# Minutes of the Radiation Protection Advisory Committee Meeting 14<sup>th</sup> Floor Conference Room Rachel Carson State Office Building, Harrisburg, PA December 12, 2013

Call to order - 9:05 a.m.

#### **Members in Attendance:**

Mr. John Keklak, Mr. Shawn McNeeley, Mr. Michael Sheetz, Mr. Vincent Roding, Dr. Paul Houle, Mr. Kent Lambert, Dr. John Pammer, Mr. Eric Boeldt, Ms. Marjorie Hughes, Mr. Joseph Och, Mr. Anthony Montagnese

#### **Members Absent:**

Ms. Margaret Blackwood, Dr. Douglas Eggli, Dr. Charles Chambers, Dr. Charles Stoup, Dr. Richard Purse, Ms. Jean Gresick-Schugsta, Ms. Janice Wirth, Dr. Peter Smith, Dr. William Thorne

### **Personnel Representing DEP:**

Mr. David Allard, Director, Bureau of Radiation Protection (BRP); Mr. Joseph Melnic, Chief, Division of Radiation Control; Mr. Robert Zaccano, SC Regional RP Manager; Mr. Dwight Shearer, SW Regional RP Manager; Mr. Ben Seiber, RP Program Analyst; Ms. Sandra Martin, Chief, X-Ray & Accelerator Licensing; Ms. Sharon Trostle, DEP Executive Assistant; Mr. Robert Altenburg, DEP Policy Office; Ms. Kristina Hoffman, RP Program Analyst; Ms. Dyran Altenburg, Management Technician; Mr. Curtis Sullivan, RP Counsel; Mr. Robert Lewis, Chief, Division of Radon; Ms. Denise Bleiler, Chief, Radon Monitoring Section; Ms. Kelley Oberdick, Chief, Radon Certification Section; Mr. Robert Maiers, Chief, Division of Decommissioning and Environmental Surveillance; Mr. John Winston, SWR Inspector

# **Members of the General Public in Attendance:**

Ms. Karen Colucci; Mr. Kevin Stewart; Mr. Ray Urciuolo

#### Introduction of Members and Staff:

Mr. Melnic introduced Mr. Tony Montagnese as a new Member-at-Large. Mr. Montagnese is the Radiation Safety Officer at Lancaster General Hospital. Mr. Melnic also announced that Marge Hughes, Citizens Advisory Council Executive Director, will be retiring January 3, 2014.

#### Adoption of Agenda:

Today's agenda was approved unanimously.

# **Approval of Minutes:**

The April minutes were approved unanimously.

#### **Open Floor:**

Kevin Stewart, Director of Environmental Health with the American Lung Association (ALA) in Pennsylvania, wished to acknowledge the good relationship ALA has with the Radon Division. He also wanted to voice a concern from the radon industry the ALA has been made aware of involving some of the provisions and processes pertaining to the current regulatory environment. The ALA supports the need for a well regulated radon industry program and

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encourages a collaborative relationship between the regulatory body and the industry on developing the new regulations. He closed by wishing all parties success with this process. Mr. Keklak thanked Mr. Stewart for his comments and assured him that all regulations will be reviewed by RPAC.

Karen Colucci, Radiation Safety Officer for Lehigh Valley Health Network, addressed the committee with concerns regarding the importance of infection control in the hospital setting and the use of extremity dosimetry. She noted that her facility's administrative council is committed to abiding by the national safety goals of the Joint Commission in efforts to reduce infection. The administrative council determined that the staff working in the operating room should not wear ring dosimeters because of concerns of infection control. Mr. Montagnese reiterated the same concerns at his hospital. He noted that there are two risks. One is the risk of infection and the other is the risk of an unmonitored extremity. In either case, both are in conflict and common ground needs to be found. It should be noted though that infection control takes priority in every hospital setting. He further stated a physician would rather deal with an inappropriate regulation than a potential lawsuit. Mr. Allard pointed out that this is not strictly a Pennsylvania issue; it is a nationwide issue. He said there is a draft NUREG (nuclear regulatory guide) currently out for public comment. Comments are due by December 24, 2013. He asked that if there is a paper or a study addressing this problem to forward it to him so he can present it to the national Conference of Radiation Control Program Directors (CRCPD). Mr. Sheetz noted the standard for infection control in an operating room is "nothing from the elbows down."

