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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 REPORT DCAS-PER-043, "INTERNAL DOSIMETRY ORGAN, EXTERNAL DOSIMETRY ORGAN, AND IREP MODEL SELECTION BY ICD-9 CODE REVISION"

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S. COHEN & ASSOCIATES: ***Technical Support for the Advisory Board on Radiation & Worker Health Review of NIOSH Dose Reconstruction Program***	Document No. SCA-TR-PR2014-0089 Effective Date: Draft – August 18, 2014
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Project Manager: _____ Date: _____ John Stiver, CHP	Reviewer(s): John Stiver

Record of Revisions

Revision Number	Effective Date	Description of Revision
0 (Draft)	08/18/2014	Initial issue

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS

CCL	chronic lymphocytic leukemia
CM	Clinical Modification
DCAS	Division of Compensation Analysis and Support (formerly OCAS)
DHHS	(U.S.) Department of Health and Human Services
DOL	(U.S.) Department of Labor
DR	dose reconstruction
EEOICPA	Energy Employees Occupational Illness Compensation Program Act of 2000
ICRP	International Commission on Radiological Protection
ICD	International Classification of Diseases
IMBA	Integrated Modules for Bioassay Analysis
IREP	Interactive RadioEpidemiological Program
NCHS	National Center for Health Statistics
NIOSH	National Institute for Occupational Safety and Health
NOS	not otherwise specified
OCAS	Office of Compensation Analysis and Support (now DCAS)
ORAUT	Oak Ridge Associated Universities Team
PEP	Program Evaluation Plan
PER	Program Evaluation Report
POC	probability of causation
SC&A	S. Cohen and Associates (SC&A, Inc.)
SEC	Special Exposure Cohort
TIB	technical information bulletin

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, 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* (OCAS 2006), Revision 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%.

During a teleconference by the Advisory Board's Procedures Subcommittee meeting on April 16, 2014, SC&A was tasked by the Board to conduct reviews of three PERs. Included among the PERs is DCAS-PER-043, *Internal Dosimetry Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code Revision* (DCAS 2013). In conducting a PER review, SC&A is committed to perform the following five subtasks, each of which is discussed in this report:

Subtask 1: Assess NIOSH's evaluation/characterization of the "issue" and its potential impacts 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 Table 1 (and discussed in Section 3.1 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 written report that contains the results of the Subtask 4 DR audit, along with our review conclusions.

2.0 SUBTASK 1: IDENTIFY THE CIRCUMSTANCES THAT NECESSITATED THE NEED FOR DCAS-PER-043

Under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), the organs or tissues for which doses must be estimated are those that are delineated by the specified ICD-9 code that is received from the U.S. Department of Labor (DOL). Thus, coding of the cancers is conducted by DOL on the basis of ICD-9. The U.S. Department of Health and Human Services (DHHS) National Center for Health Statistics (NCHS) has issued a related document, International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM; DHHS 2008), which is widely used in the United States. ICD-9-CM is revised on an annual basis. While many ICD-9 codes are clear in their intended organ or tissue, additional guidance is necessary to identify the appropriate organs or tissues for internal and external dose estimation and the Interactive RadioEpidemiological Program (IREP) model to use for the organ or tissue.

ORAUT-OTIB-0005, *Internal Dosimetry Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code,* provides guidance on selection of (1) the appropriate International Commission on Radiological Protection (ICRP) organ or tissue model to estimate the internal dose for specific ICD-9 codes, (2) the appropriate organs or tissues to estimate external dose, and (3) the appropriate model in IREP. ORAUT-OTIB-0005 also provides information for selecting and assessing likely primary cancers for secondary cancers.

Revision 0 of ORAUT-OTIB-0005 was issued on March 11, 2003. Since that time, changes have been introduced that have mandated the following nine revisions to ORAUT-OTIB-0005.

Revision #	Issue Date
Revision 0	11/3/2003
Revision 1	11/23/2004
Revision 1 PC-1	3/5/2004
Revision 1 PC-2	5/7/2004
Revision 1 PC-3	10/29/2004
Revision 2	12/2/2005
Revision 2 PC-1	2/10/2006
Revision 3	2/26/2010
Revision 4	4/18/2011
Revision 5	12/20/2012

While some changes in these revisions increased doses, others reduced doses. Since corrective actions mandated by DCAS-PER-043 only need to consider those changes that could result in an increase in dose (and the POC), our review is restricted to those changes that may increase organ doses as summarized below:

- Revision 1 incorporated guidance for the selection of the **external** organ for a given ICD-9 code into ORAUT-OTIB-0005, which was previously contained in OCAS-IG-001. This revision did **not** introduce a change to the estimate of the organ dose.

- Revision 1 PC-1 added the **bone cancer model** as a possible option to ICD-9 code 238.7 [lymphoproliferative disease, not otherwise specified (NOS)].

