreted to mean under the physician's purview. By virtue of the exception as it's written in the current regulation shielding would be situational if needed. If the institution feels this is going to interfere with the image, then they should not shield. A question was raised if there should be a regulation at all on this. However, a licensee policy in place to not shield based on certain needs will suffice to meet this regulation as peace of mind for patients can be relevant with some procedures. This can be put in an FAQ if necessary and changed at the next regulation revision.

Discussion of Current Chapter 225, 227, 228 Regulations on Analytical X-ray Equipment and CRCPD Model State Regulation SSR Part H for Radiation Generating Devices

- DEP has restructured the CRCPD model suggested state regulation (SSR) Part H into a PA format. The existing Chapter 227 will be reserved and replaced with this new restructured Chapter 227a. Also, Chapter 228 will need a definition edited as our regulations point to the NRC's regulations, and our definition for accelerators conflicts with NRC's. We will use the NRC's definition moving forward. Non-medical radiation-generating devices will be located in Chapter 227a while field work with X-rays that use non-medical applications are being left in Chapter 225.
- A paragraph (d) should be added to the Purpose and Scope of Chapter 225 to show that this chapter does not apply to the use of radiation-producing machines for permanent radiographic systems, cabinet x-ray systems, shielded x-ray rooms. Currently the industrial radiography definition is very broad, and needs reviewed. The definition of analytical X-ray machines in 227a is very similar, except it talks about structure instead of microstructure. That definition should be clarified. The definition of field radiography should also be reviewed as there are two different definitions, one in 225 and one in 227a.

- A question arose of why the term "Radiation Generating Devices" should be used. Should Chapter 227a be changed to Radiation-Producing Machines, as they are defined

in other places of the regulations? Several other terms have definitions but are not used in the regulations. Examples are certifiable cabinet X-ray system, mobile equipment, portable equipment, stationery equipment and stray radiation.

- The term “at any time” in the definition of open beam radiating generating device can also include when the beam is off. “During normal operations” or “when the beam is energized” should be used instead of “at any time.”
- Would a hospital testing a leaded apron for defects of fluoroscopy be considered a shielded room by the definition? This is nonmedical. DEP will look at “shielded room” and where it is used. This will be crafted more to the NCRP definition for unrestricted or restricted shielded room to demonstrate compliance with 10 CFR Part 20 in the state regulations. In Chapter 227a.14, there is a limit to the equivalent of a shielded room to 0.25 mrem per hour, so those dose constraints are not needed in the definition. Chapter 227a.55 notes the shielding criteria for a shielded room. Part of the problem is that when the cabinet X-ray regulations were moved here, what was true then is not the same for the scope of all applications now covered by this chapter. If shielded room was moved back to Chapter 225 under Industrial Radiography that would be more acceptable. Look at the definition for shielded room and when the requirements in 227a need to be met and include specific exclusions. A subcommittee should be established to polish things up and to note the difference between industrial uses and analytical uses in human use areas.
- Do electron microscopes meet the exemptions in 227a(c)(3)? Are electron microscopes incidental? Paragraph (c)(4) of this regulation should instead be (d). For clarity purposes we should explain that electron microscopes are not part of the exception. Under 227a.13(b) Radiation Emission Limits, Change the wording at the beginning and then delete the last few sentences because it has 2.5 mrem per hour and then a different limit in other places. Under § 227a.14, A leakage radiation of 0.25 mrem per hour at a distance of 5 cm is half of the current regulations in this section. This should be 0.5 mrem. There may be equipment that meets it now and fails the new regulations. Chapter 227a.15(a)(1) doesn’t match what was done for the human use regulations, the 12 months should be 14 months. It was suggested to remove annual survey with the frequency being the issue.
- Questions were asked regarding whole body scanners such as the ones in the prisons. These are fixed, extremely low dose machines; they’re not going to change unless a component is changed, or a repair is made. Why should a physicist have to come back in a year and just prove that it hasn’t changed? That’s not done for CT units or other X-ray units and these machines have less output. Also, the registrant has to have access to calibrated surveying. Does that mean you want prisons to buy survey meters and calibrate them annually when they don’t know how to use them? No, they only need access to a meter.
- In Chapter 227a.40 why are we suddenly having to write a justification for using X-ray equipment? It is regulatory overreach? This is less restrictive than what DEP previously required in our regulations. Perhaps the way the regulations were written previously made more sense in that it told every user what they had to do to ensure the safe use of that open beam device and also had accountability and now it isn’t there anymore.
- It is excessive to require eight hours of training for a radiation safety officer for security screenings. It’s not required when a doctor opens an office and puts in an X-ray machine. These are machines that in the worst case, deliver 0.25% of a chest X-ray in a year if you scan a prisoner 100 times. It was suggested that they should have one-hour training, no RSO, and just a point of contact with only initial surveys unless something

goes wrong as the health risk hasn't been proven. The ANSI standard used here is also excessive. DEP notes these people have zero education in radiation. Too often you see managers responsible and that unit gets moved all around opening up the machine for issues. Also, these suggestions make for X-ray units out in the environment with basically no regulatory oversight. There have been inspector reports from three facilities so far that "do not use the equipment" until DEP comes and inspects the unit, but when the inspectors got there, they saw images on the whole-body scanners of guards scanning each other for fun. It's suggested that less than eight hours of radiation safety training is needed. We will check the ANSI standards for reference and review the section of the regulations.

- Again, a suggestion was made to create a sub-committee to review Chapters 225, 277, and 228 regulations and submit comments to it.

- Dr. Rizzo's interest in the bill for RT licensure was mentioned, along with the note that no progress has been made thus far.

- Next meeting is March 19, 2020. October 29, 2020 will be the Fall date.

Adjournment – 3:00 p.m.