DRAFT

DCAS-PER-043, SUBTASK 4:

REVIEW OF FOUR CASES REASSESSED FOR THE EVALUATION OF REVISIONS TO ORAUT-OTIB-0005, "INTERNAL DOSIMETRY ORGAN, EXTERNAL DOSIMETRY ORGAN, AND IREP MODEL SELECTION BY ICD-9 CODE"

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Revision 0

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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.: DCAS-PER-043, Subtask 4 Review Effective Date: Draft – December 17, 2014
DCAS-PER-043, SUBTASK 4: REVIEW OF FOUR ADVISORY BOARD CASES REASSESSED FOR THE EVALUATION OF REVISIONS TO ORAUT-OTIB-0005, "INTERNAL DOSIMETRY ORGAN, EXTERNAL DOSIMETRY ORGAN, AND IREP MODEL SELECTION BY ICD-9 CODE"	Page 2 of 28
Task Manager: _____ Date: _____ U. Hans Behling, PhD	Supersedes: N/A
Project Manager: _____ Date: _____ John Stiver, MS, CHP	Reviewer: John Stiver

Record of Revisions

Revision Number	Effective Date	Description of Revision
0 (Draft)	12/17/2014	Initial issue.

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LIST OF EXHIBITS

ABBREVIATIONS AND ACRONYMS

ACS	American Cancer Society
Advisory Board	Advisory Board on Radiation and Worker Health
BCC	basal cell carcinoma
CADW	Chronic Annual Dose Workbook
CCL	chronic lymphocytic leukemia
DCAS	Division of Compensation Analysis and Support
DCF	dose conversion factor
DOL	(U.S.) Department of Labor
DR	Dose Reconstruction
EE	Energy Employee
FMPC	Feed Materials Production Center
ICD	International Classification of Diseases
ICRP	International Commission on Radiological Protection
IMBA	Integrated Modules of Bioassay Analysis
IREP	Interactive RadioEpidemiological Program
keV	kiloelectron volts
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOCTS	NIOSH/OCAS Claims Tracking System
NOS	not otherwise specified
OCAS	Office of Compensation Analysis and Support
ORAUT	Oak Ridge Associated Universities Team
PC	page change
PER	Program Evaluation Report
POC or PoC	Probability of Causation
PRSC	Procedures Review Subcommittee
rem	Roentgen equivalent man
SC&A	S. Cohen and Associates (SC&A, Inc.)
SRS	Savannah River Site
TBD	Technical Basis Document
TIB	Technical Information Bulletin

1.0 RELEVANT BACKGROUND INFORMATION

S. Cohen and Associates (SC&A) was tasked by the Advisory Board to conduct a review of DCAS-PER-043, *Internal Dosimetry Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code Revisions*. ORAUT-OTIB-0005 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 the Interactive RadioEpidemiological Program (IREP). ORAUT-OTIB-0005 also provides information for selecting and assessing likely primary cancers for secondary cancers.

Revision 00 of ORAUT-OTIB-0005 was first issued on November 3, 2003 (ORAUT 2003), which was followed by four revisions and four page-change (PC) revisions, with the issuance of Rev. 05 on December 20, 2012 (ORAUT 2012b). While some changes in each of the 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, the National Institute for Occupational Safety and Health (NIOSH) only considered those revisions that had the potential to increase the dose/probability of causation (POC) of **previously** completed claims, as summarized below:

- Revision 01 (ORAUT 2004a) 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 01 PC-1 (ORAUT 2004b) added the **bone cancer model** as a possible option to ICD-9 Code 238.7 [lymphoproliferative disease, not otherwise specified (NOS)].

- Revision 01 PC-2 (ORAUT 2004c) changed the designated **internal** organ for codes 231.8, 235.8, and 235.9 from **lung** to **"medical review."**[1]

- Revision 01 PC-3 (ORAUT 2004d) introduced two changes, both of which resulted in a decrease in dose and are, therefore, **not** impacted by DCAS-PER-043.

- Revision 02 (ORAUT 2005) 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 02 PC-1 (ORAUT 2006) updated Table 3-1 to reflect guidance in OCAS-TIB-012, Rev. 1 (OCAS 2006) (internal and external organs for ICD-9 series 200 through 204 changed from "Reserved" to the specified organ).

[1] Due to the complexity of determining the appropriate internal organ for some ICD-9 Code cancers, a medical review/recommendation by an Oak Ridge Associated Universities Team (ORAUT) physician is required for determination of internal organ.

- Revision 03 (ORAUT 2010) 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 04 (ORAUT 2011) 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 05 (ORAUT 2012b) added ICD-9 Code 204.1 [chronic lymphocytic leukemia (CLL)] that is briefly described in **ORAUT-OTIB-0082** (ORAUT 2012a) and in greater detail in Apostoaei and Trabalka (2012).

On August 18, 2014, SC&A submitted to the Procedures Review Subcommittee (PRSC) our review of NIOSH's program evaluation report (PER), DCAS-PER-043 (SC&A 2014). In conducting a PER review, SC&A is committed to perform five subtasks, as specified below:

Subtask 1: Assess NIOSH's evaluation/characterization of the "issue" and its potential impacts on dose reconstruction (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. 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 DR audits under Subtask 4, along with our review conclusions.