- Revision 1 PC-2 changed the designated **internal** organ for codes 231.8, 235.8, and 235.9 from **lung** to **"medical review".**[1]

- Revision 1 PC-3 introduced two changes, both of which resulted in a decrease in dose and are, therefore, **not** impacted by DCAS-PER-043.

- Revision 2 modified handling adenocarcima of the lower third of the esophagus. The revised method required modeling of the esophagus and the stomach to determine which is higher.

- Revision 3 changed the **internal** organ for ICD-9 code 155.1 (malignant neo intrahepatic ducts) from gallbladder to liver/gallbladder. The liver is to be used for intrahepatic ducts; the gallbladder for gallbladder; and a medical review is required to determine the appropriate internal organ for any other specific organ.

- Revision 4 changed internal and external target organs for ICD-9 codes 238.0 (uncert behave neoplasm nec/nos) and 239.2 (bone/skin neoplasm nos). The **internal** target organ changed from "**medical review**" to **bone surfaces**; and the **external** target organ changed from **red bone marrow** to **bone surface**.

- Revision 5 added code 204.1 [chronic lymphocytic leukemia (CLL)] that is briefly described in **ORAUT-OTIB-0082** and in greater detail in Apostoaei and Trabalka (2012).

SC&A Comments

Based on summary information provided above, only seven of the nine revisions contributed to the need for DCAS-PER-043:

- Revision 1 and Revision 1 PC-3 introduced changes that **decreased** dose and are therefore **not** relevant to DCAS-PER-043.

- Revision 1 PC-1, Revision 1 PC-2, Revision 2, Revision 3, and Revision 4, introduced changes that (1) added ICD-9 codes, (2) changed internal and/or external target organs, or (3) revised the handling of esophageal cancer of the lower third section. These changes all have the potential for increasing dose.

- Revision 5 introduced CLL as a newly recognized radiogenic cancer (ICD-9 code 204.1 series).

[1] Due to the complexity of determining the appropriate internal organ for some ICD-9 code cancers, a medical review/recommendation by an ORAUT physician is required for determination of internal organ.

Pertaining to revisions introduced in ORAUT-OTIB-0005 that necessitated the need for DCAS-PER-043, Sections 2.0 and 4.2 of OTIB-0005 (Revs. 03, 04, and 05) provide the following explanation regarding responsible parties for the assignment of ICD-9 codes and the appropriate selection of target organs/tissues for internal and external dose estimates:

From Section 2.0

> *Under EEOICPA, the organs or tissues for which doses must be estimated are those that are delineated by the specified ICD-9 code* ***that is received from the U.S. Department of Labor (DOL)****. While many ICD-9 codes are clear in their intended organ or tissue, additional guidance is necessary to identify the appropriate organs or tissues for internal and external dose estimation and the IREP model to use for the organ or tissue. This TIB designates the appropriate internal dosimetry organ and tissue selection for the various ICD-9 coded cancers, the appropriate organs and tissues to estimate external dose, and the appropriate IREP model.*
>
> ***Coding of the cancers is conducted by DOL on the basis of ICD-9****. The U.S. Department of Health and Human Services (DHHS) National Center for Health Statistics (NCHS) has issued a related document, International Classification of Diseases, Ninth Edition, Clinical Modification (****ICD-9-CM****; DHHS 2008), which is widely used in the United States.* ***ICD-9-CM*** *is revised on an annual basis. . . . Although the ICD-9-CM coding provides detail that is not in ICD-9, this has not historically been required for assessment under EEOICPA. However, because ICD-9-CM is widely used in the United States, DOL might provide some codes that did not appear in earlier versions of this TIB. . . . Due to the complexity of determining the appropriate organs for lymphatic/hematopoietic cancers, the NIOSH Division of Compensation Analysis and Support (previously the Office of Compensation Analysis and Support or OCAS) conducted a comprehensive review of the state of knowledge regarding the etiology and diagnosis of the various lymphomas, leukemias, and multiple myeloma. This TIB incorporates the findings from this review as set forth in OCAS-TIB-012, Selection for Internal and External Dosimetry Target Organs for Lymphatic/Hematopoietic Cancers (NIOSH 2006).* [Emphasis added.]

From Section 4.2

> *Due to the complexity of determining the appropriate organs and tissues for some ICD-9 code cancers, a medical review by an Oak Ridge Associated Universities (ORAU) Team physician is required to determine the organs and tissues to use in IMBA for those cancers. These cancers have been designated in Table 3-1 as "Medical review." The ORAU Team physician will recommend to the dose reconstructor the appropriate organs and tissues for dose estimation purposes.*

SC&A concludes that revisions to ORAUT-OTIB-0005 (that necessitated DCAS-PER-043) were exclusively introduced by parties that are generally not within the scope of SC&A's review. We

assume that changes and additions to ICD-9 codes reflect updates/revisions to the International Classification of Diseases and ORAUT's improved understanding of corresponding internal and external target organs.

Therefore, SC&A accepts changes introduced to ORAUT-OTIB-0005, and there are no findings.

