#### DRAFT

# **OCAS-PER-009, SUBTASK 4**

# REVIEW OF THREE CASES REWORKED FOR THE EVALUATION OF LYMPHOMAS AFFECTED BY CHANGES TO INTERNAL AND/OR EXTERNAL TARGET ORGANS

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# 1.0 RELEVANT BACKGROUND INFORMATION

During the full Board conference call held on November 27, 2007, SC&A was directed to perform a review of Program Evaluation Report (PER) OCAS-PER-009. The purpose of a PER is to establish a formal process for evaluating the effects of new information on previously adjudicated claims that have been denied.

As a result of ongoing internal reviews, it became apparent to NIOSH that the methods being used to reconstruct the doses to workers that contracted lymphoreticular neoplasms (cancer of the lymph nodes) required revision; revisions that could result in very large increases in the derived doses to the organs of concern and the possible reversal of previously denied claims.

NIOSH's standard procedure for deriving doses to lymph nodes had been based on the assumption that an upper bound on the doses to the lymph node could be derived by using the colon (or the highest non-metabolic organ) as a surrogate organ.

The issuance of OCAS-TIB-012 changes the internal target organ for most forms of non-Hodgkin's lymphoma and some other forms of lymphoma (primarily in the 200–202 ICD-9 series) from the highest non-metabolic organ (HNMO) or remainder to the thoracic lymph nodes (LN(TH)) or extrathoracic lymph node (LN(ET)). The calculated internal doses in these cases are almost invariably higher, resulting in a higher probability of causation (POC).

In addition, the external target organ was changed from bone marrow to various other organs (stomach, spleen, thyroid, lung, bladder, etc.), for most forms of lymphoma, as described in OCAS-TIB-012. Because the organ-specific dose conversion factors (DCFs) are lower for red bone marrow than for most other organs, this change also results in an increase in organ dose and the resulting POC.

In order to correct this problem, NIOSH implemented OCAS-PER-009, which establishes a new protocol for reconstructing the doses to the organ of concern for workers with cancer of the lymph nodes. NIOSH used this new methodology to reconstruct the doses to all workers whose reconstructed doses could be impacted by this new procedure and whose claims were previously denied. The outcome of this process was the re-evaluation of 528 claims. Of these, 152 previously denied claims were now granted compensation, 23 claims were returned to NIOSH for rework, and 348 claims remained denied.

The Advisory Board requested that SC&A review the entire process under which the 528 lymphoma claims were reviewed. Our review process was divided into the following five subtasks. This report fulfills the requirement defined in Subtask 4, "Conduct audits of DRs affected by the PER under review.

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.

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- 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, 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, based on important elements such as (1) the number of target organs/tissues that may be impacted by a PER, (2) the method/data that were employed in the original DR, and (3) the time period, work location, and job function(s) that characterize the DR of a claim. (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.

In summary, OCAS-PER-009 has the potential to change (1) the internal exposure from HNMO to either LN(TH) or LN(ET) and/or (2) the external exposure from bone marrow to various other organs (e.g., stomach, spleen, thyroid, lung, bladder, etc.). For many types of lymphomas, both the **internal** and **external** target organ changed, while for a minority of cases, only the external target organ changed. Thus, for selecting a minimum number of cases for audit, SC&A requested two cases (representing lymph nodes LN(TH) and LN(ET) along with change in the external target organ). Alternatively, a total of four cases would be required in the event that both the LN(TH) and LN(ET) lymphomas retained the original external target organ.

On December 4, 2013, NIOSH identified and forwarded three cases to SC&A for review/audit. Table 1-1 summarizes changes introduced in the revised dose reconstructions of lymphomas that reflect the selection of internal/external target organs and their impacts on their respective POC values.

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# Table 1-1. Changes and Impacts Associated with OCAS-PER-009 onThree Lymphoma Cases

	<b>Revision of Target Organs</b>		Revision of POC
Case No. / Lymphoma Type	Internal	External	From $\rightarrow$ To
	$From \rightarrow To$	$From \rightarrow To$	$r_{10} \rightarrow 10$
#[A-redacted]/ B-Cell lymphoma	Heart wall $\rightarrow$ LN(TH)	DCF of $1 \rightarrow DCF$ of $1$	$19.57 \% \rightarrow 33.984\%$
#[B-redacted]/ Lymphosarcoma	Heart wall $\rightarrow$ LN(TH)	Remainder organs $\rightarrow NA^*$	$37.51\% \rightarrow 94.87\%$
#[C-redacted]/ Hodgkin's Lymphoma	Heart wall $\rightarrow$ LN(ET)	Thyroid $\rightarrow NA^*$	$2.17\% \rightarrow 68.32\%$

\* Revised DR reflects a partial dose reconstruction that was limited to internal occupational exposure to the lymph node.