Mr. Montagnese also noted that he became aware that DEP is beginning to define the fluoroscopic beam as a High Radiation Area. He stated that he has never heard of such a designation and that the intent of defining a High Radiation Area was never meant to be for fluoroscopic beams. If the Department is to continue in that realm, additional requirements would need to be enforced. Mr. Allard agreed that X-ray rooms are exempt from being classified as High Radiation Areas.

Mr. Och requested further clarification regarding extremity dose. Mr. Melnic replied that we would like to see, at a minimum, that this issue has been discussed with the radiation safety committee. Mr. Allard said we can accept analysis such as digital video studies showing actual recordings. Mr. Och agreed that would be better accepted because it is performance based rather than regulatory based, which is a good step. Mr. Allard reassured the committee that BRP will take the subject to CRCPD for further discussion and perhaps a task force can review it further. He reiterated that it would be helpful if anyone can forward any type of documentation to him.

# **Radiation Protection Program Update:**

<u>Decommissioning</u>: The Decommissioning Division is engaged in a number of site cleanup activities, including the Safety Light Corporation site.

<u>Nuclear Safety</u>: Nuclear Safety participated in a hostile action-based (HAB) graded exercise for TMI. It was the first graded HAB exercise in the country and it went very well, resulting in a satisfactory rating. Limerick Generating Station also had a successful exercise.

Radon: January is Radon Action Month; public service announcements are being prepared. Mr. Allard announced that BRP would like to take a survey at the next RPAC meeting to see how many members had their home tested for radon. Mr. Lambert noted there may be a liability

in doing so because having a number requires disclosure. Mr. Allard responded that it is better to know that number than to delay a potential home sale.

<u>Sabbatical Project</u>: Dr. David Simpson, a professor of Health Physics at Bloomsburg University, spent his sabbatical with BRP working on a training material project for X-ray operators. BRP is currently reviewing his work and is anticipating providing continuing education training for X-ray operators.

<u>TENORM Study</u>: The Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM) Study is ongoing and involves all program areas. DEP is looking at three major issues:

- 1) Do we need to regulate worker radiation exposures that exceed the public dose limit?
- 2) Are there any other unknown environmental contamination issues?
- 3) Waste disposal management. (Unlike Ohio, Texas, and other states, we do not have deep well injection.)

Mr. Boldt asked how the Department is going to assess employee exposure at well sites and if it will be treated the same as airline crews. Mr. Allard said the dose is approximately 300 mrem per year for airline crews. So far results at well pads do not seem to be that high and are not an issue; however, there may be some other operations that could be. Studies are ongoing. A brochure of the TENORM study was distributed to members. A summary, scope and all protocols are posted on the DEP website.

Radiation Control: BRP released three Information Notices since the last RPAC meeting:

IN-2013-03: Expiration of Transportation Package Certificate for QSA Global Inc., Model 660. The Certificate of Compliance expired June 30, 2013. This is an Industrial Radiographer's transportation package. The IN was sent to all of Pennsylvania licensed industrial radiographers to inform them that this package will no longer be permitted for use.

