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ADVISORY BOARD ON RADIATION AND WORKER HEALTH

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

A REVIEW OF NIOSH'S PROGRAM EVALUATION REPORTS OCAS-PER-025 AND OCAS-PER-033, "HUNTINGTON PILOT PLANT TBD REVISIONS"

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Disclaimer

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ABBREVIATIONS AND ACRONYMS

Advisory Board or ABRWH	Advisory Board on Radiation and Worker Health
CFR	*Code of Federal Regulations*
Ci	curies
DOL	Department of Labor
DR	dose reconstruction
HPP	Huntington Pilot Plant
keV	kilo electron volt
NIOSH	National Institute for Occupational Safety and Health
NOCTS	NIOSH/OCAS Claims Tracking System
OCAS	Office of Compensation Analysis and Support
ORAUT	Oak Ridge Associated Universities Team
pCi	picocuries
PEP	Program Evaluation Plan
PER	Program Evaluation Report
POC	probability of causation
SC&A	S. Cohen and Associates (SC&A, Inc.)
TBD	Technical Basis Document
TIB	Technical Information Bulletin
yr	year

1.0 STATEMENT OF PURPOSE

To support dose reconstruction (DR), the National Institute for Occupational Safety and Health (NIOSH) and the Oak Ridge Associated Universities Team (ORAUT) have assembled a large body of guidance documents, technical basis documents (TBD), workbooks, computer codes, and tools. In recognition of the fact that all of these supporting elements in DR 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, misinterpretation of guidance, changes in policy, and/or programmatic improvements.

The process for evaluating potential impacts of programmatic changes on previously completed DRs has been proceduralized in OCAS-PR-008, *Preparation of Program Evaluation Reports and Program Evaluation Plans*, Rev. 2, dated December 6, 2006. This procedure describes the format and methodology to be employed in preparing a Program Evaluation Report (PER) and a Program Evaluation Plan (PEP).

A PER provides a critical evaluation of the effect(s) that a given issue/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 impact(s) on the Probability of Causation (POC) of previously completed DRs with POCs of <50%.

As needed, a PEP may be issued that serves as a formal notification of an impending PER. The PEP provides a preliminary description of the issue(s) that will be addressed in the PER, and summarizes the likely scope of the effort required to complete the PER.

S. Cohen and Associates (SC&A) was tasked by the Advisory Board on Radiation and Worker Health (Advisory Board) to conduct a review of OCAS-PER-025 "*Huntington Pilot Plant TBD Revisions*" and OCAS-PER-033 "*Reduction Pilot Plant TBD Revision."* The terms *Huntington Pilot Plant* and *Reduction Pilot Plant* are often used interchangeably; therefore, the term Huntington Pilot Plant (HPP) will be used in this report. In conducting a PER review, SC&A is committed to perform the following five subtasks (as per protocol outlined in SCA-TR-PR2009-0002, 2009), each of which is discussed in this report:

Subtask 1: Assess NIOSH's evaluation/characterization of the "issue" and its potential impact(s) on DR. 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 that is supported by document(s) [e.g., white papers, technical information bulletins (TIBs), 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 brief summary/conclusion of this 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 re-evaluation. The second step may have important implications in instances where the universe of previously denied DRs is very large and, for reasons of practicality, NIOSH's re-evaluation is confined to a subset of DRs that, based on their scientific judgment, have the potential to be significantly affected by the PER. In behalf of Subtask 3, SC&A will also evaluate the timeliness for the completion of the PER.

Subtask 4: Conduct audits of DRs affected by the PER under review. Based on information contained in the PER (and discussed in Section 5 below), 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.)

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

2.0 SUBTASK 1: ASSESS NIOSH'S IDENTIFICATION OF THE ISSUES AND THEIR IMPACT ON DR

NIOSH has issued a TBD for the HPP, along with a number of revisions. As stated in OCAS-PER-025 and OCAS-PER-033, these documents have been utilized to perform DRs for claims from the HPP. Although many of the revisions only added annotation and attribution or corrected errors that did not affect the DR methods, there were a number of substantial changes made that could affect the outcome of a DR. In preparation of OCAS-PER-025 and OCAS-PER-033, the technical changes made in the revisions of the TBD were reviewed to determine if any previously completed DR would result in an increased dose using the current methods. The review was limited to identifying any increase in assigned dose, rather than any change or an overall increase.

