Minutes of the Radiation Protection Advisory Committee Meeting
14th Floor Conference Room
Rachel Carson State Office Building, Harrisburg, PA
April 11, 2013

Call to order – 9:08 AM

Members in Attendance:
Mr. John Keklak, Ms. Margaret Blackwood, Ms. Jean Gresick-Schugsta, Dr. William Thorne, Ms. Janice Wirth, Mr. Joseph Och, Dr. Peter Smith, Mr. Shawn McNeeley, Mr. Michael Sheetz, Mr. Vincent Roding, Mr. Kent Lambert, Dr. John Pammer, Mr. Eric Boeldt, Ms. Marjorie Hughes

Members Absent:
Dr. Douglas Eggli, Dr. Charles Chambers, Dr. Charles Stoup, Dr. Richard Purse, Dr. Paul Houle

Personnel Representing DEP:
Mr. David Allard, Director, Bureau of Radiation Protection; Mr. Joseph Melnic, Chief, Division of Radiation Control; Mr. Terry Derstine, SE Regional RP Manager; Ms. Niki Noll, SE RAM Supervisor; Mr. Robert Zaccano, SC Regional RP Manager; Mr. Dennis Ferguson, SC X-ray Supervisor; Mr. Ben Seiber, RP Program Analyst; Ms. Sandra Martin, Chief, X-Ray & Accelerator Licensing; Ms. Jessica Shirley, DEP Policy Office; Mr. Robert Altenburg, DEP Policy Office; Ms. Kristina Hoffman, RP Program Analyst; Ms. Dyran Altenburg, Management Technician; Mr. Curtis Sullivan, RP Counsel

Members of the General Public in Attendance:
Mr. Ray Urciuolo; Widener University Law students

Introduction of Members and Staff:
Mr. Melnic introduced Mr. Eric Boeldt as a new Member-At-Large. Mr. Boeldt is the Radiation Safety Officer at the Pennsylvania State University. A group of Widener University Law School students attended the meeting as part of an Environmental Law course.

Adoption of Agenda:
Today's agenda was approved unanimously.

Approval of Minutes:
Prior to approval of the October 18, 2012 minutes, Ms. Blackwood noted the minutes need to be modified to include the formal election of the chair and vice-chair. The minutes were approved with this modification, which Mr. Melnic will make.

Open Floor:
Ms. Gresick-Schugsta commented that she had asked her veterinarian if he would be interested in reviewing the new regulations that will be proposed. Mr. Allard asked if he would be willing to join a subcommittee when a group is formed. Ms. Gresick-Schugsta noted he may not be able to come to a meeting since he has a busy practice, but she agreed to give Mr. Melnic the veterinarian's name and contact information.

Mr. Melnic discussed the NRC Information Notice (IN) regarding industrial radiographers and overexposures throughout the nation. Pennsylvania issued its own IN in January 2013 because one of the examples the NRC provided involved a radiographer from Pennsylvania. Mr. Melnic noted that we issue our own IN whenever NRC publishes something relevant to our state. Mr. Roding commented that overexposures occur because radiographers are not following the training they are given. Mr. Allard stated that the bureau just completed NRC-sponsored inspector training, and the instructor relayed an incident where an industrial radiographer in Rhode Island working at a facility containing fixed nuclear gauges started a job without any survey meters. Unknowingly, the source was open and he serviced it. The man ended up losing some fingers from this preventable event.

RP Program Update:
The radiation protection (RP) program has purchased new X-ray test equipment to improve the efficiency of our inspections. The equipment is AccuGold from Radcal. This new equipment along with the mobility project will allow inspectors to interface results into our agency database. We also are looking at a small compact stand-alone meter called ThinX from Unfors RaySafe to be used to verify results.

The BRP is reviewing the X-ray and Radioactive Materials procedures and will update if necessary.

