MARYLAND RADIATION CONTROL ADVISORY BOARD
MINUTES
December 4, 2017

Maryland Department of the Environment
Air and Radiation Administration
Radiological Health Program

<table>
<thead>
<tr>
<th>MEMBERS PRESENT</th>
<th>MEMBERS ABSENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Richard Hudes, M.D. (Chair)</td>
<td>Thomas Beck, Ph.D.</td>
</tr>
<tr>
<td>Allen Brodsky, Ph.D.</td>
<td>Jeanette Linder, M.D.</td>
</tr>
<tr>
<td>David O’Neill, Ph.D.</td>
<td></td>
</tr>
<tr>
<td>Mr. John S. Wojtowycz</td>
<td></td>
</tr>
<tr>
<td>Josephine M. Piccone, Ph.D.</td>
<td></td>
</tr>
<tr>
<td>Mahadevappa Mahesh, Ph.D.</td>
<td></td>
</tr>
<tr>
<td>Mr. Gregory Smith</td>
<td></td>
</tr>
<tr>
<td>Mr. David Bisson</td>
<td></td>
</tr>
<tr>
<td>Mr. Sean Austin</td>
<td></td>
</tr>
<tr>
<td>Ms. Doreen Williams</td>
<td></td>
</tr>
</tbody>
</table>

OTHERS PRESENT

Maryland Department of the Environment Staff:
Ms. Eva Nair, Manager, Radiological Health Program
Mr. Alan Jacobson, Radiological Health Program
Ms. Shannon Page, Radiological Health Program
Mr. James Lewis, Radiological Health Program
Mr. Michael Kurman, Radiological Health Program
Mr. James Ways, Radiological Health Program
Ms. Bonnie Reynolds, Radiological Health Program

Others Present:
Stewart Becker, University of Maryland Medical Center
Meeting Convened

The December 2017 Radiation Control Advisory Board (RCAB) meeting was held at St. Agnes Hospital, Baltimore, and was called to order at 2:00 p.m. by the RCAB Chair Richard Hudes.

Radiological Health Program Staffing Changes

Eva Nair advised the Board of key personnel changes in the Radiological Health Program (RHP). Eva is now Program Manager of the Radiological Health Program. Alan Jacobson is now Chief, Radioactive Materials Division. Alan Goldey is now Head of the Inspection Section, Radioactive Materials Division. Shannon Page has been appointed Chief of the Radiation Machines Division. Ian Forrest has been appointed Head of the Inspection Section, Radiation Machines Division. A new inspector has been hired in the Radiation Machines Division, and a new health physicist has been hired in the Certification Section of the Radiation Machines Division. Talya Langbaum has stepped down as Head, Certification Section, and this position is currently vacant. RHP is continuing to fill its remaining vacant positions.

Mid-Atlantic Meeting

Eva Nair also announced that Maryland will be hosting the Mid-Atlantic States Annual Meeting on September 19 and 20, 2018. Four states rotate in hosting this event (Maryland, Pennsylvania, New Jersey, and Delaware). There will be presentations on radiation events, emerging technology, machines, radon, materials, and emergency response. Additional presentations are welcomed; please let RHP know by February 2018. Location in Maryland is to be determined. RHP is expecting 75 - 80 attendees.

Regulations Update

Mike Kurman provided an update on COMAR 26.12.01.01 Supplement 29. This Supplement, which includes regulations which transfer diagnostic misadministrations from Part D to Part F and establish the term diagnostic medical radiation events (DMRE’s), was scheduled for proposal but then held for further review by a gubernatorial committee; then released for publication in December, but then as of the morning of the RCAB meeting held again. Regarding the dose regulations for misadministrations, Richard Hudes asked whether dose requirements will be included in DRME regulations. Mike replied in the negative. Supplement 29 also includes revisions to an NRC regulation on transfer of radioactive materials adopted in Supplement 28, as required by NRC (see discussion following). Mahadevappa Mahesh asked if RHP would advise RCAB of the date the proposal will be published; this will be done.

Mike Kurman reported that Supplement 30 is being worked on, which will include regulations specific to electronic brachytherapy, security screening of persons at institutions, and a requirement that control panels for certain new CBCT machines be located outside the treatment room with a door interlock. There are no new NRC regulations to adopt at this time.
RCAB members asked questions, and Mike Kurman and Shannon Page responded, regarding the manufacturer of the type of CBCT to be regulated, the door interlock requirement, and shielding requirements.