SC&A's review of DCAS-PER-043 identified no findings. Specifically, our review found that (1) NIOSH's selection criteria in the PER properly identified the population of claims requiring re-examination, and (2) SC&A agrees with the NIOSH corrective action approach taken in the PER.

This report fulfills the requirement defined in Subtask 4, "Conduct audits of DRs affected by the PER under review." In summary, changes introduced in ORAUT-OTIB-0005 affected a total of 36 previously completed claims, which NIOSH re-evaluated. Of these, 2 claims resulted in a revised POC greater than 50%; the remaining claims resulted in revised POCs of less than 45% and represent the pool of claims from which a **subset** of DRs is selected for audit by SC&A.

From a pool of 34 DRs subject to audit, SC&A recommended the selection of one claim from each of the following revisions and/or ICD-9 Codes:

- Revision 02: 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 POCs of <50%.**

- Revision 03: ICD-9 Code 155.1. This changed 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 04:
  - ICD-9 Code 232 – added basal cell carcinoma to the considered cancer models for code 232 when cell type was not specified. **Select one claim from 16 reworked claims with POCs of <50%.**

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

The PRSC agreed with our recommendation for case selection and NIOSH forwarded to SC&A the list of 36 claims cited for re-evaluation in DCAS-PER-043 (see Exhibit 1). From this list, SC&A **randomly** selected the following three claims, one from each category: [**Case B**]; [**Case C**], and [**Case D**].

For the selection of the fourth case, there was but one claim involving ICD-9 Code 238. Exhibit 1 identifies this claim as [**Case A**].

As with all PER audits, SC&A's review of re-evaluated claims under Task 4 is a focused review that is limited to corrective actions specified in DCAS-PER-043 in the reconstruction of dose.

It should also be noted that, for 34 of the 36 cases impacted by revisions to ORAUT-OTIB-0005, NIOSH simply performed an internal evaluation of the cases, which was documented in a one-page MS Word file, and determined that the original dose reconstructions would result in a POC

<50%. Therefore, for these 34 claims, no formal DR reworks were performed and no revised DRs were submitted to the U.S. Department of Labor (DOL).

Presented in Sections 2.0 through 5.0 of this report is SC&A's focused review to determine whether the applicable external doses and the internal doses associated with the four selected cases were re-evaluated by NIOSH in accordance with DCAS-PER-043.

Exhibit 1: List of Claims Reassessed by NIOSH under DCAS-PER-043

CODE	Claim ID	
150	[Redacted]	
150	[Redacted]	originally ran as stomach; no rework necessary
150	[Redacted]	
150	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
155.1	[Redacted]	
232	[Redacted]	
232	[Redacted]	
232	[Redacted]	org ran as BCC
232	[Redacted]	
232	[Redacted]	
232	[Redacted]	
232	[Redacted]	
232	[Redacted]	
232	[Redacted]	
232	[Redacted]	
232	[Redacted]	
232	[Redacted]	
232	[Redacted]	org ran as BCC
232	[Redacted]	org ran as BCC
232	[Redacted]	
232	[Redacted]	
232	[Redacted]	
238	[Redacted]	

2.0 REVIEW OF DCAS-PER-043 ISSUES FOR [CASE A]

2.1 RELEVANT BACKGROUND INFORMATION

[Case A] represents an energy employee (EE) who worked at [redacted] from [redacted] through [redacted]. The EE was diagnosed with a **neuroendocrine carcinoma (Merkel cell cancer) of the chest wall in** [redacted] (ICD-9 Code 209.35). It appears that an initial DR was conducted for the EE that was confined to the cancer with ICD-9 Code 209.35 diagnosed in 2010.

Subsequently, this DR was revised and issued by NIOSH on April 22, 2011, in order to include the "second cancer" diagnosed on [redacted]. The "second cancer" was identified in the revised DR as **anaplastic neuroendocrine carcinoma, metastatic to bone** with the assigned ICD-9 Code of **238.0**.

Owing to Rev. 04 of ORAUT-OTIB-0005 (ORAUT 2011) and the issuance of DCAS-PER-043, which changed the internal target organ for Code 238 from "medical review" to bone surface, **[**Case A**]** met the criteria stated in PER-043 for a re-evaluation of dose and POC. Table 2-1 identifies (1) organ doses assigned in the first DR revision (issued on April 22, 2011) for each of the two cancers, and (2) revised organ doses that addressed applicable changes to DR specified in DCAS-PER-043.