The Integrated Materials Performance Evaluation Program (IMPEP) conducted by the NRC is scheduled for October 2013. IMPEP is an audit conducted by the NRC to verify that PA is regulating radioactive materials per the Agreement. Our initial IMPEP in 2009 went very well. There was only one recommendation, and it was addressed immediately. The BRP is planning to self-assess our inspections with Frank Costello and Dwight Shearer prior to the October 2013 IMPEP.

NCRP Meeting: Mr. Allard addressed technologically enhanced naturally occurring radioactive material (TENORM) at the Act 5 Scientific Committee of the National Council on Radiation Protection (NCRP) meeting. NCRP is looking at publishing a report on TENORM. The focus of the NCRP meeting was radiation dose and impacts and population exposures. The meeting also covered the Fukushima accident and the work being done because of it. John Till, a nationally recognized health physicist, presented the Lauriston S. Taylor Lecture on risk assessment.

The International Commission on Radiological Protection (ICRP) has a new report out, ICRP Publication #103. Our regulations are mostly based on ICRP Publications #26 & #30 (circa 1976-77 standards). The Occupational Safety and Health Administration (OSHA) regulations are still based on Report #2 (circa 1960). Mr. Allard is a state observer for the Interagency Steering Committee on Radiation Standards (ISCORS), and the NRC has directed their staff to evaluate ICRP #103.

The EPA is the standard-setting agency. They published a Federal Guidance (FG-14) on diagnostic X-ray for comments. This is an update of the federal guidance that was created during the Ronald Reagan era. John Winston, of the Western RP Program, is a subcommittee member of the ISCORS for this guidance document.
http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OAR-2010-1064-0001
http://www.epa.gov/radiation/docs/federal/FGR14%202012-10-10.pdf

Nuclear Safety:

- The Appalachian States Low-Level Waste Compact meeting was held in November 2012.
- Waste Control Specialists in Texas is licensed to accept low-level radioactive waste disposal, and they take Class B and C wastes. Most waste in PA is Class A.
- Limerick Generating Station (LGS) is going through the license renewal process. LGS is Pennsylvania's last nuclear power plant seeking renewal, but it is now being held until the NRC completes an Environmental Impact Statement on the Waste Confidence Rule for spent nuclear fuel.
- The NRC regulates the nuclear power plants; the Federal Emergency Management Agency (FEMA) regulates off-site response capabilities. DEP's RP Program is reviewed by FEMA 2-3 times a year for graded exercises, which are mostly plume-phase exercises. In the next two years, Pennsylvania will be conducting Hostile Action-Based exercises. The first one to be evaluated in the nation is at Three Mile Island on Tuesday, April 16, 2013.
- Our triennial nuclear power plant fee review is due. The last time this was amended was in 2007. After this review, we will be looking at all other fees; however, the nuclear power plant fees will be in a separate package from current regulatory revisions in development.
- BRP continues to monitor the post-Fukushima work from the NRC task force.

Decommissioning & Surveillance:

- Decommissioning of Strube sites is almost complete.
- Lock Haven Court is also getting close to being finished.
- Keystone Metal Reduction is an old uranium mill-tailing site, circa 1920s, with potentially several hundred tons of ore requiring clean-up.
- The Shallow Land Disposal Area (SLDA) is the only licensee that did not come under our authority from the NRC when we became an Agreement State. SLDA has enriched uranium in ten low-level waste (LLW) trenches, which were added to the Formerly Utilized Sites Remedial Action Program (FUSRAP) list. The US Army Corps of Engineers (USACE) was remediating SLDA and ran into some problems with criticality issues. USACE shut the project down to reassess everything and terminated the license. They have a new contractor and hopefully the project will be starting up again next year.