IN-2013-04: Licensing Requirements for Sentinel Lymph Node Biopsy. It was brought to BRP's attention by one of our inspectors who learned that these types of biopsy procedures are at times sent to a non-licensed pathology lab. The concern was for non-radiation workers handling radioactive samples. When BRP looked into this a little deeper, we found an NRC Regulatory Issue Summary (RIS) addressing this situation. RIS 2008-31 gives specific limits stating the sample should not exceed 100  $\mu$ Ci of Tc-99m. Since Pennsylvania incorporates by reference the NRC regulations, we thought it a good idea to share this RIS with our regulated community. What wasn't anticipated were the concerns from licensees. It was investigated further and found an argument given by the Advisory Committee for Medical Use of Isotopes (ACMUI) stating this limit is too stringent. Mr. Melnic said he requested NRC to reevaluate the RIS and provide us with updated guidance. We are still awaiting their response. Mr. Allard suggested we contact the Organization of Agreement States and to formally request a reevaluation by the NRC. There are a number of different scenarios, and Mr. Allard requested they be sent to him.

IN-2013-05: Importance of Verification of Treatment Parameters for High-Dose Remote Afterloader Administration. Mr. Melnic noted that, thankfully, there were no examples listed in the NRC IN from PA licensees. Nevertheless, it is essential to remind licensees of the importance of verifying treatment parameters.

Due to the government shutdown the Integrated Materials Performance Evaluation Program (IMPEP), initially scheduled for the week of October 7, was rescheduled for January 13-17, 2014. IMPEP is an evaluation by the NRC to determine if an Agreement State is performing adequately. This audit occurs every four years. BRP's first IMPEP was successful with only one recommendation, which was immediately addressed. The NRC has already performed the inspection accompaniments for this IMPEP, and the Department feels confident the final result will be satisfactory (the highest assessment given).

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

There have been 17 events since the last RPAC meeting. Eight were medical accelerator events (3 wrong doses; 3 wrong sites; 2 wrong patients); 2 Y-90 under-doses; 2 leaking sources; 2 gauges damaged; 1 source shielding malfunction; 1 fire and explosion; and 1 lost source in West Virginia by a PA licensee.

# **Regulatory Revisions (Radon):**

Two public meetings will be offered on the Radon regulation revisions following publication in the *Pennsylvania Bulletin*. Steps involved in the regulatory revision process were discussed. The process, which involves advisory committee review at both proposed and final regulation stages, takes approximately two years from start to finish. Ms. Hughes distributed copies of a brochure developed by the Policy Office describing the regulation process.

The Chapter 240 Radon revisions constitute a large regulatory package. There are no major changes to the basic structure of the regulations; however, the regulations are being strengthened. Most of what is being added is already occurring in practice within the radon industry. There is an increase in the volume of the regulations as a result of incorporating EPA testing protocols, Quality Assurance (QA) requirements, and PA Radon Mitigation Standards as well as reference to one American Association of Radon Scientists and Technologists (AARST) testing protocol. Dr. Houle asked if any other AARST protocols will be incorporated. Mr. Lewis responded that at this time only the ANSI/AARST MSMF-2010, Protocol for Conducting Radon and Radon Decay Product Measurements in Multi-family Buildings, is being incorporated

Regulations are added for mitigator firm employees to take a course to become certified. The certified mitigation firm pays the fee, and the employee cannot work on his or her own. A certified mitigator has more requirements regarding accountability, pays a fee, takes a course and passes an exam, does 16 hours of continuing education, proves competency and can work on his/her own. A firm (listed) employee works under the responsible charge of a certified mitigation individual. Mr. Allard suggested that development of a PowerPoint presentation would help to clarify the process.

The RPAC asked for clarification of the term "resident" in relation to § 240.2(a)(1) (relating to scope). It seems to be very similar to subsection (a)(6). "Person" is defined as an individual, corporation or public institution. Clarification is needed as to whether "reside" means to occupy or sleep in. It was suggested that "person" be changed to "individual" and a definition be added for "corporation." Mr. Lambert gave an example: Drexel is eligible to test in their buildings under (a)(1), but not under (a)(6), and Philadelphia School District has five conditions to do testing in their buildings. He doesn't understand the difference. Does DEP really want to exempt every business? There is also a question of why a company or school does not need to have someone certified to test their buildings when it affects other people. There are exemption

criteria in (a)(6)(iii) for an employee in a local government or school who performs testing in those buildings; there is no requirement to test. Mr. Lambert also asked what would be approved under (a)(6)(iv) (Department-approved scientific research) or if there is a department-wide approval policy in place. The Department responded that no policy exists. A one-page form could be created, and perhaps research that has gone through an independent review board would be approvable. More thought needs to be given to this.

