2025 Program Evaluation Report Protocol Revision Proposal

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Evolution of SC&A's program evaluation report review process (1 of 2)

- **June 24, 2004:** Board authorized SC&A to review 33 documents including 2 program evaluation reports (PERs); PERs evaluated using SC&A's protocol for review of National Institute for Occupational Safety and Health's (NIOSH's) procedures and methods
- **December 13, 2006:** Board authorized SC&A to review 45 documents including 4 PERs
- **June 23, 2007:** At the request of the Designated Federal Official, SC&A submitted a proposal for reviewing PERs to the Centers for Disease Control and Prevention Contracting Officer
- **July 19, 2007:** Board approved SC&A's PER protocol to include six subtasks

Evolution of SC&A's program evaluation report review process (2 of 2)

- **November 27, 2007:** Board tasked SC&A with the review of OCAS-PER-009, "Target Organs for Lymphomas"
- **March 24, 2008:** SC&A issued subtasks 1–3 review of OCAS-PER-009
  - Contract Evaluation Panel recommended elimination of the first subtask (assess circumstances that lead to identifying the "issue" which prompted the PER) under the PER protocol
- **December 1, 2009:** SC&A issued revision 1 of the PER protocol, which removed the initial subtask 1 and expanded on the remaining five subtasks, as shown on the following slide

SC&A's 2009 revision 1 PER protocol subtasks 1–2

- **Subtask 1:** Assess NIOSH's evaluation of the "issue" and its potential impacts on dose reconstruction. Our assessment intends to ensure that the "issue" was fully understood and characterized in the PER.
- **Subtask 2:** Assess NIOSH's specific methods for corrective action. In instances where the PER involves a technical issue not previously reviewed, SC&A will review the scientific basis and/or sources of information to ensure the credibility of the corrective action and its consistency with current/consensus science.

SC&A's 2009 revision 1 PER protocol subtasks 3–5

- **Subtask 3:** Evaluate the PER's stated approach for identifying the universe of potentially affected dose reconstructions (DRs); and assess the criteria by which a subset of potentially affected DRs was selected for reevaluation. SC&A will also evaluate and give due consideration to the time to effect the PER.
- **Subtask 4:** Conduct audits of DRs affected by a PER under review. The number of DRs selected for audit for a given PER will vary and be selected by the Board.
- **Subtask 5:** Prepare a comprehensive written report that contains the results of above-stated subtasks along with our review conclusions.

SPR discussions of PER protocol

- **October 22, 2009:** SPR tasked SC&A with review of OCAS-PER-012, "Evaluation of Highly Insoluble Plutonium Compounds" ("PER-012")
- Review became test case for completion of all SC&A's protocol subtasks
- Best approach:
  - Complete subtask 1–3 reviews including suggested case review selection criteria and submit written report
  - After selection of cases, perform subtask 4 case reviews and submit separate written report
- **March 18, 2010:** SC&A submitted PER-012 subtasks 1–3 report
- **July 20, 2012:** SC&A submitted PER-012 subtask 4 report
- **July 31, 2012:** SPR approved review of PER-012 and agreed with SC&A's revised protocol

SPR request to update SC&A's PER protocol

- Throughout the years of reviewing PERs, SPR chairperson had recommended that SC&A's PER protocol be updated to reflect what was most effective in practice
- As a result of SC&A's 2024 contract rebid, SC&A revisited PER protocols to determine if the review guidance was still applicable and efficient
- **November 8, 2024, SPR meeting:** SC&A requested and obtained approval from SPR to propose modifications to PER review protocol
- **March 26, 2025:** SC&A submitted "Task 3: A Protocol to Review NIOSH's Program Evaluation Reports"

2025 protocol to review NIOSH's program evaluation reports, subtasks 1–2

- **Subtask 1**: Assess NIOSH's evaluation and characterization of the issue addressed in the PER and its potential impacts on DR. [Note: this subtask remains unchanged from previous protocol.]
- **Subtask 2**: Assess NIOSH's specific methods for corrective action.
  - If the basis is supported by documents (e.g., technical information bulletins, procedures, or other instructions for the DR) that have not yet been subjected to review by the Board, subtask 2 will include an evaluation of the scientific basis and/or sources of information to ensure the credibility of the corrective action and its consistency with current credible science.
  - If technical documentation has been reviewed by SC&A and the Board, subtask 2 will provide a summary and conclusion of that review process.

2025 protocol to review NIOSH's program evaluation reports, subtasks 3–4

- **Subtask 3:** Evaluate the PER's stated approach for identifying the universe of potentially affected DRs.
  - Assess the criteria by which a subset of potentially affected DRs was selected for reevaluation.
  - SC&A will also evaluate and give due consideration to the time to effect the PER.
  - A written report will be submitted to the SPR discussing findings of our review of subtasks 1–3.
- **Subtask 4:** Conduct audits of cases selected by the SPR that are affected by the PER under review.
  - SC&A's review of these cases will typically be limited to reviewing only those methods and corrective actions introduced in the reevaluated dose that relate to issues addressed in the PER.
  - Information or inconsistencies that warrant bringing to the attention of the SPR will be expanded on as deemed appropriate.
  - SC&A will provide the SPR with a comprehensive report of its DR review findings.

Questions?