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# 2.0 REVIEW OF OCAS-PER-009 ISSUES FOR CASE #[A-REDACTED]

## 2.1 BACKGROUND INFORMATION FOR CASE #[A-REDACTED]

Case #[**A-redacted**] represents an energy employee (EE) who worked as a [**redacted**] intermittently at the Hanford Site from [**redacted**] through [**redacted**], and [**redacted**] through [**redacted**].

In the initial dose reconstruction (DR) approved on March 8, 2005, the EE was diagnosed with **two primary cancers**:

- (1) B-cell Lymphoma Intermediate Grade Large Cell in left neck (ICD-9 code 202.81) on [redacted]
- (2) B-cell Lymphoma Intermediate Grade Large Cell in right tonsil (ICD-9 code 202.81) on [redacted]

Less than 7 months **after** the first DR Report had been issued on March 8, 2005, the EE was diagnosed with a malignant neoplasm of the **bladder** on [redacted].

A revised DR Report for the EE that addressed changes in DR identified in OCAS-PER-009 was issued on October 1, 2007. The revised DR also derived doses for the bladder cancer that had not been diagnosed at the time of the original DR. Lastly, the Department of Labor (DOL) identified the following revised cancers to NIOSH for DR:

- (1) Malignant neoplasm, bladder (ICD-9 code 188.2)
- (2) Lymphoma, lymph node, right tonsil, left neck (ICD-9 code 202.01)

In summary, for the revised DR, which addressed changes mandated by OCAS-PER-009, the DOL also changed its original position that treated (1) the B-Cell Lymphoma Intermediate Grade Large Cell left neck and (2) the B-cell Lymphoma Intermediate Grade Large Cell, right tonsil, as two separate primary cancers to a **single primary lymphoma**.

Due to DOL's decision to reclassify the two primary lymphomas as a **single primary lymphoma** (which introduced a significant change in the methodology for estimating organ dose and POC), SC&A reviewed DOL files in order to understand the basis for this change. Summarized below is a chronological citation of statements contained in DOL files with the changing ICD-9 codes assigned to the EE's claim file highlighted; redacted copies of these documents that comply with the Privacy Act are provided in Attachments A-1 through Attachment A-6.

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Summary Statements/Data Contained in Attachments

<u>Attachment A-1</u>. <u>*Amended NIOSH Referral Summary Information*</u>, dated October 8, 2002, identifies the following **two primary** cancers and their ICD-9 codes:

(P)rimary or	Cancer	ICD-9 Code	Date of
(S)econdary			Diagnosis
P	B-Cell Lymphoma Intermediate	<mark>146</mark>	[redacted]
	Grade Large Cell, Right Tonsil		
P	B-Cell Lymphoma Intermediate	200.01	[redacted]
_	Grade Large Cell, Left Neck		

This is to correct the ICD 9 code for cancer of the left neck & right tonsil.

Attachment A-2. DOL e-mail correspondence dated December 15 and December 16, 2004:

#### E-mail, December 15, 2004

The NIOSH HP reviewing this claim asked if DOL would review the ICD code for the Tonsil lymphoma. NIOSH currently has **146** as the ICD9. [Emphasis added.]

E-mail, December 16, 2004

... regarding this ICD code, I researched this and discovered the **correct** ICD code should be **202.81** since it is a lymphoma of the head/neck rather than a cancer. [Emphasis added.]

<u>Attachment A-3</u>. <u>*Amended NIOSH Referral Summary Information*</u> dated December 20, 2004, listed the following cancer information for **each primary cancer**:

<b>Primary</b> [X] or Secondary (Metastatic)	[]
Cancer Description/Type	lymphoma of the right tonsil
Associated ICD-9 Code	202.81
Date of Cancer Diagnosis	[redacted]

<b>Primary [X]</b> or Secondary (Metastatic) [	]
Cancer Description/Type	lymphoma of the left neck
Associated ICD-9 Code	202.81
Date of Cancer Diagnosis	[redacted]

<u>Attachment A-4</u>. <u>Notice of Recommended Decision Sheet</u> dated April 11, 2005, included the following statements:

... [the EE] submitted a medical report from [EE's physician] dated [redacted] indicating a diagnosis of large B-cell lymphoma. Also submitted was a pathology report of the right tonsil and left neck dated [redacted], which formed the basis

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for the diagnosis of lymphoma. This medical evidence is sufficient to document the diagnoses of cancer under the EEOICPA.

A copy of the case file and a National Institute for Occupational Safety and Health (NIOSH) Referral Summary was forwarded to NIOSH for dose reconstruction in February of 2002. On 3/21/2005, the Office received the "NIOSH Report of Dose Reconstruction under EEOICPA," dated 3/82005, which provided the estimates of dose to the primary cancer sites of the right tonsil and left neck.

