

**Minutes of the Radiation Protection Advisory Committee Meeting  
Room 105  
Rachel Carson State Office Building, Harrisburg, PA  
October 18, 2012**

**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, Dr. Paul Houle, Mr. John Miller, Mr. Vincent Roding, Mr. Kent Lambert, Ms. Marjorie Hughes

**Members Absent:**

Dr. Douglas Eggli, Dr. Charles Chambers, Dr. Charles Stoup, Dr. Richard Purse, Dr. John Pammer

**Personnel Representing DEP:**

Mr. David Allard, Director, Bureau of Radiation Protection; Mr. Joseph Melnic, Chief, Division of Radiation Control; Mr. James Yusko, SW Regional RP Manager; Mr. Robert Zaccano, SC Regional RP Manager; Mr. Ben Seiber, RP Program Analyst; Mr. John Chippo, Chief, Radioactive Material Licensing; Ms. Sandra Martin, Chief, X-Ray & Accelerator Licensing; Mr. Bryan Werner, Decommissioning Section; Mr. Robert Altenburg, DEP Policy Office; Ms. Kristina Hoffman, RP Program Analyst; Mr. Denis Ferguson, SC Regional RP Supervisor; Ms. Sharon Trostle, Executive Assistant; Mr. Tom Mainzer, DEP CAC.

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

Mr. Ray Urciuolo, Ms. Maria Faiola

**Introduction of Members and Staff:**

Mr. Keklak opened the meeting with a moment of silence in remembrance of our past chair and colleague Mr. Robert Forrest.

Mr. Melnic introduced Mr. Kent Lambert as a new Member-At-Large. Mr. Lambert is a Radiation Safety Officer at Drexel University, and Eastern Regional Medical Center, a Cancer Treatment Centers of America Hospital.

An election was conducted with unanimous approval for John Keklak and Margaret Blackwood to fill the chairman and vice-chairman positions, respectively.

**Adoption of Agenda:**

Today's agenda was approved unanimously.

**Approval of Minutes:**

Prior to approval of the April 17, 2012 minutes, Mr. Och stated one of his comments made during the April meeting was not included in the minutes. He requested it be added to the minutes. In particular, during the medical physicist licensure discussion, Mr. Melnic stated that physicist credentials are reviewed for all licensure protocols and thus having a separate State Licensure program would be redundant. Mr. Och pointed out that not all medical physicist services are reviewed by the department, such as fetal dose calculations, brachytherapy, and CT protocol changes.

Due to the request for this additional comment to be added to the minutes, Mr. Keklak tabled action on the minutes to allow text to be drafted during the break for consideration later in the meeting. Additional text was added to the April minutes before the meeting adjourned, and all members approved unanimously.

#### Future Meeting Dates:

Mr. Allard suggested the RPAC may want to hold three meetings next year due to the regulatory revisions package that will be forthcoming. The entire package will be presented after the Nuclear Regulatory Commission publishes an effective date for the pending Part 37 inclusion. The department will then have two years to implement all revisions. The committee agreed to the following dates:

April 11 and 12, 2013 (two-day meeting);

October 17, 2013;

December 12, 2013 (Tentative)

#### Open Floor:

Per the suggestion made at the April meeting, the Open Floor portion was moved to the beginning of the meeting to accommodate members of the general public who may have comments or questions.

