SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

Committee on Radiopharmaceuticals
June 10, 2016

Minutes

Participants: Sally Schwarz, Cathy Cutler, Ethan Balkin, Bob Atcher, Roy Brown, Jim Ponto, Steve Dragotakes, Jeff Norenberg, Steve Zigler, Ashley Mishoe, Dennis Swanson, Alan Packard, Alan Ketring, Marc Berridge, Jeanne Link, Steve Mattmuller, Kathy Seifert, Michele Egberts, Neil Petry, Sue Bunning, Kendall Horvath, Caitlin Kubler

1. Welcome – Ms. Schwarz called the meeting to order at 8:05 am and welcomed participants. The minutes and agenda were approved.

2. Committee updates/Chair transition – Ms. Schwarz thanked the Committee for all their hard work over the year and prompt replies to action items. Cathy Cutler will be taking over COR as the Chair as Sally Schwarz will be President of SNMMI. Ms. Schwarz updated the group that the Joint Compounding Task Force will be rolling COR as an ad hoc group. Steve Dragotakes will be the Chair of this ad hoc group. Cathy Cutler will be taking over COR as the Chair as Sally Schwarz will be President of SNMMI.

3. USP Update – Jim Ponto provided an update from USP. Mr. Ponto reported that USP received more than 5,000 comments for USP 797. The group expressed consensus that radiopharms should be a separate chapter for USP. Somewhat like hazardous drugs because there are so many exemptions. USP is intended to do a roundtable sometime late summer. Mr. Ponto suggested that individuals from this committee will be invited to participate in this group. Mr. Ponto will keep COR informed as he receives updates. Specifically, radiopharmaceutical compounding. USP is still working on specific dates and topics. Mr. Ponto reported that 821 and 823 were revised in entirety. 1823, which is an educational chapter – those comments are currently being accepted. Assuming approval those will go into approval next year 2017. Mr. Ponto reported that a new expert panel was created for radioactive drugs to update monographs.

4. Department of Energy Update – Ethan Balkin provided a brief update for the DOE. The DOE is working to help produce increase the distribution of stable isotopes, though does not directly compete with industry. The DOE goal being mitigate dependence on foreign sources. Mr. Balkin reported that protocols are in place should an international provider come available (e.g. how that will be handled regarding the supply and whether that will be able to meet the US demand). Additionally, NSAC – subgroup on isotopes, issued report for 2015 with updated recommendations for DOE. Participants can stop by booth 1744 and pick up copy of report. Mr. Balkin agreed to share his ppt with COR.

5. Isotope Supply/Reimbursement - Roy Brown provided a brief update on isotope supply. Industry has been working hard to increase compacity given the NRU reactor will be shutting down. Mallinckrodt has increased from 4 to 5 days per week of Mo-99 production. NRU and National resources Canada working on a plan that NRU can be used in an emergency. NORDION – has agreed to make after October 31st shutdown of NRU. Additionally, Mr. Brown reported that OECD – increased capacity issues – new outlook from them more positive than before. Shine is working on NRC approval and Northwest has filed for approval, and a few others have begun to make progress as well. Also, CMS has said they expect to extend 10 add on payment through 2017.

6. Compounding Update – Ms. Schwarz reported that the Joint Compounding Task Force will be rolling under COR as a subgroup. Steve Dragotakes provided a brief update on compounding. We are currently waiting on FDA to come up with specifically guidance for radiopharmaceuticals. FDA has mentioned that it is still a priority for them and is working on it. However, Jane Axelrad has recently left FDA so it is unclear how much of a priority it will be. Ms. Axelrad is currently working with USP, which could prove beneficial for the group.

7. No other business was discussed.

8. The meeting adjourned at 9:00 am.