

**DRAFT Minutes of the Radiation Protection Advisory Committee (RPAC) Meeting
14th Floor Conference Room
Rachel Carson State Office Building, Harrisburg, PA
April 7, 2016**

Call to order – 9:07 a.m.

Members in Attendance:

John Keklak	Margaret Blackwood
Eric Boeldt	Tiffany Whitcomb
Kent Lambert	Anthony Montagnese
Shawn McNeely	Michael Sheetz
Paul Houle	Joseph Och
Victor Rizzo	Katherine Hetherington Cunfer
Janice Wirth	Steven King

Members Absent:

Vincent Roding	Peter Smith
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DEP Staff in Attendance:

David Allard	Lisa Funk
Joseph Melnic	John Chipppo
Kristina Hoffman	Bob Lewis
Ben Seiber	Terry Derstine
Sharon Trostle	Jessica Shirley

Guests in Attendance:

Karen Colucci	Tim Difelice
Kendall Berry	

Introduction of Members and Staff:

Introductions were made. Due to retirements, a number of vacancies on the committee need to be filled to maintain a diverse group of members. With Dr. Stump's retirement, a representative from the dental sector is needed, and with Eric Miller's job change, another non-medical representative would be welcomed. Mr. Keklak also noted the need for one or more physicians on the committee. For example, the recent retirements of Drs. Purse, DO; Pammer, DC; Chambers (cardiologist); and Eggli (nuclear medicine) have resulted in a loss of physician perspectives.

Adoption of Agenda:

Today's agenda was approved unanimously.

Approval of Minutes:

Meeting minutes from July 23, 2015, were approved unanimously.

Open Floor:

Once again a concern was brought up regarding surface dose irradiators, aka, superficial X-ray machines. In particular, advertisers are now referring to superficial X-ray devices as being “electronic brachytherapy” (eBx) as well as HDR (high dose rate) devices. As discussed during the last meeting, these machines are not eBx or HDR devices; they are therapy devices that fall under the “Therapeutic X-Ray Systems with Energies Less Than 1 MeV” section of Chapter 221, relating to X-rays in the Healing Arts. Pennsylvania currently has eight registrants using superficial X-ray devices, primarily the new Sensus and Esteya devices. Both devices are very safe, and our inspectors have seen no concerns regarding safety issues. The equipment requirements, surveys, calibrations, spot checks and operating procedures all fall under the current therapy regulations. Operator training is not addressed; however, the Department is advising registrants that operation should be administered by the physician, i.e., the Dermatologist, or by a radiologic technologist with a therapy specialty (ARRT-T). Committee members’ biggest concern is that some dermatologists don’t know or understand the importance of radiation protection. They feel training requirements are not being addressed appropriately. The Department will engage the PA Academy of Dermatology for a response to these concerns.

The Department of Health (DOH) issue was also discussed as in previous meetings. Once again, DOH is attempting to regulate radiation protection matters which fall under DEP’s authority. Numerous examples were given regarding discrepancies with DOH regulations resulting in continual frustration within the regulatory community. It was pointed out that DOH will be revising their regulations, and the committee suggested that DEP become involved with DOH’s regulatory process. DEP’s policy director will be reaching out to DOH to engage in this discussion.

A DEP inspector, Joe Koshy, requested the RPAC Chair, Mr. Keklak, to reintroduce his previous comment on the importance of a peer review for radiation therapy facilities. A motion was formally introduced, and approved unanimously, recommending that DEP develop a license condition to assure a high level of quality assurance (QA) and a peer review process for unaccredited facilities performing radiation therapy. The new condition can be implemented during the license renewal process.

RP Program Update

Regulation updates –

- Part 37 was finalized in January and became effective in March 2016. DEP had some questions from licensees, but the transition is moving forward without any major issues.
- The Fee package is being presented to the EQB on April 19, 2016. The RPAC will be notified when it will be published in the PA Bulletin for a 60-day public comment period. Formal comments are recommended to be provided through the eComment process online. Fees might be effective by the summer of 2017. No changes were made to the annex that RPAC endorsed. Any comments on the broad scope license fee should be submitted to eComment during the public comment period.

[Editor’s Note: The Department revised the medical broad scope license fee (Category 7B) from an increase of 50% to an increase of 25% in the proposed rulemaking that the EQB adopted.]

- The Radiological Health Regulations package is tentatively set to be presented to the EQB this summer, followed by a 45-day public comment period. DEP will consider holding workshops for outreach regarding the radon revisions.

Decommissioning/Environmental Surveillance – All buildings and towers at the Safety Light site have been torn down by the EPA. DEP is working on cleanups at Whittaker and Tenmile Creek with the acid mine drainage issue. At PSC Metals, a scrap metals recycling facility in Beaver Falls, a radium source was shredded and then shipped to Ohio. Significant contamination was detected at the facility within a 5,000 sq. ft. footprint. All operations were shut down. This will most likely be a multimillion dollar cleanup. The Beaver Falls facility had operating radiation monitors, but they failed to detect the radiation. It wasn't until alarms went off at a facility in Ohio that the magnitude of the problem became known.