- Mr. Och requested that, when non-ionizing radiation regulations are considered, magnetic resonance imaging (MRI) safety be addressed as a priority. He said consequences of an MRI accident are immediate and catastrophic, and currently there is no regulatory oversight. Ms. Blackwood noted The Joint Commission (JC) does address safety aspects. Mr. Allard offered to have counsel look into it, but we may not have the authority, it may fall under OSHA's oversight. Mr. Miller agreed with Mr. Och that MRI operations can be a hazard.
- Mr. McNeely asked about high dose rate sources arriving at a hospital during off-hours, who takes acceptance and are there regulations in place. He's concerned these sources, at times, can sit out on the docking area not necessarily under any one's control. Ms. Gresick-Schugsta noted that the regulations are clear in that sources must be under surveillance and control and, if a facility does not comply, they are in violation. She also added that the JC incorrectly interfered and misinterpreted the regulations with deliveries of radio-pharmaceuticals to hot labs but admitted their error. Ms. Blackwood added that the JC still is interpreting nuclear medicine responsibilities erroneously. Unfortunately, information does not filter down to everyone. Mr. Miller suggested an Information Notice (IN) may be necessary. Mr. Lambert said Part 20 is clear in stating the requirement of constant surveillance of materials, or they may be stored in a secure area.
- Mr. Sheetz asked again for a resolution regarding attestation for accelerator licensure. Mr. Melnic confirmed that attestation will no longer be required for verification of qualifications of authorized personnel. The application will be revised eliminating the 313A forms as a requirement.

#### Permit Review Process and Permit Decision Guarantee: A New DEP Initiative

Mr. Melnic stated that on July 24, 2012, Governor Corbett signed an executive order (EO 2012-12) directing the Department to, among other things, establish a Permit Review Process and Decision Guarantee (PDG), which will replace the Money-Back Guarantee created under Executive Order 1995-1. Likewise, members may have heard from the public media about Project Syllabus, which received its name because, much as a course syllabus reflects

expectations for a student and a professor, our own syllabus will clearly outline expectations for Department staff and applicants regarding the permitting process. Many of the components of Project Syllabus are directives of EO 2012-12, but it is important to note that Project Syllabus is larger in scope than those components.

The PDG establishes clear guidance that describes permit application requirements and includes “a predictable processing time for each permit application covered by the permit decision guarantee.” Fortunately, the bureau does not have a problem with timely processing of applications. Mr. Keklak added he is very satisfied with our turn-around time, and all members agreed. Nevertheless, Mr. Melnic said a webinar will be developed for the public to view and hear about our process for issuing an x-ray registration, accelerator license, RAM license, and radon certification.

### **RP Program Update:**

Dave Allard presented to the RPAC the Bureau’s Radiological Safety Culture Brochure produced as a result of, and in concurrence with, the recently released NRC’s Safety Culture Statement. This effort is not a regulatory requirement; it is a means to promote a safety culture. The bureau’s Safety Culture encompasses all aspects of our authority from medical diagnostic and therapeutic operations to non-medical applications.

Last month the BRP had an All-Hands Meeting. The purpose of the meeting was to have all bureau members (inspectors, CO personnel, clerical and management) to meet for three days to discuss bureau operations. The opportunity to interact with all members to discuss problems and concerns was beneficial to the bureau as a whole.

Mr. Allard gave an update to the circa 1920’s one curie radium source(s) found in a dumpster. Philotechnics handled the transfer and, when the container was emptied of the four needle sources, another source of lesser activity was found underneath the inner container. All sources were eventually shipped as special form waste to the Pacific Northwest National Laboratories (PNNL) for recycling into Ra-223. The transportation cost for the bureau was approximately \$30,000. BRP may do more outreach to find out where these sources were for the last 90 years.

There has been an ongoing continuation of work with TENORM issues within the solid waste area.

### *Nuclear Safety:*

- BRP is continuing oversight at the power plants. Peach Bottom Atomic Power Station recently had a release and contamination incident.
- The Low-Level Waste Advisory Committee meeting was held earlier in the month.
- There are two INs coming: WCS in Texas coming online, and CRCPD assisting states through the SCATR program.
- Pennsylvania will be the first state to host a graded “Hostile Action Based” Exercise. It will occur at Three Mile Island in April 2013.

### *Radon:*

BRP is advocating for schools to test for radon. January is Radon Awareness Month. There will be public service announcements coming out in January (radio and television spots). The next

EPA budget lined out state indoor radon grants (\$13 million). BRP will not lose any positions, but the bureau's outreach efforts will be impacted by this budgetary restriction.

*Decommissioning and Environmental Surveillance:*

- BRP is trying to push the cleanup of Safety Light. The structures are falling down and remain a hazard to the area.
- Work continues on Keystone Metals Reduction; there may be buried tailings.