Table 2-1. Assigned Organ Doses to Claim [Case A] in Current DR Report Issued April 22, 2011, and PER-043 Revised Organ Doses

Dose Categories		External (rem)	Medical X-Ray (rem)	Internal (rem)	Total (rem)
Neuroendocrine Carcinoma of the chest wall (ICD-9 Code 209.35)	Current DR	1.217	1.901	1.833	**4.951**
	PER Dose	1.074	0.595	0.132	**1.801**
Anaplastic Neuroendocrine Carcinoma, Metastatic to Bone (ICD-9 Code 238.0)	Current DR	0.921	0.540	1.918	**3.379**
	PER Dose	1.095	0.831	17.991	**19.917**

Inspection of Table 2-1 shows that doses to the neuroendocrine carcinoma of the chest wall (ICD-9 Code 209.35) decreased from 4.941 rem to 1.801 rem. However, these changes were **not** impacted by PER-043. For the anaplastic neuroendocrine carcinoma metastatic to bone (ICD-9 Code 238.0), revisions under PER-043 increased the dose from 3.379 rem to 19.917 rem. When combined, PER-043 revised organ doses raised the POC from 8.18% to 35.23%

2.2 SC&A'S COMMENTS/FINDINGS

SC&A reviewed the revised PER dose estimates for the second cancer with the ICD-9 Code 238.0 and concluded the following:

(1) Had the second cancer (with ICD-9 Code 238) been identified as a **primary** cancer, the revised PER-043 dose estimates would have been appropriate.

(2) However, the EE's second cancer should have never been assigned the ICD-9 Code 238.0, as explained below.

Enclosed as Exhibit 2 is the first page of a fact sheet prepared by the National Cancer Institute (NCI) that identifies the etiology and defining features of a metastatic cancer. As cited in Exhibit 2, most notably is the fact that:

> *. . . metastatic cancer has the same name and the same type of cancer cells as the original, or primary cancer. For example, breast cancer that spreads to the lung and forms a* ***metastatic*** *tumor is a* ***metastatic*** *breast cancer,* ***not*** *lung cancer.* [Emphasis added.]

Thus, the assignment of **two different** ICD-9 Codes for the EE's two cancers (of which the **second cancer** was identified as, Anaplastic neuroendocrine carcinoma, **metastatic** to the **bone**) contradicts the very nature of a metastatic cancer. As stated in the NCI Fact Sheet, the EE's "second/metastatic" cancer should have been assigned the ICD-9 Code of the primary cancer (or Code 209.35).

In order to assess the circumstances under which this error occurred, SC&A reviewed records in the EE's file and constructed the following timeline. (Note: Due to confidential and/or privileged information, some of the records will only be cited as a reference herein):

(1) Some time prior to April 4, 2011, [**Case A**] had been returned by OCAS to DOL due to an additional cancer with ICD-9 Code 238.0, which requires a **medical review**.

(2) On April 4, 2011, an email was submitted by DOL that acknowledged the need for a "medical review" regarding the EE's additional cancer. Distribution included Dr. Ronald E. Goans, PhD, MD, MPH, Senior Medical Consultant, as well as DOL and ORAUT staff members.

(3) On April 6, 2011, Dr. Goans forwarded his "medical review" (see Exhibit 3) of the EE's additional cancer with ICD-9 Code 238.0, along with the following conclusions:

> *In my professional opinion, the anaplastic neuroendocrine tumor metastatic to the bone is a secondary metastatic tumor, undifferentiated from the primary Merkel cell tumor of the chest wall. I think the ICD code of the primary appears to be correct and I have not tried to change the ICD code for the metastatic tumor. I will be happy to do so if you choose, but I generally do not change ICD codes on my own.*

(4) On April 7, 2011, a "note to reviewers" (Exhibit 4) was forwarded that acknowledged the "metastatic" nature of the secondary cancer and the fact that the ". . . internal organ applied to the **bone cancer** was the **same** as that applied to the Merkel call [sic] cancer (skin)." [Emphasis added.]

(5) In spite of the medical review, which emphatically identified the second cancer as a **metastatic** cancer, the first revision to the EE's Dose Reconstruction Report issued on **April 22, 2011**, correctly identifies the EE's additional cancer as ". . . Anaplastic neuroendocrine, carcinoma, **metastatic** to bone," but Dr. Goans' recommendation to change the ICD-9 Code of 238.0 of the second cancer to the ICD-9 Code 209.35 of the primary cancer was ignored.

In summary, based on conclusions stated in the medical review (see Exhibit 3), which identified the EE's "additional" cancer as a **metastatic** cancer derived from the EE's primary cancer (i.e., Merkel cell tumor of the chest wall), SC&A identified the following two findings:

Finding #1: Failure to revise the ICD-9 Code 238.0 to that of the primary cancer, Code 209.35. Had the ICD-9 code for the "metastatic" cancer been changed to 209.35, [**Case A**] would **not** have required re-evaluation under the stated criteria of DCAS-PER-043.

Finding #2. As a **metastatic** cancer for which the primary cancer (i.e., Merkel cell tumor of the chest wall) was identified, there was neither a need to assess the dose to the metastatic cancer (since it is essentially identical to that of the primary cancer), nor include such a dose for the calculation of the POC.

Exhibit 2: Metastatic Cancer Fact Sheet (Page 1) – National Cancer Institute

Metastatic Cancer

Key Points

- Metastatic cancer is cancer that has spread from the place where it first started to another place in the body.
- ***Metastatic cancer has the same name and same type of cancer cells as the original cancer.***
- ***The most common sites of cancer metastasis are, in alphabetical order, the bone, liver, and lung***.