A summary of the HPP TBD (OCAS-TKBS-0004) revisions are listed below:

- 10/31/2003, Rev. 00 (OCAS 2003)
- 01/16/2004, Rev. 01 (OCAS 2004)
- 08/12/2008, Rev. 02 (OCAS 2008)

SC&A noted that the 2008 edition of the TBD has the same revision number assigned as the original 2003 edition. Each page of the 2008 edition is labeled as Revision No. 00, when it would appear it should read Revision No. 02. SC&A will use the Rev. 02 notation in this report to refer to the 2008 edition to avoid confusion with 2003 edition.

2.1 ISSUANCE OF PER-025 AND PER-033

OCAS-PER-025

On September 28, 2007, NIOSH issued OCAS-PER-025, which contained the following major sections:

Section 1.0 – This section provides a description of the reason there is a need to consider the changes in the revised HPP TBD (Rev. 01 of January 16, 2004) that could potentially increase assigned dose to claimants whose claims had previously been processed, with a resulting POC <50%, using an earlier version of the HPP TBD (Rev. 00 of October 31, 2003).

Section 2.0 – This section provides a summary of the issue identified by NIOSH from their evaluation of the changes in the HPP TBD as follows:

> *The revision to the Huntington Pilot Plant TBD provides an estimate of shallow dose (electron dose) that did not appear in the original version. This dose is used primarily for skin dose estimates but also for breast and testes. Claims in which the external target organ is skin, breast, or testes may be affected if they were completed prior to revision 1 of the TBD.*

Section 3.0 – This section states that there was one HPP potentially impacted claim completed with a POC <50% prior to the issuance of the January 16, 2004, TBD revision. This section provides a plan of corrective action to resolve the issue created by the revision by requesting that this claim be returned for a new dose estimate. A new DR will be completed using the latest revision to the HPP TBD.

OCAS-PER-033

On December 9, 2011, NIOSH issued OCAS-PER-033, which contained the following major sections:

Section 1.0 – This section provides a description of the reason there is a need to consider the changes in the revised HPP TBD (Rev. 02 of August 13, 2008) that could potentially increase assigned dose to claimants whose claims had previously been processed, with a resulting POC <50%, using an earlier version of the HPP TBD (Rev. 01 of January 16, 2004).

Section 2.0 – This section provides a summary of the issues identified by NIOSH from their evaluation of the changes in the HPP TBD as follows:

> *Several changes in the Dose Reconstruction methodology occurred in this revision to the TBD. Most changes reflect a decrease in the estimated dose. However, the estimate of internal dose increased from 1956 through 1963 and for 1978 and 1979. The inhalation estimate for operators went from approximately 3.83 pCi/day (1400 pCi/yr) to 44 pCi/day. The original intake was the geometric mean of a lognormal distribution with a geometric standard deviation of 4.3. The new estimate is a single bounding value.*
>
> *While the internal dose estimate increased, other exposure pathways decreased. Due to the nature of some of the changes, the magnitude of the effect on individual dose estimates will vary from claim to claim.*

Section 3.0 – This section states that there were 32 HPP potentially impacted claims completed with a POC <50% prior to the issuance of the August 13, 2008, TBD revision. This section provides a plan of corrective action to resolve the issues created by the revision by recalculating the dose for each of the 32 claims using all current DR methods, including the current version of the TBD. From that recalculated dose, a new POC was determined.

2.2 SC&A'S ASSESSMENT OF THE DEVELOPMENT OF PER-025 AND PER-033

SC&A's review of the applicable HPP TBD revisions, OCAS-PER-025, and OCAS-PER-033 indicates that NIOSH properly outlined the necessary steps to re-evaluate the claims potentially impacted by the revisions in the TBD as proceduralized in OCAS-PR-008, *Preparation of Program Evaluation Reports and Program Evaluation Plans,* Rev. 02.

SC&A will provide detailed analyses of their review in the following sections of this report.

3.0 SUBTASK 2: ASSESS NIOSH'S SPECIFIC METHODS FOR CORRECTIVE ACTION

In instances where the PER involves a technical issue that is supported by documents [e.g., white paper(s), TIB(s), and/or procedure(s)] that have not yet been subjected to a formal SC&A review, Subtask 2 will assess 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 brief summary/conclusion of this review process.

3.1 SC&A'S EVALUATION OF CHANGES IN HPP TBD

A complete formal review of all the applicable HPP TBD revisions would be out of the scope and time resources of SC&A's task of evaluating OCAS-PER-025 and OCAS-PER-033, and would be considered a complete HPP site profile review. SC&A had performed in the past, or presently performed, the following evaluation/review of the HPP site profile and related documents:

(1) SC&A Reviewed HPP TBD in 2013 – The HPP technical document (OCAS-TKBS-0004, Rev. 02, August 13, 2008) was previously reviewed by SC&A in 2013. That revision of the TBD would contain the changes in the TBD that would be relevant to OCAS-PER-025 and OCAS-PER-033. A short summary of SC&A's evaluation of the TBD is provided in Attachment A of this report.