Decommissioning Funding Plans: Mr. Keklak asked questions regarding regulatory changes and existing plans that are now being reviewed. Mr. Werner noted that there were packets of information received from the NRC in which plans are required to be reviewed every three years. He and his section attempts to meet with each of the licensees and discuss the regulatory requirements. Mr. Keklak noted some rule changes have been implemented, such as lines of credit are no longer allowed as the funding instrument, and contract labor estimates are required for clean-up. Mr. Werner suggested only sending in the cost estimate portion first and at a later time submitting the mechanism for covering the plan. Mr. Sheetz noted that his facility just completed the process and it was "relatively painless." He said he followed NUREG 1757 and appreciated Mr. Werner's site visit. Mr. Allard suggested that an IN might be helpful to the licensees who may be involved with a Decommissioning Plan.

Highlights from the OAS conference held in Milwaukee, WI

Chuck Casto, NRC representative, gave a very good talk on NRC's insights from Japan's Fukushima event

Pat Gardner, NJ RAM Supervisor, gave an update on the contaminated tissue boxes

Frank Costello, DEP SER inspector, spoke on Medical Events Involving Prostate Brachytherapy  
Michael Fuller, NRC representative, gave an update on Permanent Implant Brachytherapy – still working on the definition.

Safety Culture – besides PA, NC and one other state issued a Safety Culture policy.

A discussion involving a PA licensee working under reciprocity in NJ had a substantial over exposure during an irradiator source change.

Mr. Allard provided a discussion regarding the one Curie radium source found in a PA dumpster.

Mr. Keklak asked if ICRP 103 (International Conference of Radiation Protection) was discussed at the OAS meeting, and Mr. Allard affirmed that there was talk and he will also be attending an IAEA (International Atomic Energy Agency) meeting next week. Changes will be implemented, but it may take many years before anything official is released. Mr. Keklak shared Steve King's comments on how the Europeans are coping with the lower limits. They apparently are wearing their dosimetry under their lead apron and consequently have no problem keeping within the limits. Mr. Allard said if we were to truly have some professionals who cannot stay within the lower limits they may be handled similar to how astronauts are handled, that is, allow special provisions for certain professions.

**Radiation Control:**

**Update regarding DEP Amnesty Program**

Final results: 21 new registrations, totaling \$21,525 in fees

(Breakdown reveals 15 from the SER; 3 from SCR; and 3 from SWR)

**Diquad update for dental intraoral devices**

The Diquad project continues with our inspectors performing measurements side by side with their equipment and comparing results with the Diquad device. We will do these side by side measurements for a one-year period in order to get a statistical database. We will be working with the PA Dental Association to optimize the appropriate dose in order to achieve the best image. NCRP 172 should be out soon.

### **Information Notices Issued**

- 1.) DEP Information Notice 2012-01: High Dose Rate Remote Afterloader Physical Presence Requirements – This information notice reminds HDR licensees of the physical presence requirements described in Chapter 217 of Title 25 of the Pennsylvania Code, which incorporates by reference 10 CFR 35.615(f)(2). It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar incidents. NRC regulations, 10 CFR 35.615(f)(2), state that the licensee shall “for HDR units, require an authorized user (AU) and an authorized medical physicist (AMP) to be physically present during the initiation of all patient treatments involving the unit; and an AMP and either an AU or a physician under the supervision of an AU who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.” NRC defines “physically present” as “within hearing distance of normal voice.”
- 2.) DEP Information Notice 2012-02: FDA Safety Communication Notification of Unreviewed Handheld Dental X-Ray Devices – This information notice calls attention to dental and veterinarian registrants of the illegal sale of hand-held dental X-ray units that have not been reviewed by the U.S. Food and Drug Administration (FDA). FDA is aware of hand-held dental X-ray units being sold online by manufacturers outside of the United States and directly shipped to customers in the U.S. These devices may not be safe or effective and could potentially expose the user and the patient to unnecessary and potentially harmful X-rays. All hand-held dental X-ray units that have been certified by the manufacturer to meet the FDA's radiation safety standards bear a certification label/tag, a warning label, and an identification label/tag on the unit's housing. All labels/tags should be in the English language and permanently affixed or inscribed on each product so that they are legible and readily accessible when the X-ray unit is fully assembled for use.
- 3.) DEP Information Notice 2012-03: Collection of Certain "Class A" Sealed Sources for Disposal at Energy Solutions, Clive, Utah, Facility - This information notice refers licensees to the federal Source Collection and Threat Reduction (SCATR) Program, which is administered by the Conference of Radiation Control Program Directors (CRCPD). CRCPD/SCATR has instituted a disposal opportunity for certain unwanted sealed sources that meet the definition of “Class A” waste. This collection will last for a period of one year from the date that the first waste is received at the Clive, Utah facility and will be partially funded by the CRCPD.
- 4.) DEP Information Notice 2012-04: Similar to -03 except it involves Class A, B and C sealed sources for disposal at the WCS site, in Texas.