NIOSH estimated annual doses totaling 6.765 rem (roentgen equivalent man) each for the left neck and right tonsil lymphomas. Based on these dose estimates, the calculation of probability of causation was completed using NIOSH-IREP (NIOSH-Interactive RadioEpidemiological Program), which is an interactive software program. The total probability of causation for the two primary cancers was determined to be 19.57 percent. [Emphasis added.]

<u>Attachment A-5</u>. <u>Notice of Recommended Decision</u> dated December 20, 2007, included the following statements regarding the **revised** DR that was prompted by OCAS-PER-009 (and the new cancer of the bladder):

In support of the claim, the District Office received medical evidence which included a surgical pathology report from [redacted], dated [redacted], which diagnosed B cell lymphoma on [redacted]. The District Office also received medical evidence which included a post operative diagnosis from [redacted], dated [redacted], which diagnosed a bladder tumor on [redacted], and a medical report from [redacted] which reported a history of bladder cancer.

On 02/07/2007, the District Office referred the file to the District Medical Consultant for a determination of whether the cancer reported in the neck and tonsil supprted a diagnosis to two primary cancers or only a single primary lymphoma.

On 05/15/2007, the District Office received the report of the District Medical Consultant, who **opined** that "lesions to the tight [sic] tonsil and the the left sided neck mass represent one singular primary cancer, a B cell lymphoma".

In 05/2007 a copy of the case file, along with a National Institute for Occupational Safety and Health (NIOSH) Referral Summary, was forwarded to NIOSH for dose reconstruction for lymphoma and bladder cancer. [Emphasis added.]

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Attachment A-6. Cover Page of Revised DR which Addresses OCAS-PER-009

Concurrent with DOL's decision to reclassify the two primary lymphomas as a singular primary cancer, DOL also assigned yet a **third ICD-9 code of 202.01** to the tonsillar large B-cell lymphoma.

<u>Finding #1: SC&A Questions the Technical Basis/Protocol for the Assignment of and/or</u> <u>Subsequent Change(s) to ICD-9 Codes</u>. SC&A was unable to find any of the EE's medical records, which might offer an explanation for multiple changes in the assignment of ICD-9 codes and, more importantly, the consolidation of two primary lymphomas to one lymphoma.

#### 2.2 COMPARISON OF NIOSH'S ORIGINAL AND REWORKED DRs

NIOSH approved/finalized the **original** DR for Case #[A-redacted] on March 3, 2005. At that time, the EE had only been diagnosed with **two primary lymphomas** (one in the left neck and one in the right tonsil) with each assigned the ICD-9 code 202.81.

On [redacted], the EE was diagnosed with a malignant bladder cancer. On March 8, 2007, OCAS-PER-009 was issued, which determined that the **internal** and **external** dosimetry target organs for various forms of lymphomas had changed.

The revised DR Report for Case #[A-redacted], therefore, included dose estimates for the bladder cancer (which had not been included in the original DR) and reworked dose estimates in accordance with OCAS-PER-009 that were now limited to a **single** primary B-cell lymphoma. Due to the fact that the malignant bladder cancer in the revised DR is not affected by OCAS-PER-009, derived doses to the bladder are **not** included in this audit.

NIOSH indicated in both the **original** and **revised** DRs that the EE's radiation doses were overestimated using claimant-favorable assumptions.

# 2.2.1 Original DR: Summary Assumptions, Methods, and Doses for External and Internal Exposures

<u>External Doses</u>. Estimates assigned to each of the two primary lymphomas for recorded dosimeter doses, missed dose, onsite ambient dose, and occupational medical dose are summarized in Table 2-1 below.

External Source	Dose (rem)		
External Source	Lymphoma Neck	Lymphoma Tonsil	
Dosimeter recorded	5.870	5.870	
Missed Photon	0.040	0.040	
Onsite Ambient	0.637	0.637	
Occupational Medical	0.108	0.108	
Tota	6.655	6.655	

Table 2-1.	<b>External Doses</b>	Assigned in	<b>Original DR f</b>	or Case #[ <mark>A-redacted</mark> ]

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<u>Internal Doses</u>. Internal dose estimates were derived for the **heart wall** as the HNMO for each of the two primary lymphomas from missed plutonium and associated radionuclides, missed fission products, and missed strontium. These doses are summarized in Table 2-2 below.