Radon:

BRP is updating its radon regulations. This was last done in the 1990s. EPA Region III is conducting a Radon Stakeholders Meeting in Martinsburg, West Virginia, on April 10 and 11 where a number of BRP staff are participating. In the past, we have received an EPA grant for public service announcements and outreach awareness. The recent federal budget has no State Indoor Radon Grant (SIRG) money. This will most likely terminate state radon outreach programs. We will be able to maintain the radon program; however, the American Lung Association and Rutgers subcontracts for training real estate agents will be terminated if this SIRG money is not part of the final budget. Recently we learned of a brand new home in southeast PA that has 800 pCi/L of radon. The action level is 4 pCi/L, and the EPA estimates an average house is 2 pCi/L. We are working with the homeowner and builder. When we see numbers over 100 pCi/L, we occasionally do "Hot-Spot" surveys around the house in question. We reach out to the local municipality and get a list of houses in the vicinity, and we offer the owners free radon test kits. The geology and soils are the cause for these high levels. With

radon resistant new construction, fans aren't typically installed during the initial construction of the home. After the home is complete, and the occupants are living there, then a radon test should be performed. One cannot predict the radon levels in any given house without doing the actual radon test. If elevated radon levels are detected, then a fan is installed in the already existing piping system. We are continuing to encourage radon resistant new construction techniques be installed during new home construction.

Radiation Control:
The Government Accountability Office (GAO) is auditing RAM licensees throughout the nation. This time they are looking at non-medical facilities. In March 2012 the GAO investigated medical facilities, and their report to Congress on the radioactive materials in medical facilities was controversial. Their scathing report implied that there are radioactive materials available for anyone to take at any time, and security is vulnerable. The Bureau, as well as the NRC, disagrees with their assessment. We have recently sent a letter to all non-medical facilities to alert them to possible audits. If anyone is contacted by the GAO, we would like to know. So far there has been one facility in Pennsylvania contacted by the GAO—a federal facility in the southeastern region. Even though DEP does not regulate federal facilities, the GAO allowed BRP to accompany them on this audit. BRP would like to accompany the GAO on any other audits in the Commonwealth. Everything BRP does is open to the public; however, for security reasons, we do not publish license or other information relating to radioactive materials. Mr. Sheetz asked if the National Nuclear Security Administration (NNSA) is working with the GAO on these audits. Mr. Melnic replied that NNSA did attend the audit in Pennsylvania with the GAO. NNSA has been funding enhancement upgrades for the security of radioactive materials.

Lung Cancer Screening Using Low-Dose CT – In the past there has been a CT screening moratorium. Recent studies are showing low-dose CT screening is helping to save lives. There are two types of screening. *Healing arts screening,* as defined in our regulations, is a type of screening that does not require a physician's prescription. An example of this is osteoporosis screening using X-ray devices to test bone density. A registrant needs to submit a number of regulatory requirements to DEP for approval in order to conduct this screening. We will permit *healing arts screening* if it is suitable and all questions are answered appropriately. Conversely, there have been times in the past when frivolous requests have been submitted. An example is when *healing arts screening* is requested for the primary purpose of soliciting legal action against a company, such as, scanning former workers from an asbestos factory. We do not approve these types of requests. Regarding lung cancer screening, the National Institute of Health (NIH) is releasing a study on this subject. We consult with the PA Department of Health (DOH) if a proposed screening procedure results in a dose over 100 mrem; CT scans are over that limit. Ms. Gresick-Schugsta asked if that is what happened when she sent in the application for her hospital. Mr. Melnic said no, her hospital is not requesting *healing arts screening* approval; they are submitting a procedure for using low-dose CT. A protocol was submitted in which a number of criteria are reviewed and approved by a physician and then a signed prescription for the individual is written. Because of that, it falls outside the realm of *healing arts screening*. There's an order or prescription being written, and typically there is a patient/physician relationship where the results are being shared with the personal physician and individual. Some facilities are offering cessation programs. Mr. Och asked where BRP is going with this; for example, are we opening up to self-referrals? Mr. Melnic reiterated that if protocols are met and a prescription is written, the department will not prevent a low-dose CT lung scan. If it is going to help save lives, and a number of studies are indicating these scans are saving lives, BRP will not impede these procedures. Ms. Gresick-Schugsta asked if this

may become an approved screening in the future. Mr. Allard affirmed that it may be, but he would like to officially hear from the DOH that it does save lives. Mr. Sheetz is concerned about who ensures that a 'low-dose' technique is utilized.