### **Radium-223 use**

The therapeutic use of Ra-223 is likely to increase substantially in the coming months and years. Pennsylvania has two licensees that have this promising isotope on their license currently in the R&D stage (under 1000 materials use). It appears FDA is in the final approval

stage and has requested NRC's concurrence. Once it is approved, it will most likely be considered 300 materials. We have been getting a few calls asking when will this occur, but we cannot answer for certain. It remains an FDA decision.

Ra-223 is used for treatment of bone metastases in patients. Because it's an alpha emitter, with a short energy range, it does not damage bone marrow, as would Sm-153 and Sr-89, beta-emitters currently being used. However, because it is an alpha emitter, special guidance will be issued addressing its use.

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

Eighteen events were reported since the last meeting: nine non-medical and nine medical.

#### *Non-medical NMED events:*

Lost tritium exit signs (2 lost signs);

A bag of personnel dosimeters were left in a shooting cell and were irradiated;

Two leaking sources: 1.) Ni-63 plated foil inside an ECD (Electron Capture Device)

2.) Ni-63 inside a gas chromatography;

Lost material – Cs-131 implant seeds (4 seeds at 3.90 mCi/seed - 10 day ½ -life);

Three shutter failures (one Ci Am-241 source; two 20 mCi Cs-137 sources);

One industrial radiography operation event; during retrieval the source got stuck.

#### *Medical events:*

Three medical accelerator events; two wrong locations (one misalignment and one unfused MR/CT image), and one wrong patient treated;

Three under doses from Y-90 microsphere treatments;

One Y-90 microsphere to the wrong site (wrong artery was used for infusion);

Prostate seed implant under dose. The follow-up CT confirmed 32% under dose;

High-Dose Rate Brachytherapy treatment overdosing a patient by 71% due to human error and possible software error (investigation is ongoing).

### **Continuation of Discussion Addressing Needed Revisions to Radiological Health Regulations:**

The internal process for the revision of regulations was reviewed. Once the bureau makes the revisions and an internal review is completed, the package is sent to RPAC, followed by the Environmental Quality Board (EQB). Mr. Keklak requested there be a public session through RPAC prior to publication in the *PA Bulletin* for comments.

#### *Chapter 227 Analytical X-Ray Equipment:*

Human non-medical use (as seen at most airports)

Two types of whole body scanner: 1) Backscatter technology is based on the X-ray Compton scattering effect of X-rays, a form of ionizing radiation, 2.) In contrast, a millimeter wave scanner, which creates a 3D image, comes in two varieties: active and passive. Active scanners direct millimeter wave energy at the subject and then interpret the reflected energy. Passive systems read only the raw energy that is naturally emitted from the human body or objects concealed on the body. Both types use microwave energies (non-ionizing radiation).

#### *Chapter 230, Transportation Section:*

We are looking at adding some kind of regulatory tie-in to address DOT special permits. Metal recyclers are rejecting any load that sets off radiation monitors. Special permits are now being approved for returning these loads.