1. What is metastatic cancer?

Metastatic cancer is cancer that has spread from the place where it first started to another place in the body. A tumor formed by metastatic cancer cells is called a metastatic tumor or a metastasis. The process by which cancer cells spread to other parts of the body is also called metastasis.

Metastatic cancer has the same name and the same type of cancer cells as the original, or primary, cancer. For example, breast cancer that spreads to the lung and forms a metastatic tumor is metastatic breast cancer, not lung cancer.

Under a microscope, metastatic cancer cells generally look the same as cells of the original cancer. Moreover, metastatic cancer cells and cells of the original cancer usually have some molecular features in common, such as the expression of certain proteins or the presence of specific chromosome changes.

Although some types of metastatic cancer can be cured with current treatments, most cannot. Nevertheless, treatments are available for all patients with metastatic cancer. In general, the primary goal of these treatments is to control the growth of the cancer or to relieve symptoms caused by it. In some cases, metastatic cancer treatments may help prolong life. However, most people who die of cancer die of metastatic disease.

2. Can any type of cancer form a metastatic tumor?

Virtually all cancers, including cancers of the blood and the lymphatic system (leukemia, multiple myeloma, and lymphoma), can form metastatic tumors. Although rare, the metastasis of blood and lymphatic system cancers to the lung, heart, central nervous system, and other tissues has been reported.

Exhibit 3: Memo from Ronald E. Goans RE: NIOSH [Case A]

From: Ronald E. Goans
Sent: Wednesday, April 06, 2011 9:21 PM
To: Karlene K. Dysland
Cc: DRAssignments; Steven R. Reed; Susan L. Winslow; Jodie Phillips; Ronald E. Goans
Subject: RE: NIOSH [Case A]

Hi Karlene and all,

I have reviewed claim [Case A] and supporting documents. In NOCTS we have the following notations:

Primary	Neuroendocrine carcinoma of the chest well - Merkel cell tumor 2/19/2010 209.35
Primary (Secondary)	Anaplastic neuroendocrine carcinoma to bone - Metastatic to bone 3/22/2011; (238.0)

In my professional opinion, the anaplastic neuroendocrine tumor metastatic to bone is a secondary metastatic tumor, undifferentiated from the primary Merkel cell tumor of the chest wall. I think the ICD code for the primary appears to be correct and I have not tried to change the ICD code for the metastatic tumor. I will be happy to do so if you choose, but I generally do not change ICD codes on my own.

Best regards,
Ron Goans

Ronald E Goans PhD, MD, MPH
Senior Medical Consultant, MJW Corporation
[Redacted]

Exhibit 4: Note to Reviewers

Note to reviewers,

Based on the email from Dr. Goans stating "the anaplastic neuroendocrine tumor metastatic to bone is a secondary metastatic tumor, undifferentiated from the primary Merkel cell tumor of the chest wall" – the internal organ applied to the bone cancer was the same as that applied to the merkel call cancer (skin).

Jodie Phillips
04/07/2011

3.0 REVIEW OF DCAS-PER-043 ISSUES FOR [CASE B]

3.1 RELEVANT BACKGROUND INFORMATION

[**Case B**] represents an EE who worked at the [**redacted**] as a [**redacted**] for two time periods: [**redacted**] to [**redacted**]; and [**redacted**] to [**redacted**]. On [**redacted**], the EE was diagnosed with adenocarcinoma of the distal esophagus with the assigned ICD-9 Code 150.5.

NIOSH completed a DR for [**Case B**] on September 30, 2004. In the original DR, the doses to the distal **esophageal** tissue from external, medical, and internal exposures were estimated. Under Rev. 02 of ORAUT-OTIB-0005 (ORAUT 2005), NIOSH recalculated a dose of 3.874 rem using the stomach as the internal and external organ. Exhibit 5 shows NIOSH's one-page DR reassessment form, which offers a comparison of the original (identified as "current dose") and the reassessed doses that reflect DCAS-PER-043.

Inspection of Exhibit 5 shows that when the "stomach" is considered as the default internal/ external organ and IREP model, the internal dose significantly increased. This increase, however, was offset by a nearly identical reduction of external and medical exposures, resulting in a POC value that decreased from 12.96% to 11.73%.

3.2 SC&A'S COMMENTS AND FINDINGS

SC&A reviewed and compared derived external and internal dose estimates to the **esophagus** in the current DR to reassessed external and internal dose estimates to the **stomach** as an optional choice under DCAS-PER-043. In addition to the change in target organ from esophagus to stomach, there were several other changes that affected dose estimates, as stated in Exhibit 5.

For external dose, most notable among these changes was the elimination of previously "assumed" external exposures to <30 keV photons from plutonium. This revision reduced external dose from 2.941 rem to 1.740 rem. For internal exposure, the DCAS-PER-043 revised dose estimate was based on ORAUT-OTIB-0018, which likely overestimated the dose.