(2) SC&A Current Evaluation – In conjunction with the evaluation of OCAS-PER-025 and OCAS-PER-033, SC&A recently performed a paragraph-by-paragraph comparison of the following documents to determine if there were any changes in the later revisions that could potentially increase the assigned dose:

- 01/16/2004, Rev. 01, was compared to 10/31/2003, Rev. 00
- 08/12/2008, Rev. 02, was compared to 01/16/2004, Rev. 01

From this evaluation, SC&A identified the following changes that have the potential to increase assigned dose during dose reconstruction (DR):

Comparing Rev. 01 to Rev. 00:

Electron Skin Dose – Page 12 of Rev. 01 contains a paragraph concerning the assignment of electron dose to the skin. This paragraph was not contained in Rev. 00, and could result in an increase in assigned dose in some cases. However, this change was addressed in OCAS-PER-025 and was the basis for initiating OCAS-PER-025. SC&A evaluated OCAS-PER-025 and found it to sufficiently address this issue. SC&A had no findings from this comparison.

Comparing Rev. 02 to Rev. 01:

Occupational Medical Dose – The Occupational Medical Section 9.0 of Rev. 02 (page 17) recommends using ORAUT-OTIB-0006 to assign medical x-ray doses. However, it is recommended in Rev. 01 to use organ doses as listed in Table 8, page 12, of the TBD. Comparing the recommended dose in ORAUT-OTIB-0006, Table 6-5, to Table 8 of the TBD Rev. 01 indicates that this change could cause an increase in dose to the skin, stomach, and thymus in some cases. However, if a new DR is performed as recommended by OCAS-PER-033 using the current TBD, this issue will be addressed.

Shallow Dose – Table 6 of Rev. 02 (page 17) provides for lower annual deep and shallow dose assignments than those recommended on page 12 of Rev. 01; except Rev. 02 recommends an annual dose of 1.000 rem shallow dose to the hands and forearms for Operators and Maintenance personnel, whereas only 0.85 rem per year skin dose is recommended in Rev. 01 (page 12), without reference to hands or forearms. This could result in an increase in assigned skin dose in some cases. However, if a new DR is performed as recommended by OCAS-PER-033 using the current TBD, this issue will be addressed.

Period of Internal Intake – Table 5 of Rev. 02 (page 16) provides a summary of the recommended inhalation and ingestion intakes for the periods 1956–1963 and 1978–1979. However, Rev. 01 addresses the period 1951–1963, but does not specifically address the period 1978–1979. Therefore, in some cases, the inclusion of the period 1978–1979 could increase the assigned dose. However, if a new DR is performed as recommended by OCAS-PER-033 using the current TBD, this issue will be addressed.

Internal Intake Values – Table 5 of Rev. 02 (page 16) provides a summary of the recommended inhalation and ingestion intakes for the periods 1956–1963 and 1978–1979. The values assigned in this table were derived from an updated inhaled intake of 44 pCi/day of total uranium. Table 5 of Rev. 01 (page 8) recommends only 3.83 pCi/day; therefore, in some cases, this change could increase the assigned dose. However, if a new DR is performed as recommended by OCAS-PER-033 using the current TBD, this issue will be addressed. This change was the basis for initiating OCAS-PER-033.

SC&A had no findings from these comparisons.

3.2 SC&A'S EVALUATION OF NIOSH'S CORRECTIVE ACTION PLAN

OCAS-PER-025

According to OCAS-PER-025, NIOSH will identify the claims that were completed prior to the issuance of Rev. 01 (January 16, 2004) of the HPP TBD, and which had a POC below 50%. NIOSH will then request that these claims be returned for a new dose estimate. A new DR will be completed using the latest revision to the HPP TBD.

SC&A evaluated the TBD changes (concerning electron dose to the skin) and concurs with NIOSH's corrective action plan.

OCAS-PER-033

NIOSH will identify the claims that were completed prior to the issuance of Rev. 02 (August 13, 2008) of the HPP TBD, and which had a POC below 50% and the worker was employed at HPP from 1956–1963 or 1978–1979. NIOSH will recalculate the dose for each of the claims using all current DR methods, including the current version of the TBD. From that recalculated dose, a new POC will be determined.

