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Advisory Board on Radiation and Worker Health
National Institute for Occupational Safety and Health

Task 3: A Protocol to Review NIOSH's Program Evaluation Reports

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Prepared by

Kathleen Behling

SC&A, Inc.
2200 Wilson Blvd., Suite 300
Arlington, VA 22201-3324

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SC&A, Inc. technical support for the Advisory Board on Radiation and Worker Health's review of NIOSH dose reconstruction program

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Abbreviations and Acronyms

ABRWH, Board	Advisory Board on Radiation and Worker Health
CDC	Centers for Disease Control and Prevention
DFO	Designated Federal Official
DR	dose reconstruction
N/A	not applicable
NIOSH	National Institute for Occupational Safety and Health
ORAUT	Oak Ridge Associated Universities Team
PEP	program evaluation plan
PER	program evaluation report
POC	probability of causation
SPR	Subcommittee for Procedure Reviews

1 Background Information

To support dose reconstruction (DR), the National Institute for Occupational Safety and Health (NIOSH) and Oak Ridge Associated Universities Team (ORAUT) have assembled a large body of guidance documents, workbooks, computer codes, and tools. In recognition of the fact that all these supporting elements may be subject to revisions, provisions exist for evaluating the effect of such programmatic revisions on the outcome of previously completed DRs. Such revisions may be prompted by document revisions due to new information, updated clarification of current DR guidance, general changes in policy, and/or regular programmatic improvements.

The process for evaluating the potential impact of programmatic changes on previously completed DRs was previously proceduralized in OCAS-PR-008, revision 2, dated December 6, 2006 (NIOSH, 2006). This procedure described the format and methodology to be employed in preparing a program evaluation report (PER) and, when necessary, a program evaluation plan (PEP), which served as a formal notification of an impending PER.

A PER critically evaluates the effects that a given issue or programmatic change may have on previously completed DRs. This includes a qualitative and quantitative assessment of potential impacts. Most important in this assessment is the potential impacts on the probability of causation (POC) of previously completed noncompensable DRs.

2 The Evolution of SC&A's PER Review Process

The Advisory Board on Radiation and Worker Health (ABRWH, Board) and the Board's Subcommittee for Procedure Reviews (SPR) began tasking SC&A with the review of PERs in 2007. SC&A's initial PER reviews and review protocol has evolved over time as follows:

- **June 12, 2007:** At the 47th Board Meeting, the Designated Federal Official (DFO) first requested that SC&A submit a cost proposal for the review of 30 procedures and three PERs (ABRWH, 2007a, pp. 241–242).

- **June 23, 2007:** SC&A submitted a cost proposal to the CDC Contracting Office that included a proposal for reviewing PERs. SC&A proposed a review/audit protocol that consisted of six subtasks as follows:

    - Subtask 1: Conduct a critical review and analysis of the "issue" that served as the basis for the PER.
    - Subtask 2: Assess NIOSH's evaluation/characterization of the "issue" and its potential impacts on dose reconstruction.
    - Subtask 3: Assess NIOSH's specific methods for corrective action.
    - Subtask 4: Evaluate the PER's stated approach for identifying the universe of potentially affected DRs; and assess the criteria by which a subset of potentially affected DRs was selected for reevaluation.
    - Subtask 5: Conduct audits of DRs affected by a PER under review.

  - Subtask 6: SC&A will prepare a comprehensive written report that contains the results of our findings associated with of the all above-stated subtasks along with our review conclusions.

- **June 26, 2007:** An SPR teleconference briefly addressed SC&A's proposed review/audit of PERs consisting of six subtasks (ABRWH SPR, 2007, pp. 63–68). During the SPR meeting, it was noted that SC&A had completed its review of four PERs. However, SC&A's review of these four PERs was performed by means of the generic protocol used for the review of NIOSH's implementation guides, procedures, and technical basis documents.

- **July 19, 2007:** The Board continued its discussion regarding SC&A's proposed review protocol for PERs and approved SC&A's PER protocol to include six subtasks (ABRWH, 2007b, pp. 41–46).

- **November 27, 2007:** At a teleconference meeting, the Board authorized SC&A to begin review of OCAS-PER-009, along with the audit of three DRs (ABRWH, 2007c, pp. 96–101).

- **June 20, 2008:** SC&A issued a final draft report pertaining to our review of PER-009 (SC&A, 2008). During discussions of SC&A's review of PER-009, the DFO recommended eliminating subtask 1 of the SC&A proposed protocol for the review of PERs.

- **December 1, 2009:** SC&A issued revision 1 (SC&A, 2009) of the protocol to review NIOSH PERs, which consisted of five subtasks as follows:

  - Subtask 1: Assess NIOSH's evaluation/characterization 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, 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.