External Source	Dose (rem)		
External Source	Lymphoma Neck	Lymphoma Tonsil	
Missed Pu and others	0.015	0.015	
Missed Fission Products	0.096	0.096	
Missed Sr	< 0.001	< 0.001	
Total	0.111	0.111	

 Table 2-2. Internal Doses Assigned in Original DR for Case #[A-redacted]

When internal and external doses are combined, the total dose of 6.766 rem was **assigned to** each of the two primary lymphomas, yielding a POC value of 19.57%.

## SC&A Comments/Findings/Observations for Original DR Report

Although SC&A generally agrees with the assigned doses that pre-date the issue date of OCAS-PER-009, as part of the audit, SC&A compared the doses cited in Tables 2-1 and 2-2 against values and statements cited in the text of the DR Report and found the following discrepancies:

(1) As a general assumption, the DR Report states:

... The external dose for the neck and tonsil lymphomas was determined by using the dose calculated for the "remainder organs"... use of the "remainder organs" to calculate the external dose to the neck and tonsil lymphomas is a claimant-favorable assumption. [Emphasis added.]

A review of DCF values in OCAS-IG-001 for photon energies of 30–250 keV identifies values for "remainder organs" that are well below 1.00. In conflict with the above-cited statement, in a subsequent section of the DR Report, the dose reconstructor states:

For the purpose of this dose reconstruction, the distribution of the [EE's] exposure geometry and radiation energies were selected to maximize dose. ... For photon radiation, a 100% 30–250 keV energy range with an organ dose conversion factor of 1.00 was applied. [Emphasis added.]

(2) In behalf of **missed dose**, the dose reconstructor stated the following:

... The total number of zero dosimeter readings assigned was 4 for photons. ... this results in a maximum potential missed dose for [the EE] of **0.080 rem** to the affected organs from photons. ... **this value was used** as the 95<sup>th</sup> percentile of a lognormal distribution for the purpose of calculating probability of causation. [Emphasis added.]

(<u>Note</u>: These statements imply an assigned dose of **0.020 rem** for each of the four years for "missed dose.")

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A review of the IREP Input tables in Attachment 1 of the DR Report (rows 14 through 17), however, shows missed doses of **0.010 rem** with a **GSD of 1.52** for the years [redacted], [redacted], [redacted], and [redacted].

<u>Note</u>: Similar parallel discrepancies between the text and values cited in the IREP Input tables were identified in the revised DR Report discussed below.

<u>Observation #1</u>. Inconsistencies between statements/values cited in the text of the DR Report versus values cited in IREP Input tables of the report introduce confusion and loss of credibility that should be avoided. Discrepancies of this nature have been identified in other DR audits and reflect the tendency of dose reconstructors to make use of generic wording/phrases found in guidance documents and DR templates that are inappropriate for a given EE's DR.

<u>Finding #2: Unknown Basis for Assignment of Occupational Medical Doses</u>. For occupational medical doses assigned to each lymphoma, organ doses were based on the following reference: Attachment E of the ORAUT-PROC-0006, *External Dose Reconstruction*, Rev. 00, June 27, 2003. A review of ORAUT-PROC-0006 shows that there is no Attachment E. Thus, the basis for the assigned occupational medical dose is unknown.

# 2.2.2 Revised DR: Summary Assumptions, Methods, and Doses Cited for External and Internal Exposures to the Singular Lymphoma

As previously noted, the two primary lymphomas assessed separately in the original DR Report were combined and assessed as a single lymphoma in the revised DR that was prompted by OCAS-PER-009.

<u>External Doses</u>. Dose estimates for the "singular lymphoma" from external sources included: recorded dosimeter values, missed dose, onsite ambient, and occupational medical dose. Table 2-3 below cites external doses assigned to the singular lymphoma.

External Source	Single Lymphoma (rem)
Dosimeter Readings	5.870
Missed Photon	1.680
Onsite Ambient	0.636
Occupational Medical	0.261
Total	8.447

 Table 2-3. Assigned External Doses in the Revised DR

Since OCAS-PER-009 primarily impacts internal dose, and since both DRs defaulted to a DCF of 1.0, all external doses would have been expected to remain the same.

Comparison of Table 2-1 to Table 2-3, however, shows that only the dosimeter readings of 5.870 rem and onsite ambient dose of 0.636 rem remained the same, while missed photon dose and occupational medical dose **increased** from 0.040 to 1.680 rem and from 0.108 to 0.261 rem, respectively.

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A questionably claimant-favorable approach was used in the revised DR to derive missed dose. Although the original DR identified only four recorded zero readings, the dose reconstructor in the revised DR elected to assign a total of **168 missed doses** for a total missed photon dose of 1.680 rem. This conflicts with the facts that (1) the EE was only intermittently onsite at the Hanford facility during the 14-year period; and (2) actual records identify recorded doses for all but **four monitoring periods**.