SC&A evaluated the TBD changes (concerning occupational medical dose, extremity shallow dose, periods of internal intake, and internal intake values) and concurs with NIOSH's corrective action plan.

3.2.1 Conclusions

SC&A found that OCAS-PER-025 and OCAS-PER-033 sufficiently addressed the changes in the HPP TBD and that the PERs recommended proper corrective actions.

4.0 SUBTASK 3: EVALUATE THE PERs' STATED APPROACH FOR IDENTIFYING THE NUMBER OF DRs REQUIRING RE-EVALUATION OF DOSE

OCAS-PER-025

According to Section 3.0 of OCAS-PER-025, at the time OCAS-PER-025 (September 28, 2007) was issued, NIOSH identified one claim that was completed prior to the issuance of Rev. 01 (January 16, 2004) of the HPP TBD, and which had a POC below 50%. NIOSH is requesting that this claim be returned for a new dose estimate. A new DR will be completed using the latest revision to the HPP TBD.

SC&A used the NIOSH/OCAS Claims Tracking System (NOCTS) database to verify that only one HPP claim was impacted by OCAS-PER-025, and that a new DR has been performed for this claim.

OCAS-PER-033

According to Section 3.0 of OCAS-PER-033, at the time OCAS-PER-033 (December 9, 2011) was issued, NIOSH identified 32 HPP claims that were completed prior to the issuance of Rev. 02 of the HPP TBD (August 13, 2008), and which had a POC below 50% and were employed at HPP between 1956–1963 or 1978–1979. NIOSH recalculated the dose for each of the 32 claims using all current DR methods, including the current version of the TBD. From that recalculated dose, new POCs were determined. The table on pages 2 and 3 of OCAS-PER-033 summarizes the results and shows that the TBD revisions resulted in an increase in the POC for 12 of the 32 claims (37.5%), while the POC decreased for the remaining 62.5% of the claims. The highest revised POC did not exceed 50%. Therefore, NIOSH will not ask the Department of Labor (DOL) to return any of the previously completed Reduction Pilot Plant (or HPP) claims based on the revision to the TBD.

SC&A used the NOCTS database to verify that there were 32 HPP claims impacted by OCAS-PER-033. Using the appropriate search criteria, the NOCTS database identified 55 potential claims; of these 55 claims, SC&A found 14 to be duplicate claim numbers (i.e., worked at HPP during several different periods), 3 of the claims had previously been returned to DOL for other reasons, 4 of the claims had employment periods prior to 1956, and 3 of the claims had second DRs performed using the new 2008 TBD prior to OCAS-PER-033 being issued (55 – 14 – 3 – 4 – 3 = 32). It is recommended that SC&A review the 32 remaining claims, as will be described in Section 5 of this report.

5.0 SUBTASK 4: CONDUCT AUDITS OF A SAMPLE SET OF DRs AFFECTED BY OCAS-PER-025 AND OCAS-PER-033

Selection of DRs to Audit for PER-025

Because there was only one case that was impacted by OCAS-PER-025, it is recommended that SC&A review this case and evaluate the recalculated and assigned doses to verify that they conform to the new recommendations in the revised TBD and OCAS-PER-025.

Selection of DRs to audit for PER-033

Because there was numerous (32) claims impacted by OCAS-PER-033, it is recommended that SC&A review this list of claims and select 5 to 10 of the claims that would most likely be impacted by OCAS-PER-033. SC&A will then evaluate the recalculated and assigned doses to verify they conform to the new recommendations in the revised TBD and OCAS-PER-033.

6.0 SUBTASK 5: PREPARE A COMPREHENSIVE WRITTEN REPORT THAT CONTAINS THE RESULTS OF THE ABOVE-STATED SUBTASKS, ALONG WITH OUR REVIEW CONCLUSIONS.

This report consists of SC&A's evaluation of OCAS-PER-025 and OCAS-PER-033 (Subtasks 1, 2, and 3). When the Advisory Board has selected the number of cases that should be reviewed, SC&A will review these cases (Subtask 4) using the methods previously outlined in this report, and will then summarize the evaluation of these selected cases and provide an additional report to the Advisory Board (Subtask 5).

7.0 REFERENCES

42 CFR 82, 2002. *Methods for Radiation Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol.67, No. 85/Thursday, May 2, 2002, p. 22314.

Enterline, P.E., and G.M. Marsh, 1982. *Mortality among Workers in a Nickel Refinery and Alloy Manufacturing Plant in West Virginia*, Journal of the National Cancer Institute, 1982; 6:925-933.