  - Subtask 3: Evaluate the PER's stated approach for identifying the universe of potentially affected DRs; and assess the criteria by which a subset of potentially affected DRs was selected for reevaluation. The second step may have important implications in instances where the universe of DRs is too large and, for reasons of practicality, NIOSH's reevaluation is confined to a subset of DRs. In behalf of subtask 4, SC&A will also evaluate and give due consideration to the timeliness for the completion of 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. (It is assumed that the selection of the DRs and the total number of DR audits per PER will be made by

the Advisory Board.) It is further anticipated that the scope of the DR audits may vary and reflect whether the original DR was based on a maximized dose reconstruction or whether the original DR reflects a best estimate. The difference in audit strategy is based on the following:

- Audits of DRs originally derived by best estimates will be based on a highly focused review inasmuch as all elements of the dose reconstruction other than the element(s) defined in the PER can be assumed to remain unchanged.
- A DR that was originally based on a maximized (or partially maximized) approach may not only be revised for dose element(s) affected by the PER but may be subject to revision(s) for dose elements that were previously based on maximized assumptions. Audits of such cases will require a comprehensive review.

- Subtask 5: Prepare a comprehensive written report that contains the results of above-stated subtasks along with our review conclusions.

3 SC&A's 2025 Proposed Revision of PER Review Protocol

As a result of SC&A's 2024 contract rebid, SC&A revisited the PER protocols to determine if the review guidance was still applicable. As a result, SC&A determined that not all the subtasks conformed to our current practices. Therefore, at the November 8, 2024, SPR meeting, SC&A requested and obtained approval from the SPR to propose modifications to the PER review protocol.

SC&A is proposing in this 2025 PER protocol that the number of subtasks be reduced from five to four and the descriptions of subtasks 2, 3, and 4 be expanded to include more details, as follows:

- **Subtask 1:** Assess NIOSH's evaluation and characterization of the issue addressed in the PER and its potential impacts on DR. Our assessment intends to ensure that the issue was fully understood and characterized in the PER. [Note: this subtask remains unchanged from the previous review protocol.]

- **Subtask 2:** Assess NIOSH's specific methods for corrective action. When the PER involves a technical issue that is supported by documents (e.g., white papers, technical information bulletins, procedures) that have not yet been subjected to a formal SC&A review, subtask 2 will include a review of the scientific basis and/or sources of information to ensure the credibility of the corrective action and its consistency with current consensus science. Conversely, if such technical documentation has been formalized and previously subjected to a review by SC&A, subtask 2 will simply provide a summary and conclusion of that review process.

- **Subtask 3:** Evaluate the PER's stated approach for identifying the universe of potentially affected DRs and assess the criteria by which a subset of potentially affected DRs was selected for reevaluation. The second step may have important implications where the

universe of previously denied DRs is very large and, for reasons of practicality, NIOSH's reevaluation was confined to a subset of DRs that, based on their scientific judgment, had the potential to be significantly affected by the PER. In behalf of subtask 3, SC&A will also evaluate and give due consideration to the timeliness of the completion of the PER.

SC&A will prepare a written report discussing the findings of our review of subtasks 1–3 for the SPR. This report will also provide recommendations for the case selection criteria and number of DRs that the Board may want to consider for SC&A's review under subtask 4. The sample size of DRs considered adequate for auditing for a given PER will vary based on the changes that prompted the issuance of the PER, such as the number of exposure pathways impacted, number of target organs/tissues involved, monitoring methods, affected time period, etc.

- **Subtask 4:** Conduct audits of selected DRs 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. However, if SC&A identifies questionable information or inconsistencies that warrant bringing an issue to the attention of the SPR, the review will be expanded as deemed appropriate. SC&A will provide the SPR with a comprehensive report of its DR review findings.

4 Summary Conclusions

SC&A began reviewing NIOSH PERs in 2007. Initially, SC&A's review protocol consisted of six subtasks. Due to a recommendation by the DFO to eliminate subtask 1, SC&A issued revision 1 of our PER protocol in 2009 with five subtasks.

The 2025 revised protocol proposed in this document consists of four subtasks, described in section 3, that have been modified to reflect the current practices that have been accepted by the SPR and the Board. The primary reason for the decrease from five subtasks to four is the elimination of subtask 5, which was essentially a summary document of all previous subtasks. However, it is SC&A's opinion that this last subtask is not necessary because subtasks 1–3 are summarized in a single report already, which also serves to inform the Board on suggested criteria for case audits under subtask 4 (which is likewise documented and presented to the Board).

5 References

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