<u>Finding #3:</u> Inappropriate Use of Maximizing Assumptions. While claimant-favorable/ maximizing assumptions are appropriate under select conditions of **uncertainty** or as an **efficiency** measure, neither of these conditions apply in this case.

<u>Internal Dose</u>. Internal doses to the single lymphoma were based on the internal target organ LN(TH) from internal exposure to (1) 10-year-aged fuel-grade Pu (12%) representing Pu-238, Pu-239, Pu-241, and Am-241; and (2) missed fission products as given in Table 2-4. For Pu, solubility Type Super S was assumed.

Internal Source	Single Lymphoma (rem)
Pu + Others	26.340
Missed FP	6.489
Total	32.829

Table 2-4.	Assigned	Internal	Doses i	in the	<b>Revised DI</b>	R

In summary, the revised DR yielded a POC of 33.984% and reflects the following changes:

- (1) Higher internal and external doses that reflect impacts defined by OCAS-PER-009 on a lymphoma cancer
- (2) The diagnosis and inclusion of a bladder cancer that post-dates the original DR
- (3) A decision by DOL to combine two primary lymphoma cancers to a single lymphoma

#### SC&A Comments/Findings//Observations for Revised DR Report

For **external doses**, the revised DR employed dosimeter doses and environmental doses that are identical to the original DR, which had **assumed** a "claimant favorable" DCF value of **1.0**. Under OCAS-PER-009, the external target organ for ICD-9 code 202.01 in ORAUT-OTIB-0005 identifies thymus/lung<sup>g</sup>; footnote *g* further states that ". . . The external target organ should be lung if the lymphoma is known to be a **B-cell** variety.

For **full compliance** with OCAS-PER-009, all external exposures (with the exception of occupational medical) **should** have been derived using the lower DCF value of the lung. However, due to the fact that the dose reconstructor stated the use of **claimant-favorable** assumptions, this **deviation will not be considered significant or a finding**.

SC&A's review of internal doses specifically impacted by OCAS-PER-009 found no errors/findings.

# 3.0 REVIEW OF OCAS-PER-009 ISSUES FOR CASE #[B-REDACTED]

## 3.1 BACKGROUND INFORMATION FOR CASE #[B-REDACTED]

Case #[**B-redacted**] represents an EE who worked at Bridgeport Brass Company from [**redacted**] until [**redacted**] as a [**redacted**]. However, potential exposure to radiation during the years of uranium processing at the Bridgeport Brass facility would have been limited to the years 1950–1962 with resultant dose calculated until the time of cancer diagnosis on [**redacted**]. The EE was diagnosed with lymphosarcoma, ICD-9 code 200.18.

No radiation monitoring records for external or internal exposure (inclusive of occupational medical dose) were found for the EE, and reconstruction of organ doses was based on source term information and claimant-favorable assumptions.

## 3.2 COMPARISON OF NIOSH ORIGINAL AND REWORKED DRs

## 3.2.1 Original DR

NIOSH approved the original DR for Case #[**B-redacted**] on May 26, 2004, which was based on worst-case/claimant-favorable assumptions regarding external and internal exposure during the 13 years of uranium processing (1950–1962) and from residual contamination for the 6 years of 1963–1968.

External photon doses from uranium were assumed to represent energies between 30–250 keV as well as energies >250 keV to the lymphoma. For estimates of external dose, the external target organ "remainder organs" was assumed. In addition, one annual diagnostic x-ray was assumed for the years 1950 through 1962. Table 3-1 summarizes total external organ doses for the operational and post-operational periods.

Occupational External Doses	Total Dose (rem)
Uranium Sources (1950–1962)	
- 30–250 keV	21.704
- >250 keV	26.527
Contaminated Surfaces (1950-1962)	
- 30–250 keV	0.265
- >250 keV	0.265
Residual Contamination (1963–1968)	
- 30–250 keV	0.132
- >250 keV	0.132
Occupational Medical (1950–1962)	1.430
Total	50.437

Table 3-1. Original External Doses Assigned to Case #[B-redacted]

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<u>Internal Dose</u>. Modeled assumptions for internal exposure assumed chronic inhalation and ingestion of uranium. For internal dose, the **heart wall** was selected as the highest non-metabolic organ (HNMO). For inhalation dose, absorption Type M was assumed; and for ingestion, the fractional uptake of 0.02 was assumed.

The total combined inhalation and ingestion dose for 1950 through 1972 for was 14.646 rem.

Based on claimant-favorable dose modeling, the external organ dose of 50.437 rem and the internal organ dose of 14.646 rem yielded a POC value of **37.51%**.

#### SC&A Comments/Findings/Observations

SC&A critically reviewed assumptions and methodologies used for the original reconstruction of external and internal doses assigned to the target organs assumed for the EE's lymphosarcoma. In the absence of external and internal monitoring records for the EE, SC&A concludes that the DR consistently employed claimant-favorable assumptions/methods and there are no findings. However, SC&A did identify the following **non-technical** error/observation.

