Procedures Review Finalization & Approval Process

Meeting of the Advisory Board on Radiation and Worker Health

April 14, 2021

Josie Beach, Chair, Subcommittee for Procedure Reviews/
Kathy Behling, SC&A, Inc.

Current status of SCPR activities

- 35 active technical guidance documents:
  - Reviewed by SC&A
  - Discussed at SCPR meetings
  - Findings/observations resolved and closed by SCPR
- Technical guidance documents not included in the 35 active documents:
  - Documents reviewed but have since been cancelled
  - Documents reviewed but have revisions that may need an additional review
  - Document reviews with no findings

Document finalization process

- Since 2018, document review finalization to include full Board approval
- Therefore, full Board review of 35 technical guidance documents is needed
- Current approach – SCPR makes a presentation to the Board summarizing:
  - Document review findings/observations
  - SCPR discussions
  - Resolution of issues

Alternative approach to finalizing document reviews

- SCPR will prepare an issue resolution matrix like those used by other Board work groups
- Matrix will include:
  - Summary description of document reviewed
  - Description of document review findings/observations
  - Chronology of NIOSH, SC&A, and SCPR discussion to resolve issue
  - Summary of final finding/observation resolution
- Matrix approach only for less complex documents with few findings/observations

Issue resolution matrix for ORAUT-PROC-0022, rev. 00, “Supplemental requests for DOE information”

- Procedure outlines method for requesting supplemental information about an energy employee from U.S. Department of Energy (DOE) sites
- Revision 00 issued 3/15/2005
- Revision 01 issued 8/24/2017

Issue resolution matrix for ORAUT-PROC-0022, rev. 00, finding 1

Finding number (date)	Finding description	NIOSH response	Finding resolution
Finding 1 (6/8/2006)	Title and PROC number for Privacy Act procedure needs to be correct and consistent.	**8/24/2007**. Procedure is currently being revised. In the revision, the Privacy Act reference (ORAUT-PROC-0079, "Protecting Personally Identifying Information (PII)") will be fixed so that it is correct and consistent throughout the document. **10/31/2017**. NIOSH revised this procedure and published rev. 01 on 8/24/2017. References were corrected throughout the procedure.	**11/20/2017**. SCPR agreed to close finding.

Issue resolution matrix for ORAUT-PROC-0022, rev. 00, finding 2

Finding number (date)	Finding description	NIOSH response	Finding resolution
Finding 2 (6/8/2006)	Procedure states that information should be requested from task 2, task 4, and task 5 and assumes that the reader is familiar with each task without providing the task function or description.	**8/24/2007**. Procedure is currently being revised. In the revision, references to various tasks within the ORAUT project organizational chart will be removed. **10/31/2017**. NIOSH published rev. 01 on 8/24/2017. All references to specific ORAUT project tasks were removed, as NIOSH and any ORAUT group can identify claims that need additional information and ask for supplemental request letters.	**11/20/2017**. SCPR agreed to close finding.

Issue resolution matrix for DCAS-PER-081, "Hooker Electrochemical"

- Program evaluation report (PER) determines effect of rev. 03 to DCAS-TKBS-0009, the Hooker Electrochemical technical basis document (TBD)
- Hooker Electrochemical TBD, rev. 03 reviewed separately
- This review performed under SC&A's subtask 4 protocols (case reviews)

Issue resolution matrix for DCAS-PER-081, "Hooker Electrochemical," observation 1

Observation number (date)	Observation description	NIOSH response	Observation resolution
Observation 1 (10/9/2018)	In the original and reworked DR, NIOSH used the exposure skin dose conversion factors (DCFs) from OCAS-IG-001, rev. 3, instead of a skin DCF of 1.000 from ORAUT-OTIB-0017	**2/13/2019**. During SCPR meeting, NIOSH explained that as Hooker external doses are based on MNCP modeled calculations, OCAS-IG-001 DCFs are used. If doses were based on film badge data, it is unclear whether the dose is from beta or some low-energy photon. Therefore, the favorable approach is to apply OTIB-0017 DCFs.	**11/20/2017**. NIOSH's explanation clarified SC&A's concern, and the SCPR closed the observation.

Issue resolution matrix for DCAS-PER-081, "Hooker Electrochemical," observation 2

Observation number (date)	Observation description	NIOSH response	Observation resolution
Observation 2 (10/9/2018)	Reworked internal dose assignment increased for the lymphatic tissue (as expected) but decreased slightly for the skin cancer sites.	**2/13/2019**. During SCPR meeting, NIOSH explained that the original DR was performed using overestimating assumptions and assessed lymphatic internal dose from type S solubility and skin dose using type M. The rework used best estimate protocol and used type S for all cancers.	**11/20/2017**. SC&A agreed with NIOSH's explanation, and the SCPR closed the observation.

Board followup to issue resolution matrix

- SCPR will distribute the issue resolution matrix to the Board members prior to full Board meeting
- Relevant documentation (e.g., SC&A's review report, white papers, etc.) will be attached to document in Board Review System (BRS)
- Board members will have an opportunity to discuss closure of technical guidance documents included in matrix or request additional information at a full Board meeting

Additional document finalization discussions: Presentations with no formal closeout

March 12, 2013

- ORAUT-OTIB-0052
- ORAUT-OTIB-0070
- OCAS-IG-001

July 17, 2013

- OCAS-TIB-0010
- ORAUT-OTIB-0023

October 17, 2013

- OCAS-PER-012
- ORAUT-OTIB-0010

November 6, 2014

- OCAS-PER-014

December 13, 2017

- ORAUT-OTIB-0020
- ORAUT-OTIB-0052

April 11, 2018 (closeout deferred awaiting NIOSH followup)

- ORAUT-OTIB-0017
- NIOSH-OVER-0009

Summary discussions

- Does the Board agree with the matrix approach for closing out some SCPR-approved technical guidance documents?
- Does the matrix include sufficient information for the Board to act on approving review or opening additional issues?
- How do we handle closure of those documents previously presented to the Board that were not formally closed?
- Does the Board need to be provided an overview of documents reviewed by the SCPR with no findings identified?