OCAS-PR-008. 2006. *Preparation of Program Evaluation Reports and Program Evaluation Plans*, Rev. 02, NIOSH's Office of Compensation Analysis and Support, Cincinnati, Ohio. December 6, 2006.

OCAS-PER-025. 2007. *Huntington Pilot Plant TBD Revisions*, Rev. 0, National Institute for Occupational Safety and Health, Office of Compensation Analysis and Support, Cincinnati, Ohio. September 27, 2007.

OCAS-PER-033. 2011. *Reduction Pilot Plant TBD Revisions*, Rev. 0, National Institute for Occupational Safety and Health, Office of Compensation Analysis and Support, Cincinnati, Ohio. December 9, 2011.

ORAUT-OTIB-0006. 2011. *Technical Information Bulletin: Dose Reconstruction from Occupationally Related Diagnostic X-Ray Procedures,* Rev. 04, Oak Ridge Associated Universities, Cincinnati, Ohio. June 20, 2011.

OCAS-TKBS-0004. 2003. *Technical Basis Document: Basis for Development of an Exposure Matrix for Huntington Pilot Plant*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. October 31, 2003.

OCAS-TKBS-0004. 2004. *Technical Basis Document: Basis for Development of an Exposure Matrix for Huntington Pilot Plant*, Rev. 01, Oak Ridge Associated Universities Team, Cincinnati, Ohio. January 16, 2004.

OCAS-TKBS-0004. 2008. *Technical Basis Document for the Huntington Pilot Plant, Huntington, West Virginia*, Rev 00. [02], Oak Ridge Associated Universities Team, Cincinnati, Ohio. August 13, 2008.

SCA-TR-PR2009-0002. 2009. *A Protocol to Review NIOSH's Program Evaluation Reports (PERs)*, Rev. 01. SC&A, Inc., Vienna, Virginia, and Saliant, Inc., Maryland. December 2009.

SC&A 2013. *Review of the Revised Huntington Pilot Plant Site Profile*, Rev. 0, SCA-TR-SP2013-0043. SC&A, Inc., Vienna, Virginia, and Saliant, Inc., Jefferson, Maryland. June 2013.

ATTACHMENT A: SC&A'S PREVIOUS FINDINGS CONCERNING THE HUNTINGTON PILOT PLANT TBD

On June 4, 2013, SC&A issued a draft report (SC&A 2013) SCA-TR-SP2013-0043 titled, *Review of the Revised Huntington Pilot Plant Site Profile*. This draft report presents SC&A's evaluation of the National Institute for Occupational Safety and Health (NIOSH) Site Profile for the HPP, Rev. 00 [02], of August 13, 2008 (OCAS-TKBS-0004, 2008). The following is a summary of these findings:

> ***Finding 1:*** *Since the three diffusion plants (the source of the HPP nickel) had additional isotopes of concern, NIOSH should clearly provide the basis for only specifying Pu-239 and Np-237 as isotopes of concern for recycled uranium.*
>
> ***Finding 2:*** *NIOSH should clearly state which uranium-specific activity was used in the analysis and ensure that it was used consistently throughout the analysis.*
>
> ***Finding 3:*** *There is a unit conversion error in going from Table A2 column 3 (Photons per decay ^{238}U) to column 4 (Photons per second per Ci $^{238}[U]$).*
>
> ***Finding 4:*** *The dose breakdown between 0–250 keV and >250 keV varies from 50/50 to about 70/30, depending on the gamma spectrum.*
>
> ***Finding 5:*** *Provide justification for including modern airborne nickel concentrations in the concentration distribution, when Enterline and Marsh 1982 indicate that the historical concentrations were (in most cases) of greater magnitude.*
>
> ***Finding 6:*** *Provide justification for excluding from the concentration distribution the airborne nickel concentration in the crushing, grinding, and handling areas and the area around the calciners reported by Enterline and Marsh (1982).*
>
> ***Finding 7:*** *There are three typographical errors in the numerical values given in Section 6.2 of ORAUT-TKBS-0004, 2008. Despite the erroneous numerical values, the annual doses are reported correctly, thus SC&A has characterized them as "typographical," rather than "numerical" errors. Nonetheless, because the erroneous numerical values make it difficult to understand how the annual doses were calculated, SC&A has identified these three typographical errors as a finding rather than an observation.*

Most of these findings would not directly impact the issues caused by the changes in the TBD that were addressed in OCAS-PER-025 and OCAS-PER-033. Resolution of Findings 5 and 6 could potentially result in an increase in intake, which could require the initialization of a new PER; however; the current OCAS-PER-033 correctly addresses the present TBD.