SC&A concludes that the revised DR for [**Case B**] complies with DCAS-PER-043 and other applicable guidance. There are no findings.

Exhibit 5: NIOSH's Reassessment Report for [Case B]

Claim [Case B]

Total assigned dose

Dose Categories	Current Dose (rem)	PER Dose (rem)
External	2.941	1.740
Medical X-ray	0.496	0.382
Internal	0.348	1.662
Total	**3.785**	**3.784**

PoC

Previous PoC (%)	Revised PoC (%)
12.96	11.73

External Dose Assigned:

1. Current DR uses esophagus as the external organ of interest. The PER DR uses the stomach as the organ of interest.
2. [redacted] workbook reproduced and labeled "[Case B]_ [redacted]_External Dosimetry Data". Current site specific TBD utilized.
3. Current DR applied dose from <30 keV to account for exposure to plutonium. PER DR assigns all dose as 30-250 keV, EE worked in lab, not in plutonium area.

X-Ray Dose Assigned:

1. X-ray dose applied from site specific TBD using stomach as organ of interest.

Internal Dose Assigned:

1. Current DR uses the esophagus as the internal organ of interest. The PER uses the stomach as the organ of interest for all IMBA runs.
2. Environmental internal dose calculated using CADW.
3. OTIB-0018 also applied to ensure an overestimate of internal dose.

4.0 REVIEW OF DCAS-PER-043 ISSUES FOR [CASE C]

4.1 RELEVANT BACKGROUND INFORMATION

[**Case C**] represents an EE who worked at the [**redacted**] from [**redacted**] through [**redacted**], as a [**redacted**]. The EE was diagnosed with a cholangiocarcinoma (bile duct) cancer (ICD Code 155.1) on [**redacted**].

NIOSH completed a DR for [**Case C**] on September 26, 2006, which was based on the assumption that (1) the external dose to the bile ducts was best determined by using the dose calculated for the bladder, and (2) the internal dose to the bile ducts was best determined by using the dose calculated for the **gallbladder**, as specified in Rev. 02 PC-1 of ORAUT-OTIB-0005 (ORAUT 2006).

With Rev. 03 of ORAUT-OTIB-0005 issued on February 26, 2010, the following changes were made to the organs used for Code 155.1: (1) the external organ was changed from bladder to liver, and (2) the internal organ was changed from gallbladder to liver/gallbladder, along with the following footnote *h*:

> *For ICD-9 code 155.1, for cancers that described as cancer of the **intrahepatic** ducts, select **liver** as the internal organ. For those that are described as **gallbladder carcinoma**, select **gallbladder** as the internal organ. If the description is **unclear**, a **medical review** should be conducted to determine the appropriate internal organ of interest.* [Emphasis added.]

Using the most current Rev. 05 of ORAUT-OTIB-0005 (ORAUT 2012b), NIOSH revised the original dose of 3.607 rem to 8.714 rem, which exclusively reflects the increase in **internal** dose from 0.309 rem to 5.417 rem, as shown in Exhibit 6. Exhibit 6 identifies that this increase in internal dose was the result of using the **liver** as the internal organ of interest instead of the **gallbladder**.

Exhibit 6: NIOSH's Reassessment Report for [Case C]

Claim [Case C]

Total assigned dose

Dose Categories	Current Dose (rem)	PER Dose (rem)
External	3.257	3.257
Medical X-ray	0.041	0.041
Internal	0.309	5.417
Total	**3.607**	**8.714**

PoC

Current PoC (%)	PER PoC (%)
16.67	24.84

External Dose Assigned:

4. Current DR uses bladder as organ of interest. PER DR uses liver as organ of interest. Did not change assigned dose because a DCF of 1 for each energy range was assigned (claimant-favorable).
5. There were no revisions to TBD since the completion of the current DR.

X-rays

1. There were no revisions to TBD since the completion of the current DR.

Internal Dose Assigned:

1. Current DR uses gallbladder as organ of interest. PER DR uses liver as organ of interest resulting in an increase in the assigned dose.
2. There were no revisions to TBD since the completion of the current DR.

4.2 SC&A'S COMMENTS AND FINDINGS

The "current" DR completed on September 26, 2006, identified the cancer for [**Case C**] as "**cholangiocarcinoma (Bile Ducts)** with the assigned ICD-9 Code 155.1. For the reassessed DCAS-PER-043 dose, NIOSH retained the earlier designation of "**cholangiocarcinoma**."

Given this description of the EE's primary cancer, footnote *h* of ORAUT-OTIB-0005, Rev. 05 states that ". . . If the description is unclear, a medical review should be conducted to determine the **appropriate internal** organ of interest." [Emphasis added.]

SC&A reviewed records in behalf of [**Case C**] and was unable to determine if a **medical review** had been requested in order to determine the appropriate internal organ.

The American Cancer Society (ACS 2014) identifies the fact that, for bile duct cancer (cholangiocarcioma), there are **three** general locations where cholangiocarcinoma arises in the bile drainage system (see Exhibit 7):

- within the liver (**intrahepatic**)
- just outside the liver (**extrahepatic**) also called perihilar located at the notch of the liver, where the bile ducts exit
- far outside the liver (**distal extrahepatic**) near where the bile ducts enter the intestine.