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

For corrective action, NIOSH only considered these revisions to ORAUT-OTIB-0005, which had the potential to increase the dose/POC of previously completed claims, as summarized below:

- Revision 1 PC-1 – NIOSH identified five claims that had been completed prior to this revision on March 5, 2004, which **added** the **bone cancer model** as a possible option to ICD-9 code 238.7. However, subsequent to this revision, **all five cases** had been returned for other reasons and reworked using the bone cancer model as a possible option. NIOSH stated that ". . . Therefore, no further action is necessary."

- Revision 1 PC-2 – Previously completed claims affected by changes introduced in this revision were limited to **esophageal cancer** of the **lower third** for which stomach cancer is an optional consideration. NIOSH identified a total of **six** cancers of the lower third esophagus, of which two were compensated under a Special Exposure Cohort (SEC) and **four** were re-evaluated. None of the **four** reworked claims resulted in a POC ≥50%.

- Revision 3 – For code 155.1, this revision identified the liver as the appropriate internal organ for some cases that may have previously used the gall bladder. Of 23 previously completed claims with code 155.1, 8 were compensated under an SEC. Of the 15 claims that were re-evaluated, **13 claims** remained below a POC of 50%.

- Revision 4 – This revision affected codes 232, 238, and 239.2. For code 232, this revision added basal cell carcinoma for consideration when the cell type was **not** specified. NIOSH identified a total of 16 previously completed claims with code 232 for which the cell type had not been specified. When reworked, all **16 cases** resulted in POCs less than 50%.

  For code 238.0, the internal target organ was changed from **medical review** to bone surface and the external target organ from bone surface to bone marrow. A **single** claim was affected and re-evaluated. It resulted in a POC of <50%.

- Revision 5. The final revision to ORAUT-OTIB-0005 **added** chronic lymphocytic leukemia (CLL) as a radiogenic cancer that was previously not considered under the EEOICPA. However, this change is being considered an **additional cancer** rather than a revised method for the reconstruction of dose. Since to date, no CLL claims have been processed, Revision 5 is not included in the audit of DCAS-PER-043.

SC&A Comments, Findings, Observations

SC&A reviewed all revisions stated in DCAS-PER-043 and compared these to statements cited in the text and to entries given in Table 3-1 (*Selection of Organs, Tissues, and IREP Models for Internal and External Dose Reconstruction Based on ICD-9 Code*).

SC&A found no discrepancies, and there are no findings.

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

Criteria used to determine the total population of claims that had the potential of being affected by DCAS-PER-043 included the following:

(1) Claims were completed prior to the issue date for a specific revision, which had the potential of increasing the dose;

(2) Claims with a derived POC of less than 50%;

(3) Claims that met one or more changes that were identified in a specific revision as given in Section 3.0 of DCAS-PER-043 and summarized in Section 2.0 above; and

(4) A number of claims that met criteria #1, #2, and #3, but were excluded for reasons that include the following:

– claim had subsequently qualified for inclusion/compensation under an SEC; or
– claim had been returned for other reasons and reworked using the revised applicable changes.

In summary, revisions introduced in ORAUT-OTIB-0005 affected a total of 36 previously completed claims. Of these, 2 claims resulted in a revised POC greater than 50%; the remaining 34 claims resulted in POCs of less than 45% and represent the pool of claims from which a subset is subject to audit.

SC&A's Comments/Findings

SC&A was not given access to the primary data used by NIOSH to identify and quantify those claims, which met the stated criteria and qualified for a re-evaluation of dose. SC&A is, therefore, not able to verify the above-cited number of 36 claims that were subject to dose re-evaluation.

Our assessment is, therefore, limited to the methodology/criteria employed by NIOSH to identify those claims that are/were potentially impacted by DCAS-PER-043. Based on this restrictive assessment, SC&A concludes that the screening criteria used to identify potentially impacted claims are scientifically sound.

SC&A has no findings pertaining to the identification of claims that were impacted by DCAS-PER-043.

5.0 SUBTASK 4: CONDUCT AUDITS OF A SAMPLE SET OF DRs AFFECTED BY DCAS-PER-043

Selection of DRs

Among the pool of 34 DRs that are subject to audit, SC&A recommends the selection of one claim from each of the following revisions and/or ICD-9 codes:

- Revision 2: ICD-9 code 150. This change required the need to consider **stomach cancer** (both target organ and cancer model) for esophageal cancer of the lower third portion of the esophagus. **Select one case from among four affected cases with reworked POC of <50%.**

- Revision 3: ICD-9 code 155.1. This change specified liver as the appropriate internal dose organ for cases that had previously used the gall bladder. **Select one case from 15 affected claims with reworked POCs of <50%.**

- Revision 4:

  – ICD-9 Code 232 – added basal carcinoma to the considered cancer models for code 232 when cell type was not specified. **Select one claim from 16 reworked claims with POC of <50%.**

  – ICD-9 Code 238 – changed target organs. **Select the single claim that was re-evaluated and resulted in a POC of <50%.**

6.0 REFERENCES

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