Nuclear Safety – There will be three graded exercises this year: Peach Bottom, Beaver Valley, and Susquehanna power stations. Also, the Department of Defense (DOD) will sponsor a Vibrant Response exercise in May. The exercise scenario will be a 10-kiloton dirty bomb exploding in the Pittsburgh target area. Numerous state agencies (DEP, PEMA, DOH, Ag, PennDot, etc.) along with federal agencies (DHS, NRC, EPA, etc.) will be participating in this DOD exercise.

Radon – EPA Region III hosted a Stakeholder Meeting this week in Grantville, PA. There was continuing education offered for mitigators and testers. The Department will continue to conduct outreach with the American Lung Association. Follow-up continues at a Lehigh Valley neighborhood with high levels of radon. There are 14 houses with elevated radon levels over 1,000 pCi/L. Two houses broke a 30-year record, one at 2,700 and the other at 3,700 pCi/L. Mitigation systems were installed and reduced the levels below the EPA limit of 4 pCi/L.

TENORM Study – A revision will be published, but it will not change any of the recommendations. Minor cleanups were made and Appendix M was added for non-radiological data that was collected.

The hiring freeze seems to be slowly thawing. DEP has many impending retirements. BRP is at approximately 40% turnover in retirement in the next few years. A new civil service exam for Radiation Health Physicist Trainee was developed to attract radiological health graduates with no experience to apply to the bureau.

There was a Management Review Board (MRB) meeting on February 22 to discuss DEP's periodic meeting with the NRC, at which the Bureau received the NRC's best ranking as satisfactory and compatible. The MRB mentioned and agreed with our retirement concerns. There will be another periodic meeting in June 2017, and the next three-year Integrated Materials Performance Evaluation Program will be scheduled for January 2019.

Radiation Control

Summation of Regulatory Changes – BRP made a few minor changes to the Radiological Health regulatory package, such as further clarification of definitions (e.g., supervision). There will be some minor word and grammar changes, but no substantial changes before the public comment period begins. BRP will send notice to the RPAC members when the proposed regulation will be published in the PA Bulletin.

Three Information Notices Issued –

IN-2016-01 - PART 37, PHYSICAL PROTECTION OF RADIOACTIVE MATERIAL, IMPLEMENTATION UPDATE

The DEP issued this Information Notice (IN) to bring to the attention of PA licensees the impending implementation of the new regulations in 10 CFR Part 37. For Pennsylvania licensees, DEP has incorporated Part 37 by reference in 25 Pa. Code § 215.1(e). This IN is intended to provide a brief overview of the major differences between the current IC Orders and Part 37, and to note some of the new requirements contained therein. The current IC Orders in place with each PA IC license were rescinded upon the implementation of Part 37 on March 18, 2016. Each PA license was amended as such.

IN-2015-02 - QUALITY ASSURANCE ASSOCIATED WITH FLUOROSCOPICALLY GUIDED INTERVENTIONS - The DEP issued this Information Notice (IN) to notify registrants of a recently released National Council on Radiation Protection and Measurements (NCRP) Statement to clarify recommendations given in the NCRP Report No.168, *Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures*.

NCRP Statement No. 11 emphasizes that the safe performance of FGI procedures requires controlling radiation dose in order to prevent unexpected or avoidable tissue reactions and to minimize the severity of medically unavoidable injuries. It also provides guidance for controlling dose and for patient post-procedure follow-up.

IN-2015-03 - SECURITY ADVISORY FOR LICENSEES THAT POSSESS, USE, SHIP, OR RECEIVE RISK-SIGNIFICANT RADIOACTIVE MATERIALS

The DEP issued this Information Notice (IN) to bring to the attention of PA licensees a security advisory from the U.S. Nuclear Regulatory Commission (NRC) and the U.S. Department of Homeland Security (DHS). The DHS has designated the 2015 World Meeting of Families on September 25-27, 2015 – as a National Special Security Event (NSSE).

As a prudent precautionary measure, the NRC is requesting selected licensees who may possess certain risk-significant radioactive materials to maintain heightened vigilance for potential security threats during the period surrounding the 2015 World Meeting of Families event. It should be noted that, to date, there has been no specific, credible threat toward any licensee of radioactive materials during this period.

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

MRE – Two events

There were two accelerator events that were reportable; both were wrong location of an administered dose. One was due to an incorrect alignment resulting in 40% less than the intended dose. The other event had seven fractions over a seven-day period delivered to a calibration point rather than to the isocenter on the patient, resulting in a three-centimeter misalignment. The misadministration resulted in 89% lower than the prescribed dose. It was troubling to learn that the three-centimeter misalignment caused the system to send error messages, but they were ignored by the technologists because it was a “common message” seen during normal operations.

A suggestion was made to define “wrong treatment site” more appropriately. Adding “by point or volume” could clarify the definition better. It was recommended that the suggestion be

submitted as a public comment when the proposed Radiological Health regulatory revisions are published.