In the absence of a more definitive description of the EE's primary cancer [described only as cholangiocarcinoma (bile ducts)], and the absence of a medical review (as specified in footnote *h* of ORAUT-OTIB-0005, Rev. 05), it remains uncertain whether the EE's cancer was an **intrahepatic** or **extrahepatic** bile duct cancer. Thus, the selection of the **liver** as the internal organ for the revised DR is unsupported (in the absence of a medical review) and may not be correct.

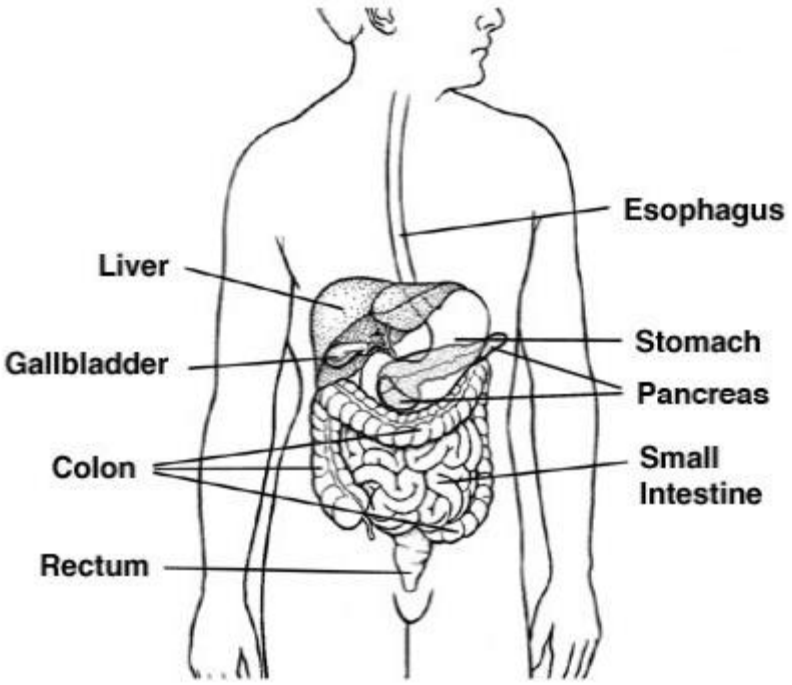
Finding #3. In the absence of a medical review that would specify the bile duct cancer as extrahepatic, NIOSH's selection of the liver as the appropriate internal organ is inappropriate and would obviate the need for [**Case C**] to be re-evaluated.

Exhibit 7: Bile Duct Cancer Description from American Cancer Society

What is bile duct cancer?

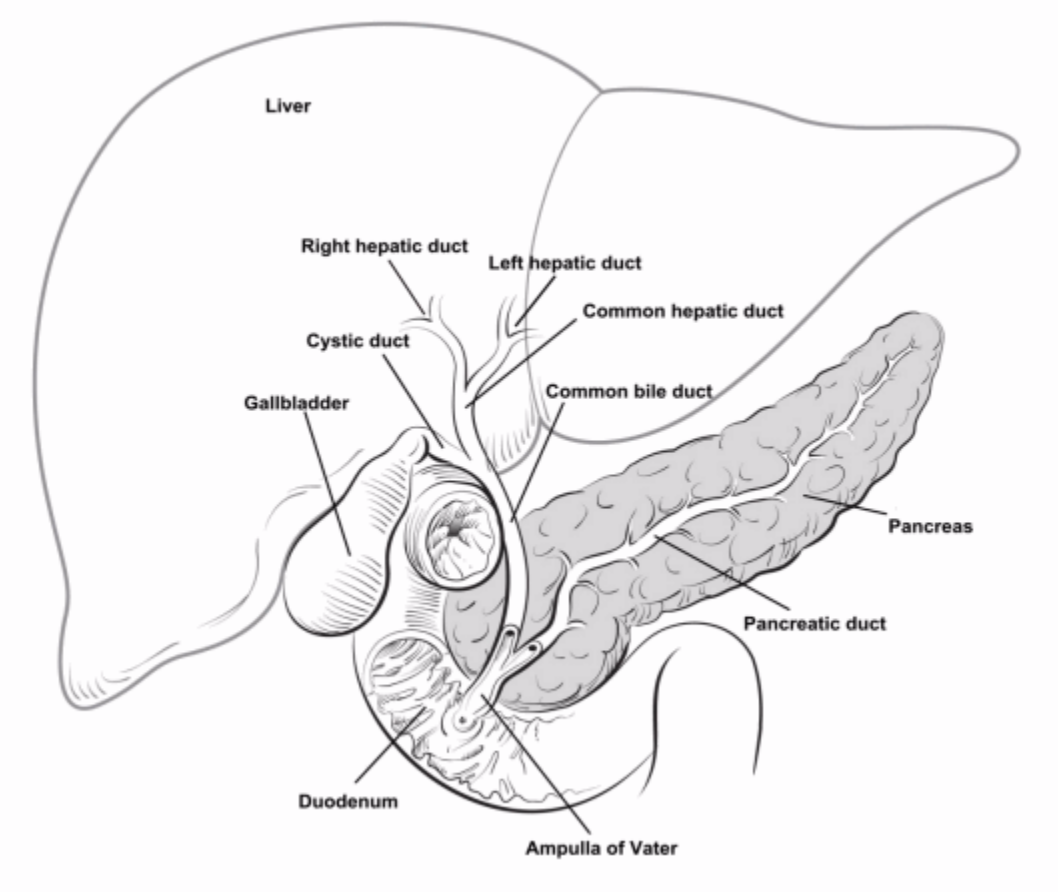
Bile duct cancer starts in a bile duct. To understand this cancer, it helps to know about the normal bile ducts and what they do.