Reimbursements for RPAC members – These reimbursements come from BRP funds; however, they still need to be sent to Commonwealth Payroll Operations Travel Audits for review and approval. That agency is requesting that RPAC members use rental cars from Enterprise to attend meetings. Otherwise, BRP must provide justification for use of a member's personal vehicle thus delaying the approval process. Mr. Allard stated he will discuss this issue with the administration. Ms. Wirth asked for the status of reimbursements from previous meetings. Dr. Pammer said that he has not received his past two reimbursements. Mr. Och would like to know to whom they can file a complaint. Ms. Hughes invited everyone to submit their comments/complaints to the Citizens Advisory Council, which is conducting a broader review of public participation. Their website and an article about their review of public participation can be accessed at the following links:
http://www.portal.state.pa.us/portal/server.pt/community/citizens_dvisory_council/14019
http://paenvironmentdaily.blogspot.com/2013/03/dep-citizens-advisory-council-asks.html

Radium-223 Dichloride Update from NRC – There are two facilities in PA doing investigative studies for the FDA. The FDA is learning that radium-223 dichloride is a beneficial therapy and they have it on a fast track for approval for clinical use. They requested the NRC to review and submit their opinion on its use. The NRC, along with the Advisory Committee for Medical Use of Isotopes (ACMUI), gave formal endorsement for this form of therapy. The procedure expands lifespan more so than simply palliative care. Mr. Allard said that there is a company that distributes this material (Bayer), and perhaps the bureau can sponsor a symposium on the subject. Mr. Melnic said once it's approved it will be classified as Part 35.300 material. The bureau would like to know which licensees will be using radium for this type of treatment, but an amendment may not be necessary if a license already is approved for 35.300. Mr. Allard suggested we issue an IN to clarify the bureau's intentions regarding this new therapy. Ms. Gresick-Schugsta said there may be a way BRP will know who, among new licensees, is using this therapy. Authorized users are required to submit a provision indicating training for alpha emitting radiopharmaceuticals. Mr. Lambert indicated the risks are minimal, so he is wondering why BRP is concerned. Mr. Melnic replied that our concern relates to the fact that it is a new therapy and the only alpha emitting isotope being used today.

Electronic Brachytherapy (eBx); A New Licensee – PA has issued its second license for electronic brachytherapy. Our first licensee uses the manufacturer Zoft. This new licensee uses a device manufactured by Zeiss. BRP does not yet have specific regulations addressing eBx; however, they are being proposed in the regulation package. Due to the type of therapy and higher risk, BRP requires licensure rather than a simple registration. Mr. Lambert asked if the regulations will be similar to 35.1000. Mr. Melnic replied yes, there will be something similar to address emerging technologies. Ms. Gresick-Schugsta asked if eBx will be under Chapter 221 or 228 regulations. Mr. Melnic said it will fall under the therapeutic section of Chapter 221, X-rays in the Healing Arts.

Diquad meeting with PDA – BRP had a meeting with the Pennsylvania Dental Association (PDA) explaining why we are using this device. The Diquad gives additional matrixes that inspectors may not look at or verify. It gives criteria that show if film or digital image is appropriate. We stress to dentists the importance of optimizing dose to image. Our inspectors

highlight NCRP reference values for different film speeds to dentists. This is beyond compliance, but if exposures are high, perhaps altering the kVp and mAs may give the same image at a lower dose. The bureau will be issuing an IN on this subject for all dentists. BRP is also modifying the medical and dental X-ray inspection procedures. Inspectors are using their survey equipment as well as the Diquad. Mr. Och asked about the image quality metric. Mr. Allard explained it can be found on Dr. Gray's website at http://www.diquad.com/. Dr. Gray is a medical physicist who developed the Diquad analyzer.

