

PTSOP minutes – December 14, 2018

Attendees:

Stacie Crandall

Reggie Morgan

Nicole Cairns

Stacie Fry

Shawn Kassner

Absent:

Susan Jackson

Dixie Marlin

Documents distributed prior to the meeting –

- FoPT Updates Next Round\_SOP Outline\_draft -
- PT SOP Subcommittee SOP Recommendation
- TNI\_PT\_acceptance\_criteria\_SOP 4-101-Rev 3 1 draft 12-15-17 – mtg comments
- PTEExecComm-Minutes-8-9-16 Attachment F

Meeting was called to order at 1:00 PM (Eastern Time)

1. Review of the big picture of what the subcommittee has been working on to make sure everyone is on the same page.
  - a. “FoPT Updates Next Round\_SOP Outline\_draft” – HISTORY - this was given to the subcommittee by Maria and the PTPEC. The charge was to either create an SOP that covers all the items in the document or include these with applicable existing SOPs.
  - b. “TNI\_PT\_acceptance\_criteria\_SOP 4-101-Rev 3 1 draft 12-15-17-mtg comments – HISTORY - draft with the subcommittees’s latest revisions – not all changes are marked as “tracked changes”. Some revisions made in previous meetings were already accepted and saved.
  - c. “PT SOP Subcommittee SOP Recommendation” – HISTORY – this was the subcommittee’s response to the request; essentially combine and expand the elements in 4-101 (acceptance limits) and 4-107 (FoPT table management).
  - d. SOP 4-102 – May 2018 minutes – subcommittee indicates today this is done and should already be back in the hands of the PTPEC for review. However, no one was certain. Eric will check with Maria and Ilona on status.
2. Develop a plan for the first few months of 2019
  - Eric discussed his concept for a revised approach for 2019 with the subcommittee.
    - o Rather than combine the SOPs 4-101 and 4-107 as discussed in the previous “PT SOP Subcommittee SOP Recommendation” document, take sections of the outline and apply them to whichever SOP they fit in better. The reasons for the revised approach are –
      - SOP 4-101 is a working SOP for the FoPT subcommittee. SOP 4-107 is a working SOP for the PTPEC. Each SOP has a different focus. To combine the two would make it harder for both the FoPT subcommittee and the PTPEC to delineate what language really applies to which of the two distinct group activities.
      - Splitting up the outline concepts and dropping them into the two current SOPs allows us to focus our efforts on the inclusion of new information into

SOPs, rather than the additional time and effort that it would take to reformat and combine language from two SOPs to make one functional document.

At some point during which or after all new concepts from the outline are incorporated into the two SOPs, we can evaluate again the possibility of merging the two documents. However, for now that concept would be shelved.

This revised approach should help to expedite the update process significantly.

- The subcommittee agreed to adopt Eric's proposal.
- Eric said he would provide the PTPEC with the subcommittee's revised plan to obtain approval before the meeting in January.
- SOP 4-101 – There are a number of comments/questions that are in the draft that require Chemistry FoPT subcommittee review first in order to provide comment and/or suggested revised (or enhanced) language. Also, the SOP subcommittee wants to make sure that any FoPT subcommittee procedural changes that have occurred since 2010 are captured in the SOP 4-101 update before further review is performed by the SOP subcommittee. The SOP Subcommittee would like to receive any SOP enhancements or changes that the Chemistry FoPT subcommittee would like to provide made directly to the SOP draft by the Chemistry FoPT Subcommittee. That would save the SOP Subcommittee time trying to comb through various comments. Also, some of the questions/comments that the SOP Subcommittee has for the Chemistry FoPT Subcommittee might require rather technical language enhancements that are much better handled by the Chemistry FoPT Subcommittee as a group. That said, there also may be instances where the Chemistry FoPT Subcommittee would like to not make a suggested enhancement or change. In those cases where no change is recommended by the Chemistry FoPT Subcommittee, separate responses explaining to some degree why in writing may be more appropriate. Therefore, Eric indicated he would request that the PTPEC have the Chemistry FoPT subcommittee review SOP 4-101 and provide any updates necessary prior to SOP subcommittee further review.

3. Next meeting will take place on Friday, January 11<sup>th</sup>.

4. Meeting adjourned at 2:00 p.m.

Respectfully submitted  
Eric Smith