About the bile ducts



The bile ducts are a series of thin tubes that reach from the liver to the small intestine. The major function of the bile ducts is to move a fluid called *bile* from the liver and gallbladder to the small intestine, where it helps digest the fats in food.

Exhibit 7: Bile Duct Cancer Description from American Cancer Society (continued)



Different parts of the bile duct system have different names. In the liver it begins as many tiny tubes (called *ductules*) where bile collects from the liver cells. The ductules come together to form small *ducts*, which then merge into larger ducts and eventually the left and right hepatic ducts. All of these ducts within the liver are called *intrahepatic bile ducts*.

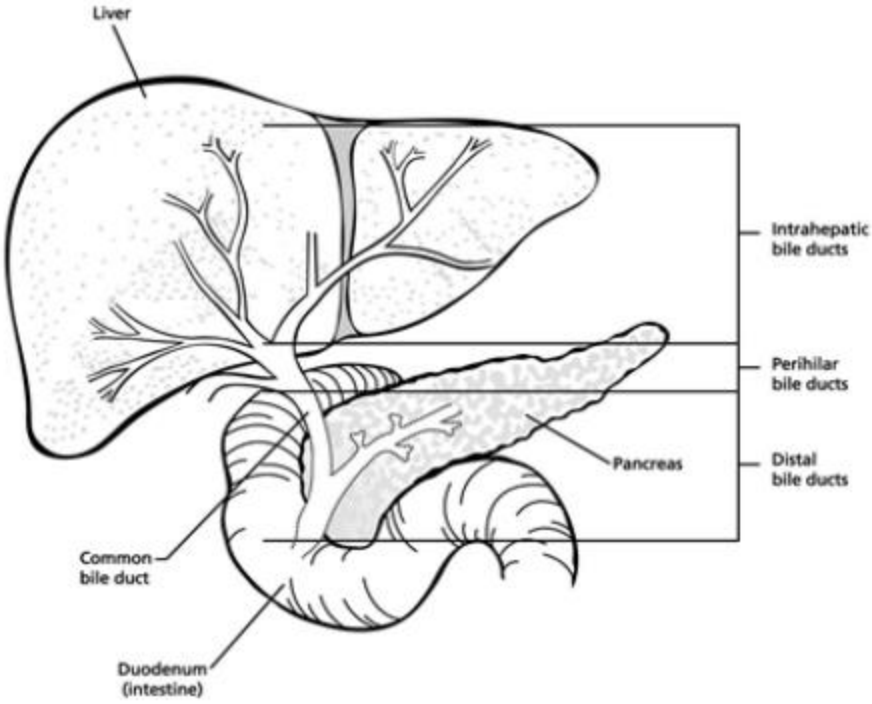
The left and right hepatic ducts exit from the liver and join to form the common hepatic duct in an area called the *hilum*. Lower down, the gallbladder (a small organ that stores bile) joins the common hepatic duct through a small duct called the *cystic duct*. The combined duct is called the *common bile duct*. The common bile duct passes through part of the pancreas before it joins with the pancreatic duct and empties into the first part of the small intestine (the *duodenum*) at the ampulla of Vater.

Exhibit 7: Bile Duct Cancer Description from American Cancer Society (continued)

Types of bile duct cancers by location

Cancers can develop in any part of the bile duct system and, based on their location (see picture below), are classified into 3 types:

- ***Intrahepatic bile duct cancers***
- ***Perihilar (also called hilar) bile duct cancers***
- ***Distal bile duct cancers***



Cancers in these different areas can cause different symptoms.

Intrahepatic bile duct cancers

These cancers develop in the smaller bile duct branches inside the liver. They can sometimes be confused with cancers that start in the liver cells, which are called *hepatocellular carcinomas*, and are often treated the same way. Only about 1 in 10 bile duct cancers are intrahepatic.

Exhibit 7: Bile Duct Cancer Description from American Cancer Society (continued)

Perihilar (also called *hilar*) bile duct cancers

These cancers develop at the hilum, where the left and right hepatic ducts have joined and are just leaving the liver. These are also called *Klatskin tumors*. They are the most common type of bile duct cancer, accounting for more than half of all bile duct cancers. These cancers are grouped with distal bile duct cancers as *extrahepatic bile duct cancers.*

Distal bile duct cancers

These cancers are found further down the bile duct, closer to the small intestine. Like perihilar cancers, these are extrahepatic bile duct cancers because they start outside of the liver. Distal bile duct cancers make up 2 to 3 of every 10 bile duct cancers.