<u>Observation #2</u>. On page 5 of the original DR Report, the EE is referenced by a **wrong name**. In the mind of the EE/claimant, such an oversight may be detrimental to the credibility of the DR and the assumed notion that a DR is **uniquely tailored** to a given individual's claim.

## 3.2.2 Reworked DR

Following the issuance of OCAS-PER-009 on March 8, 2007, Case #[**B-redacted**] was reworked/ approved on October 2, 2007.

Under OCAS-PER-009 and ORAUT-OTIB-0005, the **internal** and **external** target organs (for lymphosarcoma with ICD-9 code 200.13) were revised to lymph node thoracic (LN(TH)) and thyroid, respectively.

Based on a preliminary review of assumptions and facts that defined Case #[**B-redacted**], NIOSH suspected that a complete DR may not be required and for **efficiency reasons** focused on **internal** occupational exposure.

The EE's internal dose was calculated using only the **inhalation** intakes of natural Type S uranium from June 26, 1952, through June 26, 1963. For this partial internal DR, the derived radiation dose to the thoracic lymph node was 2,218.197 rem, yielding a POC of 94.87%. Based on the POC value, NIOSH considered this dose complete.

#### SC&A Comments, Findings, Observations

SC&A concurs with the efficiency approach, the assigned internal target organ for DR of the lymphosarcoma, and the assigned LN(TH) organ dose. There are no findings/observations.

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# 4.0 REVIEW OF OCAS-PER-009 ISSUES FOR CASE #[C-REDACTED]

## 4.1 BACKGROUND INFORMATION FOR CASE #[C-REDACTED]

Case #[**C-redacted**] represents an energy employee (EE) who worked at the Feed Materials Production Center (FMPC) from [**redacted**] until [**redacted**] as a [**redacted**]. The EE was diagnosed with lymphosarcoma on [**redacted**].

The EE was monitored for external radiation on a weekly dosimetry exchange cycle. For internal exposure, the records show a single termination urine bioassay dated March 9, 1956, which was evaluated for uranium.

#### 4.2 COMPARISON OF NIOSH'S ORIGINAL AND REWORKED DRs

#### 4.2.1 Original DR

NIOSH approved the original DR for Case #[C-redacted] on October 26, 2005, which identified the Hodgkins lymphoma by the ICD-9 code 201.61. In the report, the dose reconstructor stated that:

For the purpose of this dose reconstruction [the EE's] radiation dose was **overestimated** using claimant-favorable assumptions. [Emphasis added.]

<u>External Dose</u>. For the EE's lymphosarcoma, the **external target organ** was defined by the **thyroid**. A review of dosimeter records shows that positive dosimeter responses for the shallow dose were recorded; there were no recorded deep doses. Thus, external deep dose was defined for the 75 dosimeter cycles as "missed dose" for a dosimeter limit of detection (LOD) value of 30 mrem that was further modified by (1) a 40%/60% split in photon energies and their respective energy-dependent thyroid DCFs and dosimeter correction factors (CFs).

Based on these assumptions and default parameters, the original DR Report states:

... this results in a **maximum** potential missed dose for [the EE] of 2.646 rem from penetrating photon radiation. ... these values were **used** as the 95<sup>th</sup> percentile of a lognormal distribution for the purpose of calculating probability of causation. [Emphasis added.]

For unmonitored neutrons, the DR Report states:

The 95<sup>th</sup> percentile neutron-to-photon ratio was applied to the measured and missed photon doses to determine the **unmonitored** neutron dose. . . . this results in a maximum potential missed dose for [the EE] of 1.124 rem from neutron radiation. [Emphasis added.]

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In addition to estimated doses associated with site operation, occupational medical doses were included in external dose. The following statements were cited in the text of the EE's DR Report:

... an assumed annual X-ray procedure each year of employment, **up to the date** of diagnosis, a total X-ray dose of 0.006 rem was assigned. [Emphasis added]

Assigned organ doses from external and internal exposures in the original DR yielded a POC value of 2.17%.

#### SC&A Comments, Findings, and Observations

SC&A compared the foregoing statements in the text of the DR Report to actual doses assigned as given in the IREP Input tables of Attachment 1 of the DR Report. For example, the DR text **implies** that the EE was assigned a total dose of 2.646 rem from penetrating photon radiation and 1.124 rem from neutron radiation.

Inspection of the IREP Input table of the DR's Attachment 1 shows that the **actual** assigned photon dose was 1.323 rem and 0.562 rem for neutrons. Thus, the **assigned** doses were reduced by a factor of two, which implies that the assigned doses were based on the LOD/2 value for the film dosimeter.

