Committee Report to the
SNMMI Board of Directors
June 5-6, 2014
COMMITTEE ON PHARMACOPEIA

Committee Charges:

- To provide leadership and expertise as the resource for SNMMI in acquiring, evaluating, and disseminating information on the safe and effective use of radiopharmaceuticals for medical purposes.

- To provide input, on behalf of SNMMI, to the USP Expert Committees (e.g., Expert Committee on Radiopharmaceuticals and Medical Imaging Agents) concerning issues related to the revision and/or development of USP monographs/chapters.

- To closely study the incidence of adverse reactions involved in the administration of radiopharmaceuticals, especially with regard to newly approved therapeutic radiopharmaceuticals.

- To submit/review USP monograph revisions, and recommend USP Chapter revisions for existing Chapters.

Current Working Objectives/Goals (please reference Strategic Plan):

- Improve standardization for nuclear medicine and molecular imaging research - Review and propose revisions to relevant USP monographs. (Goal A4a)

- Support survey of adverse reactions related to radiopharmaceuticals or adjunct non-radioactive drug products.

- Review and propose improvements to Joint Commission Medication Management Standards.

- Continue to monitor, analyze, and be the primary SNMMI committee working on issues surrounding the recent USP <823> revision and ongoing <797> revisions.

- Monitor the revisions proposed in the proposed Compounding legislation as it affects Nuclear Medicine practice and centralized Nuclear Pharmacy operations.

- Hold quarterly conference calls to discuss the status of committee activities. Coordinate efforts with the Chair of the Committee on Radiopharmaceuticals.

Progress of Charge/ Objectives/ Goals to Date:

1. USP PET Monographs

The USP is interested in knowing how the PET community wishes to proceed with the existing monographs because they do not have supporting data for all the existing PET monographs. Additionally many of the monographs are outdated. The white paper entitled The Future of USP PET Monographs, was published in JNM in the March 2013 edition. The purpose of this paper is to get information out to the community regarding the current state of the monographs and seek feedback on the stated possible options to keep, update or delete the monographs.
The other monographs being drafted under the direction of the COP are on hold until the future of the existing PET monographs is determined along with better understanding of the need for additional monographs for FDA approved and non-approved radiopharmaceuticals. If the USP Monographs will no longer have investigational PET monographs as part of the USP, the Committee discussed the need for an alternate source of investigational radiopharmaceutical Chemistry Manufacturing & Control (CMC) documents to be maintained at an alternate location such as SNM or NIH.

2. Adverse Reaction

Ted Silberstein completed the data analysis and is preparing a report. Marc Berridge has now taken over data collection and reporting from Dr. Silberstein. During Annual Meeting, the Committee agreed the data collection process may need revision to an electronic method that would be more suitable for adverse reaction reporting analysis. It was the sense of the Committee that work needs to continue on this but more needs to be done to define the categories, including the addition of therapeutic radiopharmaceuticals, in order to gather the appropriate data.

3. USP General Chapter <797>

The COP continues to update the FAQs relating to USP General Chapter <797> as additional questions are presented. The SNM submitted a letter to USP requesting review, and possible revision of requirements for preparing Tc-99m RBC using the FDA approved Ultratag kit. The revision period for Chapter <797> closed on August 15, 2010, and no revisions have been published by USP. It was decided by USP management to defer those revisions for publication until the newly formed Compounding Expert Committee could consider all the revisions The committee is still monitoring any possible revisions for preparation of Tc-99m RBC using the Ultratag. Sally Schwarz reported that the revision is still in progress.

4. USP General Chapter <823>

This chapter has been recently revised, and became official on May 1, 2012. The USP has petitioned the FDA to make a rule change for 21 CFR Part 212 to refer to USP 36 rather than USP 32. This revised Chapter <823> could become the reference Chapter for the production of research PET drugs, and will be an important document to the PET community. The USP has petitioned the FDA to revise 21CFR Part 212 to the change the existing reference to Chapter<823> in the CGMP for PET rule to the Revised Chapter<823>. No response has been received to date from the FDA. The USP has convened an Ad Hoc Committee divided into 2 sections. One section will write an information Chapter <1823> and the other will revise USP Chapter 821 (Identification & Assay of Radionuclides) as well as write the companion informational Chapter <1821>.

5. Strategic Plan

The Committee met and discussed future trends and priorities for the coming three to five years. The Board of Directors met in April to discuss changes to the Strategic Plan. The COP recommended the board focus on best practices in tracer development, working toward a new FDA approval pathway to define biomarkers, better guidance on FDA inspections and compliance and support all efforts to combat radionuclide shortages.