There was an event reported to the Department that was later determined not to be a reportable event. It involved 21 patients being treated for lung cancer using external beam radiation with 20% or greater dose to wrong areas. The locum physicist and Radiation Oncology Manager decided to report these events because some patients were set up for therapy with their arms down and not up. It was later learned that having arms down during long periods of treatment are acceptable for certain therapies. In addition, arms are not considered a critical organ for this type of therapy. Nevertheless, the facility notified the patients of the purported error, resulting in unnecessary stress to them before learning that there was no problem with their treatments.

NMED – 24 events
See attached document.

DOS denial of agreements with Physician Assistants (PAs) using fluoro – The Department reached out to the Department of State (DOS) about a concern PAs had regarding a limitation of them doing fluoroscopic scans. DOS responded by stating a *“physician assistant may provide any medical service as directed by the supervising physician when the **service is within the physician assistant’s skills, training and experience, forms a component of the physician’s scope of practice, is included in the written agreement and is provided with the amount of supervision in keeping with the accepted standards of medical practice.**”* 49 Pa. Code § 18.151(b).

Discussion of Issues/Concerns and New Initiatives -

Transition phase from Increased Controls (IC) to Part 37 – John Keklak commented on the difficulty in getting fingerprints done. Many local law enforcement agencies no longer do fingerprinting for the general public. A number of suggestions were given, including local UPS stores that do fingerprinting, as well as passport offices. Dauphin County Court House also does fingerprinting. Other County Court Houses may do the same. On the other hand, the FBI website is not very helpful. It asks for the user’s zip code in order to direct the user to the closest fingerprinting office. However, as an example, when Harrisburg’s zip code is inserted, it directs the user to Washington DC.

A requirement from the IC orders and continuing with Part 37 regulations is “Reinvestigations.” This requires that criminal background checks be repeated every 10 years. Since the IC orders went into effect in 2006, the 10-year time period is this year. However, fingerprinting was not required until 2008; therefore, fingerprinting does not need to be performed until 2018. Per, 10 CFR §37.25(c) “...The reinvestigations must be completed within 10 years of the date on which these elements were last completed.” The Department recommends if you’re going to redo a criminal background check, you might as well redo fingerprinting at the same time. To synchronize both requirements.

Another concern with Part 37 involves blood irradiators that are on a broad scope license but operated by a blood bank; which entity is responsible for trustworthy and reliable (T&R) determination? Currently the blood bank performs and maintains T&R determination and records, similar to a service provider’s responsibility. A request for legal interpretation may be made to DEP’s regional office for an official response.

Still another concern involves “reviewing official” (RO). The RO must undergo the same background investigation and fingerprinting as any other individual having unescorted access to category 1 and 2 materials. However, the licensee will determine if the RO has access to materials, the security plan and/or security procedures.

The committee wanted to register a complaint about DEP’s website. No one seems to know how to find anything on the newly formatted site. DEP staff responded that the site overhaul was a Commonwealth-wide initiative for consistency among agencies.

The Department informed the committee that Cardinal Health, a radiopharmacy, did a mass mailing to all Agreement States, as well as non-agreement states, to encourage NRC to take action regarding gallium-68/germanium-68 (Ga-68/Ge-68) generators. The issue is that Ge-68 is not listed on Part 30’s Appendix B table; therefore, the use of this isotope requires financial assurance. The Department learned that NRC is doing two things: 1) developing a regulatory basis for a direct final rule that would amend the Part 30 table for Ge-68 used in generators, and 2) as an interim step, granting Regions the authority to issue an exemption when asked for it, only for generators, and only if a contract is in place with the manufacturer/distributor to take the generator back when it is time for it to be exchanged or it is no longer needed. More information will be shared as it becomes available.

The Department requested Mr. Sheetz to present on the new Elekta Leksell Gamma Knife Icon. UPMC is one of the first hospitals in the nation planning on utilizing this new radiosurgery device. The Icon is an enhancement to Elekta’s Perfexion gamma knife, having a cone beam CT and an adjustable couch for motion detection and management. Because of these enhancements, fractionated treatments can be administered with accuracy up to 0.2 mm. The NRC is planning on issuing licensing guidance for this new gamma knife.

Open Floor

An inquiry was made about what the expectations are for implementation of Part 37. During this transitional phase the Department will be offering compliance assistance and, in particular, offering a checklist to licensees comparing the IC orders to Part 37. The NRC has also issued a Q & A based on its experiences with implementing Part 37 a year ahead of the Agreement States.

Mr. Difelice wanted to make known that, in his opinion, small imaging and surgical centers do not have the same focus on quality control and quality assurance as the larger hospitals. He recommended that the Department take note of these concerns. DEP staff noted that this subject will be addressed during central office/regional office monthly calls. Our inspectors can reinforce the importance of good quality assurance and control during cyclic inspections.

Adjournment – 3:03 p.m.