SC&A concludes that the wording in the text is inconsistent with the actual method used to derive assigned doses cited in the IREP Input tables. Moreover, the use of LOD/2 for missed doses represents a **best-estimate** approach and should not be labeled as "overestimated," "claimant favorable," or by the following summary statements on page 8 of the DR Report:

- *The missed doses estimated for* [the EE] *are likely much larger than any doses that were unmonitored or unrecorded.*
- Maximizing assumptions were used to convert potential whole body dose to dose to the lymphatic system. Had more realistic assumptions been applied, the estimated dose to the lymphatic system would have been smaller.

Lastly, SC&A attempted to duplicate the **assigned** external photon doses cited in rows #1 through #9. Our assessment showed that the dosimeter CFs of 1.43 for 30–250 keV and 1.3 for >250 keV photons had **not** been included; and since the unmonitored neutron dose was based on the faulty photon dose, both assigned photon and neutron doses were underestimated. More importantly, our review showed that the failure to include the dosimeter CFs may represent a systemic error that involves the **Fernald Calculation Workbook version 1.19**.

<u>Observation #3. Wording in DR Report is Misleading</u>. In describing external organ doses from photons and neutrons, the text of the original DR Report misrepresented the **actual values** assigned to the EE as cited in Attachment 1 IREP Tables of the report. For **occupational medical dose**, the yearly **correct** dose of 0.002 rem was, in fact, assigned for

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employment years 1954, 1955, and 1956. However, the above-cited statement "... up to the date of diagnosis" is irrelevant and misleading since the diagnosis of the EE's lymphoma occurred in [redacted], or [redacted] years post-employment.

<u>Finding #4.</u> Error Identified in Workbook. The cited values for external photon and neutron doses contained an error, which appears to reflect a deficiency in the Fernald Calculational Workbook version 1.19. This error seems to have been corrected in the most current version (version 1.50) of the FEMP Workbook. However, SC&A does not know when this correction was made and whether other DRs that were completed using the incorrect workbook have been reworked.

<u>Internal Doses</u>. To calculate the internal organ dose for the EE's lymphoma, the **heart wall** was used as the selected internal target organ. A single bioassay representing a termination urinalysis was used for estimating the internal dose from inhalation and ingestion of natural uranium. The total estimated dose for all years up to the date of cancer diagnosis was 0.346 rem.

## 4.2.2 Reworked DR

A revised DR for Case #[C-redacted] that addressed changes introduced in OCAS-PER-009 and ORAUT-OTIB-0005 was approved on October 26, 2005. For the reworked DR, the original ICD-9 code 201.61 for the EE's Hodgkin's lymphoma was changed to 201.01 without explanation. For both ICD-9 codes, the internal and external target organs, however, are identical and, therefore, had no impact on revised dose estimates.

Nevertheless, an explanation/justification for a change in ICD-9 code would help the audit process and eliminate potential questions/concerns.

Given the potential impact of OCAS-PER-009 on internal exposure for select radionuclides, the revised DR was limited to a **partial** estimate of internal exposure to a lymph node of the extrathoracic region (LN(ET)), as explained by the following statements:

[the EE] submitted one bioassay termination sample . . . which was greater than the detection limit of uranium. However, it was not necessary to evaluate the potential dose from this positive result. . . . The chronic intake rate was determined using half the minimum detection activity (MDA) for that radionuclide and assigned the mode excretion rates below the detection limit. . . . For the purposes of this dose reconstruction, it was only necessary to assign missed dose considering one year of uranium intake (Jan. 1, 1955 through Dec. 31, 1955). The internal dose assigned to the lymph nodes of the extrathoracic region was 245.445 rem.

NIOSH's partially derived internal dose yielded a POC of 68.32% and was, therefore, of sufficient magnitude to consider the DR complete.

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#### SC&A's Comments/Findings/Observations

SC&A reviewed the partial DR as specified in the **reworked DR** Report, and the minimum detectable activity (MDA) value of 14  $\mu$ g/l (specified in Table 5-19 of ORAUT-TKBS-0017-5). SC&A identified the **assumed** daily urine excretion value of 6.69 pCi/d and verified NIOSH's IMBA-generated dose of 245.5 rem for an assumed chronic intake during the year 1955.

SC&A concludes that the efficiency process that employed a partial internal DR method was done correctly and compliant with OCAS-PER-009, and there are no findings.