Relating to the transportation regulations that were adopted in Supplement 28 and being changed in Supplement 29, David Bisson stated that, in the need to incorporate a QA program on transportation of radioactive materials from Johns Hopkins, when reviewing Maryland regulations, it was noted that a quality assurance program is to be submitted to NRC for approval. NRC responded to Hopkins that, while Maryland and one other state required NRC approval, the NRC intent was that review and approval should be by Agreement States. Alan Jacobson noted that Maryland and (he remembered that it was seven) other Agreement states believed that it was still a requirement that NRC approve QA programs. Alan also noted that NRC approved Supplement 28 before it was adopted. However, Maryland understands that it is RHP’s responsibility to review transportation quality assurance programs, and we will be providing some training to staff. David noted that Charles Cox has now pinned approval of the transportation QA program to a broad scope license amendment. Richard Hudes asked if these proposed changes in Supplement 29 have been approved by NRC. Mike Kurman responded that this regulation change was directed by NRC, which is a change from the initial approval before proposal of Supplement 28 in which these regulations were not flagged by NRC.

Allen Brodsky noted that it is faster to issue a regulatory guide than a regulation; that such guides can be incorporated into a license; and asked if we are able to publish regulatory guides. Alan Jacobson responded that usually the licensee incorporates by reference into their license application regulatory guide NUREG 1556, which then becomes a requirement of the license when issued. David Bisson noted that a significant amount of work was put into NUREG 1556, which is applicable to different types of licensees.

Update on Diagnostic Medical Radiation Events

Shannon Page reported on the statistical data gathered during the first year of required logging/reporting of diagnostic medical radiation events, which covered the period from November 1, 2016 through November 1, 2017. The Department received a total of 180 diagnostic medical radiation event reports during this period, averaging 15 per month. Statistics show facilities are reporting more often than they were prior to the study. Facilities continue to remain in compliance on notifying the Department within 24 hours, as well as in submitting the required log within the designated 15 day time frame.

Of the 180 diagnostic medical events reported, 72 were facilities reporting for the first time. Those facilities reporting for the first time employed corrective actions that involved changing policies and procedures, whereas repeat facilities chose to place more emphasis on re-educating and counseling. The data showed staff who had been with the facility for ten or more years had on average the highest number of diagnostic medical radiation events. The most common medical event was wrong site followed by wrong modality. Wrong modality events typically involved patients receiving a CT instead of the prescribed sonogram or mammogram. Data also reflected (a) failure to verify requisition as the most common contributing factor with distraction showing a decrease; (b) human error being the most common root cause; and (c) GP and CT being the most common modality used in error.
Mahadevappa Mahesh asked if penalties will resume in the future. Eva Nair replied that this will be evaluated after the end of the two year period November 1, 2018. Dr. Mahesh expressed interest in harm to patients as expressed by dose received. Shannon Page stated that dose will be part of the final evaluation. Richard Hudes asked if Dr. Mahesh and Shannon can work on this together. Eva Nair stated that an analysis document will be put together, which will be shared with RCAB. Richard Hudes is interested in discussing this issue at the next RCAB meeting, and suggested that the first year of data be analyzed while information is coming in for the second year. Richard asked if we have received reports of events relating to brachytherapy; Shannon replied in the negative.

**Introductions**

It was realized some time into the meeting that the bridge telephone line was not working. This was rectified, and introductions took place around the room and of RCAB members who had called in to the meeting.

**Physician Presence during Radiation Therapy**

Richard Hudes noted that there are Medicare rules about the presence of a physician during radiation therapy. Scope of practice issues fall under the purview of the Board of Physicians. Richard stated that requirements for the physical presence of a physician are not being followed by the Board of Physicians (or RHP).

There is a carrier that manages Medicare payment in Maryland, called Novitas. This firm has one policy on supervision (policies are called LCD, or Local Coverage Determination). Texas has rural access issues where doctors felt it impractical for a physician to be present for every radiation therapy treatment in these rural areas. Therefore, Novitas issued an LCD, which is applicable to all states, which provides that when the qualified radiation oncology physician is not physically present in the radiation treatment center, he/she must be immediately available by telephone or other electronic means of communication and must be able to receive and remotely review guidance images allowing the qualified physician to provide advice and/or order treatment modification. It further states that the radiation oncology physician must personally evaluate each patient undergoing radiation treatment on a weekly basis, and provide direct supervision of radiation treatment delivery of all patients being treated at least twice during each calendar week of therapy.

