Committee Report
SNMMI Board of Directors
June 2017

SNMMI Committee on Radiopharmaceuticals (COR)

Committee Charges for 2016-2017

Mission Statement - The Committee on Radiopharmaceuticals will serve the SNMMI Board of Directors as the primary source for timely advice and information necessary to work with appropriate agencies to ensure the availability and appropriate use of radionuclides and radiopharmaceuticals that are necessary for clinical practice and research.

Receiving direction from and coordinating with the Board of Directors of the Society of Nuclear Medicine and Molecular Imaging, the Committee on Radiopharmaceuticals will:

- Provide advice and data on isotope availability, including potential shortages of medically important radionuclides and enriched targets;
- Facilitate interactions with appropriate Federal agencies, legislative bodies, and other organizations to advocate for the availability of radionuclides essential to medicine and research;
- Provide advice and data on policies relevant to radiopharmaceutical availability and appropriate utilization;
- Provide timely information to the SNMMI membership regarding radionuclide and radiopharmaceutical availability and appropriate utilization; and
- Provide advice on other issues related to radionuclides and radiopharmaceuticals as necessary.

Current Working Objectives/Goals:

- SNMMI and RPSC's primary governance committee on radionuclide / radiopharmaceutical topics and related industry issues.
- Work in with FDA, DOE, and other government agency representatives on radionuclide / radiopharmaceutical topics (development, review / approval, isotope production, etc.).
- Assist the Committee on Pharmacopeia and the FDA Task Force to delegate issues, assure resource availability, and harmonize committee priorities with those of COR and SNMMI.
- Committee members are working with the Center for Molecular Imaging Innovation and Translation (CMIIT) and other outside stakeholders toward the development of guidance documents for use by professional societies to communicate standards of compliance for PET Manufacturing.

Progress of Charge/Objectives/Goals to Date:

- The Committee has been very active in the Compounding arena and has submitted comments to FDA on Insanitary Guidelines for Compounding Facilities, Recommendations on Sterile Compounding to USP, and FDA Guidance on Radiopharmaceuticals.
- The Committee continues to work with the Department of Energy regarding appropriations and funding for basic nuclear medicine research.
- The Committee is working with CTN to develop and maintain a prioritized list of isotope needs per the request of National Institutes of Health. This will be used to help inform the Department of Energy on needs of the community.

- COR coordinates with USP on prioritization of USP monograph activities. It is possible that that monographs will be replaced by radiopharmaceutical descriptors.

- COR coordinates with the Coalition for PET Drugs

- COR is monitoring isotope supply issues and coordinating with SNMMI Isotope Supply Working Group.

- COR coordinates with the 68Ga User Group to facilitate development of 68Ge/68Ga generators and 68Ga-based radiotracers.

- COR coordinates with the SNMMI Reimbursement Committee and HPRA of issues related to reimbursement for radiopharmaceuticals used in diagnostic imaging and therapy.

- COR will provide support to the RPSC working to update the radiopharmaceutical database to include information on isotope availability and to include sites from international sites which will also interface with the SNMMI Global Initiative.

- COR will provide support to the RPSC and CTN on the development of the Qualified Person Training Program to train chemists and nuclear pharmacists in the release of manufactured PET drugs.