Types of bile duct cancer by cell type

Bile duct cancers can also be divided into types based on how the cancer cells look under the microscope.

Nearly all bile duct cancers are called *cholangiocarcinomas*. Most of these are adenocarcinomas, which are cancers that start in glandular cells. Bile duct adenocarcinomas develop from the mucous gland cells that line the inside of the duct.

Other types of bile duct cancers are much less common. These include sarcomas, lymphomas, and small cell cancers. This document does not discuss these other types of bile duct cancer.

The rest of this document refers only to cholangiocarcinomas.

Benign bile duct tumors

Not all bile duct tumors are cancerous. Bile duct hamartomas and bile duct adenomas are examples of benign (non-cancerous) tumors, which aren't discussed further in this document.

Last Medical Review: 11/01/2014
Last Revised: 11/01/2014

5.0 REVIEW OF DCAS-PER-043 ISSUES FOR [CASE D]

5.1 RELEVANT BACKGROUND INFORMATION

[**Case D**] represents an EE who worked as a [**redacted**] at [**redacted**] from [**redacted**] through [**redacted**], and again from [**redacted**] through [**redacted**]. On [**redacted**], the EE was broadly diagnosed with "**skin" cancer** on the left hand.

On February 21, 2008, NIOSH completed its first DR that estimated a dose of 16.21 rem to the affected skin cancer, which was identified with the **ICD-9 Code 232.6**.

In Rev. 04 of ORAUT-OTIB-0005 (ORAUT 2011), the cancer model for Code 232 changed. Previously, both **malignant melanoma** and **non-melanoma squamous cell carcinoma** were to be assessed and the dose reconstructor was to select the one that produced the highest POC value. Revision 04 added **basal cell carcinoma** as a third option.

In the **original** DR (i.e., prior to Rev. 04 of OTIB-0005), NIOSH had selected malignant melanoma as its choice of the cancer model. Under Rev. 4 of OTIB-0005 (ORAUT 2011) and PER-043, NIOSH reassessed the POC using the original estimate of skin dose (i.e., 16.21 rem), but selected the non-melanoma skin-basal cell cancer IREP model.

This "change" in **IREP model** from **malignant melanoma** to **non-melanoma skin basal cell** caused the POC to go from 25.04% down to 24.40%.

5.2 SC&A'S COMMENTS AND FINDINGS

In behalf of ICD-9 Code 232, footnote *e* states the following:

> *. . . if the type of cancer is specified by DOL ("Malignant melanoma, Non-melanoma skin-Squamous cell, or Non-melanoma skin-Basal cell") use only the specified IREP model (note that Bowen's disease is another name for squamous cell carcinoma in situ). If the cancer is not specified, run all listed IREP models as discussed in Section 4.6.*

And Section 4.6 of ORAUT-OTIB-0005 (ORAUT 2011) states:

> *For multiple IREP models that are connected by the word "AND", separate IREP runs should be made for each listed model, and compensability is determined based on the model that results in the **highest** POC, which is favorable to the claimant. . . .* [Emphasis added.]

In order to determine whether all **three** IREP models had been considered as required by footnote *e* for selection of the highest POC value, SC&A reviewed the original DR (which had selected malignant melanoma). However, SC&A was unable to determine if the **non-melanoma skin squamous cell** model had been considered and eliminated as the IREP model yielding the

highest POC. For this reason, SC&A independently assessed the non-melanoma skin squamous cell IREP model, which yielded the lowest POC value.

SC&A concurs with NIOSH that, for [**Case D**], the IREP model **malignant melanoma** yields the highest POC value. Thus, there are no findings associated with [**Case D**].

6.0 SUMMARY CONCLUSIONS

Under SC&A's *A Protocol to Review NIOSH's Program Evaluation Reports (PERs)*, SCA-TR-PR2009-0002, Rev. 1 (SC&A 2009), Subtask 4 requires the audit of DR cases reworked as a result of the PER under review. After SC&A's review of DCAS-PER-043, *Internal Dosimetry Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code Revision*, it was determined by the PRSC that SC&A be tasked with reviewing four reworked claims. Selected for review were four cases representing discrete revisions to ORAUT-OTIB-0005 and select ICD-9 Codes, as described in Section 1.0 of this report.

SC&A's review of the four cases identified the following:

- [**Case A**] – Two findings were identified that reflect the assignment of an incorrect ICD-9 Code to a metastatic cancer that (1) triggered an independent dose estimate to the metastatic cancer, and (2) necessitated the re-evaluation of the case under DCAS-PER-043 criteria.

- [**Case B**] – SC&A concurs with NIOSH's re-evaluation, and there are no findings.

- [**Case C**] – SC&A identified one finding, which involved NIOSH's selection of the internal organ that required a **medical review**.

- [**Case D**] – SC&A concurs with NIOSH's re-evaluation, and there are no findings.

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