However, Medicare (Centers for Medicare and Medicaid Services (CMS)) requires direct supervision for radiation therapy in hospitals’ outpatient departments by a physician (or qualified non-physician practitioner only in states that do not limit such practitioner’s scope of practice and hospital privileges). The physician must be physically present and immediately available to furnish assistance and direction. The American College of Radiology in its Radiation Oncology Practice Accreditation Program (accreditation is not mandatory) requires that a radiation oncologist be available for direct care and quality review and should be on the premises whenever radiation treatments are being delivered, as well as be available to initiate (or refer for) urgent treatment on a 24-hour basis.
Richard raised this issue to make the Board and MDE aware of the discrepancy in supervision requirements between Medicare payment processing requirements and actual Medicare physician practice requirements.

General questions and comments by Board members followed regarding applicability of these requirements to use of radioactive materials and radiation machines in Maryland. Richard Hudes felt that this could be an issue in radiation machine therapy if State regulations requiring physician presence were not adopted.

**Medical Event Reporting for Brachytherapy**

Richard Hudes called the Board’s attention to a press release issued August 17, 2017 by NRC which states that NRC plans to amend the rules on medical uses of radioactive materials. Of most interest is the proposed amendment to the definition of medical events associated with permanent implant brachytherapy.

For permanent brachytherapy, activity is different than absorbed dose. Currently medical events are defined based on dose (event = dose ≥ 20% prescribed). However, it is now felt that so many changes to the prostate volume occur after administration (which affect absorbed dose) that basing a medical event on source strength (air-kerma strength) delivered is more accurate. The prostate can temporarily swell, or seeds can migrate, resulting in observed overdose or underdose. Hence, you can have good implants that are considered medical events, and bad implants that are not. The real issue is how much activity was planned to be put in the prostate, and how much activity was actually put in the prostate. The new definition of a medical event for permanent brachytherapy will be when ≥ 20% of source strength prescribed is actually implanted in the prostate.

A question was raised on the definition of permanent brachytherapy. Richard advised that in permanent brachytherapy seeds are implanted and remain permanently in the treatment site.

Josephine Piccone noted that the NRC regulations should be final early next year. A question arose as to whether Maryland will have to adopt this regulation exactly as proposed. Josephine advised that the regulation will be a Category “C”, which gives the states some flexibility in reporting frequency, recordkeeping, etc.; however, states must adopt an activity-based standard.

**Physician Supervision of Radiation Therapy**

Richard Hudes called the Board’s attention to an article in the New York Times of November 20, 2017 titled “Skin Cancers Rise, Along With Questionable Treatments.” Richard noted that not only is there concern the correct delivery of radiation treatment, but also whether you need radiation exposure to begin with. This latter decision is a result of not a weekend course in radiation therapy, but rather of the extensive training required of physicians who prescribe radiation therapy.
The article notes a significant increase (55% for Medicare patients) in skin biopsies from 2005 to 2015, as well as a significant increase in the number of physician assistants performing dermatologic procedures (15% of biopsies billed to Medicare in 2015 were performed by physician assistants or nurse practitioners who were working independently). The article looks at dermatology practices in Florida, studying one firm that owns 180 locations in the state. The Times found that in addition to the many biopsies taken, physician assistants are also recommending radiation treatment for skin lesions, incorrectly in the cases cited in the article, while missing true melanomas. Physicians to provide supervision are usually not on-site, and do not normally review all clinical decisions made by the physician assistant.

Richard noted that for such a firm, when a physician assistant recommends radiation treatments for skin growths, the physician will deliver the radiation, but Richard asked if that is a full discussion of possible options. Richard stated that prescription of radiation treatment using radiation machines should only be by persons who have the same training as physicians who prescribe radiation using byproduct materials under NRC or State regulations.

**Other Topics**

There was a brief discussion of Maryland’s self-referral law, which requires that a partner in a private group cannot read their own radiology images; it has to be an employee. This eliminates the profit that would be attained from purchase of equipment and subsequent referral for use of self-owned equipment.

It was requested that proposed whole body scanning regulations be discussed at the next RCAB meeting. Shannon Page noted that there is currently one company, Adani, providing these scanners, and that RHP currently has applications from 11 facilities for installation of these scanners. RHP is obtaining operating and QA procedures from the applicants. Mahadevappa Mahesh asked about worker safety; RHP is also looking into this. The proposed regulations will cover all of these operational aspects.

Josephine Piccone asked when the next meeting will be held. Richard Hudes replied that he would try to have the next meeting at the end of the first quarter of 2018.

**Meeting Closed**

The RCAB meeting was concluded at 3:40 p.m.