Committee Charges:

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

- To provide input, on behalf of SNM, 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):

- Review and propose revisions to relevant USP monographs.

- 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 SNM committee working on issues surrounding the recent USP <797> revisions.

- Hold quarterly conference calls to discuss the status of committee activities. These status reports will be discussed with the chairs of the committees reporting to the Commission on Radiopharmaceuticals.

Progress of Charge/Objectives/Goals to Date:

1. Monographs:
   a. FDOPA –monograph is being reviewed by Steve Ziegler. He has not completed his review.
   b. Gallium-68 Chloride - Ron Weiner submitted a monograph for the Ga-68 generator at the Annual meeting. It was suggested that it would be more appropriate to prepare a monograph on Ga-68 Chloride. Ron was interested in preparing this monograph, and is in the process of gathering the data for the monograph. He will submit his draft at the June 2011 meeting. Additionally, the RPSC will be presenting a CE session on Gallium-68 at the Annual meeting 2011. As part of the CE session, Ron will present his results in a Draft monograph format. Sally Schwarz received notification in November that Ron’s post doc is working on collecting the data needed.
c. FMISO - Sally Schwarz contacted Alfons Verbruggen, who sits on the EU Pharmacopeia Committee Group 14 (Radiopharmaceuticals). Since the EP was in process of writing the FMISO monograph, they had discussed the possibility of sharing a copy of the EU draft monograph. Sally was able to get the copy, and sent it to Jeanne Link who had offered to write this monograph using data from U of Washington. She put together a draft that was circulated to the COP for their tcon last week. After seeing the EU monograph, Jeannie is considering evaluating the EU HPLC radiochemical purity method. She will get back to COP with details.

2. Developed a policy statement regarding commercially distributed FDA approved products versus products compounded for an individual patient. A final draft will be submitted for Board approval.

3. Beyond-Use Dating:

Jim Ponto took the lead in writing this document. Jim changed use of term ‘expiration time,’ which is established by manufacturer, to beyond-use dating. This change allowed the manufacturing community to consider the concept. This document will be presented by Jeff Norenberg to the BOD in January.

4. Adverse Reaction

Ted Silberstein continues to collect data on the adverse reaction reporting. Marc Berridge contacted Ted and offered to assist with this however Ted would like to complete 5 years of data collection after which time he will develop a report. At the conclusion of this time period, set to end in 2011, Ted plans to either include the COP or to hand off the project to the COP to continue.

5. Monograph Policy on Prioritization

Jeff Norenberg is writing a COP policy to provide a method to assist the COP to prioritize writing monographs which are submitted to the committee

6. USP Chapter 823

USP PET Radiopharmaceuticals Ad Hoc Advisory Panel revised Chapter < 823>, and the document is available on the USP website. The web link is available to the public and all comments to the proposed revision of <823> may be submitted to the USP by March 21, 2011. SMM RPSC and USP are co-presenting a CE session at the Mid Winter meeting on Jan 20th to review all changes and indicate rationale behind changes. The presenters will be Ravi Ravichandran, from USP, Joe Hung, Steve Zigler, and Sally Schwarz.

7. USP General Chapter <797>

The COP continues to update the FAQs relating to USP General Chapter <797> as additional questions come in. 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. A formal announcement by the USP regarding this matter is expected in August 2011.