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

Fifteen material and accelerator events and one diagnostic fluoro event have occurred since our last meeting:

- One under dose of a microsphere (SirSpheres)
- One brachytherapy permanent seed implant under dose (<60% of the prescribed dose)
- One industrial radiographer could not retrieve a source normally.
- Two shutter gauge failures
- Five lack of control of licensed material events
    a.) Two FedEx shipments of radioactive materials dropped off during off-hours and stored in a non-radiation control area
    b.) One source delivered to a wrong address
    c.) One lost portable gauge (but recovered the same day)
    d.) A patient was released from a hospital after undergoing a radioisotope procedure, succumbed shortly afterwards and was released to a funeral home
- Five medical accelerator misadministrations
    a.) Two wrong locations treated
    b.) Two administrations of a dose >±20% of the prescribed dose.
    c.) There is one ongoing accelerator incident pending enforcement; a wrong patient was treated with another patient's script. The facility believes since the treatment was "substantially the same" no reporting was necessary. However, the department regulation stipulates a reportable event occurred if a wrong patient is treated.
- A diagnostic event occurred when an interventional radiologist conducted fluoro procedure that lasted 67 minutes. This particular hospital's policy is that if a procedure exceeds one hour, it will be reported and the patient will be evaluated for damage 48 hours later and then again four weeks later. The 48-hour check showed no harm (erythema); however, the patient did not return for the monthly check.

Continuation of Discussion Addressing Needed Revisions to Radiological Health Regulations:

Parking Board – this is a mechanism for bureau inspectors and management to tabulate questions and concerns via an internal spreadsheet for discussion of our regulations. RPAC requested at the last meeting to review this spreadsheet. The RPAC was asked to review the parking board to see if there is anything that needs to be added. Any comments should be given to Mr. Melnic.

Dave Allard stated that BRP will be adding a pointer to our regulations for Part 37 that the NRC just published. The NRC licensees have one year after it is published to implement. We believe it is three years for agreement states to implement; however we are going to try to do this in two years. We may conduct a workshop prior to the October meeting, possibly in late

summer. Pennsylvania will be hosting the next Mid-Atlantic States meeting on September 24 and 25 in the Philadelphia area. We will offer MQSA training at the same time. (The Mid-Atlantic States are comprised of Pennsylvania, Maryland, New Jersey, and Delaware.) The bureau was invited to participate one day for the radiation safety officer roundtable in State College scheduled for September 16, 2013. As such, we are trying to have our next management meeting changed to September 17 in State College.

Additional Topics:
Mr. Melnic announced that Secretary Krancer's last day with DEP is Friday, April 12, 2013. The RPAC members are invited to a reception for him today on the 16th Floor.

Ms. Hughes reminded everyone to send their comments on reimbursement to her.

TENORM Study:
Dave Allard explained that TENORM is defined in the solid waste regulations under the radiation protection action plan. There are somewhat high levels of TENORM, particularly radium-226 and -228, in the brine and flowback water that go to treatment facilities from the oil and gas industry. Hydraulic fracturing is a national issue. The industry drills down 5,000 feet and then horizontally up to 13,000 feet. This fractures the shale and releases the natural gas. There is wet gas in the southwest and dry gas in the northwest areas of PA. Water flows back and gets trucked to treatment facilities. There is elevated radium-226 in the waste water. Because of this high volume from the Marcellus shale waste, we have initiated a study. The study is from cradle to grave to review worker radiation exposure, environmental impact and solid waste issues. The study will focus on well sites, different cutting of wet versus dry gas, well pads and transportation to treatment facilities. The study will take 12 to 14 months to complete. The Field Sampling Plan, Scope of Work, Checklist and Quality Assurance Plan have been posted on the DEP website. Our Bureau of Laboratories and a contracted lab (Gel Labs in South Carolina) will be receiving and analyzing the samples collected.

Adjournment – 12:17 p.m.