The RPAC recommended establishing a subcommittee to go through these changes step-bystep. The subcommittee can include people who are not RPAC members. Mr. Keklak asked to be copied on all subcommittee work. The Department agreed to forward a Word version to the subcommittee members to edit using track changes and add notes. Paul Houle will chair the subcommittee and additional members will be added.

A question was asked about how, in § 240.305 (relating to Health and Safety Program), exposures can be kept as low as reasonably achievable (ALARA). To keep exposures ALARA the tester or mitigator should minimize time in the exposed area and provide outdoor ventilation when necessary. Exposure tracking can be accomplished by use of the pre-mitigation radon value for the particular home and the time the individual is in the affected area. They use the pre-mitigation radon value and convert that to working levels by dividing by 200, then multiply by hours worked in the affected area. Divide that result by 170 to get working level months (WLM). Keep a running total of each individual's WLM.

At the conclusion of the radon regulations discussion, Mr. Allard announced that Bob Lewis, BRP's Radon Manager, was the recipient of the CRCPD Radon Hero Award for 2013.

# Regulatory Revisions (Chapters 221-220):

Chapter 215 – General Provisions. The NRC's new security regulations, Part 37, will be referenced in this section. Pennsylvania incorporates by reference most NRC regulations, but there are some exceptions. For example, federal regulations that deal with imports and exports are not incorporated because DEP does not regulate these actions. Also, federal violations and criminal penalties are not incorporated because the Department uses its own internal compliance and enforcement guidance.

§ 215.22 – Prohibited Use. Fluoroscopy units once used in shoe stores to see a person's foot structure are not permitted per regulation. The Department is now seeing the utilization of other non-medical uses for X-rays, for example, passenger-scanning devices at airports. A new requirement is proposed that any non-medical X-ray use must be approved by the Department prior to use.

The committee suggested deleting § 215.22(a) with the addition of § 215.22(c) (relating to prohibited uses). The Department agreed with that suggestion.

Mr. Urciuolo noted that there are references to "emerging technologies" in more than one area, and it should be defined in Section 215.2, rather than in Chapter 221. § 215.24 – Human Use. This section incorporates by reference both PA Department of State (DOS) and PA Department of Health (DOH) x-ray operator qualifications. DOS regulates all doctor offices and clinics, and DOH regulates hospitals. The Department believes the DOH requirements are out of date and would prefer to have all medical facilities have the same

qualifications. In order to be consistent for all facilities, DEP accepts the DOS qualifications. Mr. Allard noted that BRP oversees all radiation protection issues, and DEP regulations supersede DOH regulations involving radiation safety.

§ 215.31 – Granting Exemptions. DEP receives numerous requests for exemptions to fees from nonprofits. This revision will not permit exemptions for fees. However, there may be a situation where a licensee purchases a building that requires decontamination/decommissioning. The Department will usually request a separate license for this type of condition and may not charge a separate licensing fee.

By incorporating most federal regulations by reference, a committee member asked if the Department regulations automatically change any time that the NRC changes its regulations. Mr. Allard explained that when the NRC proposes a change, the Department will include the same time frame for implementation as the NRC. The committee asked if there should be a statement in our regulations that clarifies this. For example, no registrant or licensee wants to be surprised with new NRC regulations that automatically become incorporated by reference within Pennsylvania regulations. Mr. Allard responded that this will be reviewed. DEP provides notification in the Pennsylvania Bulletin when the NRC proposes changes. If the NRC changes their numbering, Pennsylvania s references may become inaccurate and will need to be changed accordingly.