*Chapter 218, Fees:*

We periodically get requests to exempt a fee due to any number of reasons. We are proposing to add a line stating we do not exempt fees. The reasoning is because the bureau is strictly funded from licensing and registration fees; there are no general fund (tax payer) revenues received. To exempt one entity would require others to absorb the deficit and open the door to more exemption requests.

**Additional Topics:**

**CT Recommendation:**

Mr. Melnic wanted to share with the members a number of suggestions/recommendations he received from Mr. Och. Mr. Och addressed the members by stating that in the past only the machine(s) was tested to determine if it was in compliance with regulations. The brain perfusion incident that occurred in California would never have been caught if only the regulatory testing was performed. Instead Mr. Och began implementing at his facility a better quality assurance program for diagnostic equipment, and in particular, CT equipment. To achieve a better quality control/assurance in CT, one should evaluate patient dose and clinical image. One should assess the operation's ability to provide consistent service to the patient. Mr. Och continued by explaining a program he developed which does this. It has 4 components and the activities are performed quarterly:

1. Protocol Review: A set of protocols are reviewed to determine that no unintended changes have occurred.
2. Technologist QA: Records are reviewed to determine if they have been performed and performed correctly.
3. Patient Dose: For each applicable protocol, a set of patient exams are reviewed. The average dose for this set is obtained and compared to baseline measurements. Clinical images are verified and individual exams that exceed control levels are also reviewed for cause.
4. Image Quality: The set of exams above are evaluated for image noise. Again, average noise is compared to baseline measurements, and any outliers are evaluated.

Ms. Gresick-Schugsta confirmed that the CT subcommittee wants to focus on what is clinically relevant, rather than just only machine testing (which is also important). Mr. Allard encouraged subcommittees to discuss each of the different areas that need review. There may be some working groups or subcommittees convened for fluoroscopy, radon, general radiography, etc., to discuss revisions.

Mr. Keklak thought it might be good to get a listing of the "Parking Lot" regulatory revision topics.

Mr. Sheetz noted that they also do similar QA testing at the UPMC facilities but warned, with regards to regulation, that many smaller facilities do not have in-house physicists and can run into problems. It is important to address the consultant physicists that are at a number of smaller facilities.

Ms. Blackwood pointed out that Highmark insurance, in western PA, is offering a monetary incentive for initiating quality assurance. Dose metric (CTDI or DLP) evaluation is being considered as part of the QA plan.

Mr. Och noted his next initiative is to focus on DR (digital radiography), similarly evaluating image and optimizing dose.

**Bracco's CardioGen-82 Update:**

Mr. Melnic noted that a final CDC report is to be released. Pennsylvania currently has two facilities still using the generator. Our inspectors were instructed to verify the break-through protocols and compliance with the CDC/FDA recommendations during their inspection.

Ms. Gresick-Schugsta noted that one of the patients from her facility had an elevated count-rate (twice background) and, when she went back to review the generator used, it was considered suspect. Mr. Melnic noted that there was one patient who could not be scanned per our procedure (anterior sternum) because of a device the patient wore on his chest and was scanned posterior (through a wheelchair). This may have been the same patient with the higher counts; nevertheless, all scans were reviewed and none revealed elevated peaks in the regions of interest.

**Reimbursement Policy for RPAC Members:**

Itemized receipts are required to be submitted with the reimbursement form. Regarding lodging, hotel arrangements need to be made by the Commonwealth's travel agency ADTRAV. Their telephone number is 866.530.8899.

[http://www.portal.state.pa.us/portal/server.pt/community/travel\\_operations/3983](http://www.portal.state.pa.us/portal/server.pt/community/travel_operations/3983)

The maximum GSA allowable hotel for Harrisburg is \$106/night (plus tax).

Copies of the Management Directive "Commonwealth Travel Policy" were made available.

Mr. Allard wished to point out that October is breast cancer awareness month. The fountain in the Capitol Complex is pink, and the bureau has a display in the lobby of the Rachel Carson building. The department just renewed its contract with the FDA to inspect all mammography facilities in the Commonwealth.

**Adjournment – 12:20 PM**