- § 216.1. The purpose of this revision is to address electronic brachytherapy and the requirement to license rather than simply register this modality.
- § 216.2. This amendment requires mobile X-ray registrants to provide two days advance notice of the date and location where they will perform radiological services in the state. The Department does not restrict where the mobile units are going; however, it is necessary to know where they are.
- § 216.2(a)(3). The committee recommended that notification to DEP of changes in the number of machines a facility has should be made on the annual registration renewal instead of "within 30 days," as currently specified in the regulations. The Department agreed and will add a requirement to maintain an accurate inventory of all radiation-producing machines on-site. A suggestion was made to clarify the term "owner." The Department replied that ownership can be different than the name on the certificate. The section will be revised to notify the Department within 30 days of change of registrant name, address, ownership, or individual responsible for radiation protection.

The committee asked for further clarification of § 216.2(a)(2), which states an "individual to be responsible for radiation protection." In subsection (a)(3), it states "radiation safety officer." These terms should be consistent; RSO may not be the correct term and it could be confusing. Mr. Melnic explained that the term RSO is defined as an individual responsible for radiation protection; therefore, the terms are synonymous.

#### **Next Steps:**

Discussion of the regulatory revisions will continue at the March 6 RPAC meeting. Mr. Melnic encouraged committee members to send all comments and concerns to the chairman so they can be tabulated prior to that meeting. The comments/concerns will be entered and organized into a single document.

The committee suggested that, along with Computed Tomography (CT) regulations, another subcommittee may be needed for fluoroscopy regulations. Mr. Melnic commented that, after all comments/concerns are received, the committee can determine whether any additional subcommittees are needed. PET and simulator CT, not used diagnostically, are exempt from the QA required for diagnostic units.

Mr. Och suggested that the focus should be on monitoring and managing fluoroscopy dose to the public, rather than excessive attention to equipment inspection. RPAC members stated that quarterly measurements of fluoroscopy output are of no value. Such measurements should be performed after installation and then annually, as well as after any repairs or upgrades. There is also a resource and economic burden associated with the proposed increased measurement requirements. Mr. Och recommended adding language to the regulations addressing patient doses from fluoroscopic procedures. He suggested the possibility of adding a requirement that registrants shall have a dose management system and then develop guidance for it, similar to NCRP 168.

A member of the committee noted that the Joint Commission suggested adding a provision requiring schools to teach radiation protection to all medical students because most problems occur due to inadequate staff training regarding patient dose.

Mr. Melnic noted that the Department is adding in the regulation that vendors (service providers) are responsible for providing dosimetry for their employees who travel to different facilities with radiation areas.

#### Other Business:

Mr. Melnic informed the committee that James Yusko has retired from the RP Program's Southwest Regional Office. Jim had 32 years with the Department and was a tremendous asset to the bureau. Dwight Shearer has been selected to replace Jim as program manager in the Southwest Region.

Mr. Melnic acknowledged that calls are coming in regarding inspection practice inconsistencies between the regions and how the bureau is handling inspections, violations and penalties. This is an ongoing topic at regular RP manager meetings. BRP follows agency-wide matrices and strive for consistency throughout the Commonwealth.

The most serious concern expressed by some RPAC members in recent months is that no mechanism for review beyond the level of regional directors/managers seems to be in place. RPAC expressed concerns about misinterpretation of the regulations within at least one region. Mr. Allard noted that the Secretary and Deputy Secretaries meet quarterly to discuss matters of agency-wide concern, including consistency issues. He added that this example brings back the issue of hiring staff that have appropriate experience as well as the difficulty in promoting experienced staff to supervisory positions as a result of pay freezes for management, resulting in a lack of incentive to accept promotions.

Mr. Melnic informed the committee that blank reimbursement forms are available. He also reminded everyone to attach all receipts and, if one is not available, a "lost receipt" form must be completed in order to receive reimbursement. Submission of expenses as soon as possible is necessary to prevent reimbursement delays.

The next RPAC meeting is scheduled for March 6, 2014.

Adjournment – 3:12 p.m.