As an interesting sideline that demonstrates the quantitative impact of OCAS-PER-009, SC&A compared the internal dose to the lymph node of 0.346 rem derived in the **original DR** to the **internal dose** that would have been derived if recorded termination bioassay data had been used and calculated for an inhalation period that spanned from September 15, 1954, to March 16, 1956. For the full duration of employment (and assumed chronic internal exposure), SC&A derived an organ dose of **3,710 rem** to the LN(ET), which is more than four orders of magnitude higher than the original DR internal dose estimate of 0.346 rem.

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# 5.0 SUMMARY CONCLUSIONS

Under SC&A's *A Protocol to Review NIOSH's Program Evaluation Reports (PERs)* (SCA-TR-PR2009-0002), Subtask 4 requires the audit of a sample set of reworked DR cases that met criteria specified in OCAS-PER-009. In support of Subtask 4, NIOSH (instead of the Procedures Review Subcommittee) selected three DRs for audit in order to allow completion within SC&A's contract period.

For each of the three reviewed cases, SC&A provided a brief overview of the case and a comparison of external and internal doses assigned in the original and revised DRs. SC&A's review of the three cases identified a total of four findings and three observations, which are summarized below.

#### Findings

- Finding #1: SC&A questions the technical basis/protocol for the assignment of and/or subsequent changes to ICD-9 codes that included the consolidation of two primary lymphomas to one lymphoma.
- Finding #2: For medical occupational dose, an incorrect reference was cited for the assigned dose.
- Finding #3: Misuse of claimant-favorable/maximizing assumptions that may be appropriate under conditions of **uncertainty** or as an **efficiency measure**, but should not be used when neither of these conditions apply.
- Finding #4: In the <u>Fernald Calculational Workbook, Version 1.19</u> (which was used in the reworked DR), an error was identified which was subsequently corrected in version 1.50 of the FEMP Workbook. (Note: SC&A does not know when the correction was made and whether other DRs were based on the incorrect Version 1.19.)

#### **Observations**

- Observations #1 and #3: NIOSH's use of generic boilerplate phrases/statements taken from guidance documents not applicable, inconsistent, and/or misleading for a specific EE's DR. Note: Over the years, SC&A has repeatedly raised this concern in behalf of other DRs.
- Observation #2: In Case #[**B-redacted**], the EE is referenced by a **wrong** name. This kind of oversight is detrimental to the credibility of the DR.

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## REFERENCES

OCAS-IG-001. 2002. *External Dose Reconstruction Implementation Guideline*, Rev. 1, National Institute for Occupational Safety and Health, Office of Compensation Analysis and Support, Cincinnati, Ohio. August 2002.

OCAS-PER-009. 2007. *Target Organs for Lymphoma*, Rev. 0, NIOSH's Office of Compensation Analysis and Support, Cincinnati, Ohio. March 8, 2007.

OCAS-TIB-012. 2005. Selection for Internal and External Dosimetry Target Organs for Lymphatic/Hematopoietic Cancers, Rev. 0, NIOSH's Office of Compensation Analysis and Support, Cincinnati, Ohio. August 15, 2005.

ORAUT-OTIB-0005. 2006 Internal Dosimetry Organ, External Dosimetry Organ, and IREP Model Selection by ICD-9 Code, Rev. 02 PC-1, Oak Ridge Associated Universities Team, Cincinnati, Ohio. February 10, 2005.

ORAUT-PROC-0006. 2003. *External Dose Reconstruction*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. June 27, 2003.

ORAUT-TKBS-0017-5. 2004. *Technical Basis Document for the Fernald Environmental Management Project (FEMP) – Occupational Internal Dose*, Rev. 00, Oak Ridge Associated Universities Team, Cincinnati, Ohio. May 28, 2004.

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# ATTACHMENT A-1: AMENDED NIOSH REFERRAL SUMMARY INFORMATION

#### AMENDED NIOSH REFERRAL SUMMARY INFORMATION

DOL Case Number:

NIOSH Tracking Number:

1. Energy Employee Name:

2. Supplemental Information Not Affecting NIOSH Referral Summary Document:

3. Energy Employee Covered Cancer Information:

(P)rimary or (S)econdary	Cancer	ICD-9 Code	Date of Diagnosis
P	B-Cell Lymphoma Intermediate Grade Large Cell, Right Tonsil	146	
Р	B-Cell Lymphoma Intermediate Grade Large Cell, Left Neck	200.01	

This is to correct the ICD 9 code for cancer of the left neck + RIGHT TONSIL.

#### 4. DOL Information:

District Office Examiner Name	SEATTLE - Pasific	Region District Office	
Examiner Name			
Phone Number			
Date Prepared	10/8/02	2	10
Reviewed By			

10-18-02A11:03 RCVD

Amended NIOSH Referral Summary Information

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Claimant ID #\_ DOL Batch #\_\_ DOL D.O. #\_\_\_

NIOSH/OCA:

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# ATTACHMENT A-2: DOL E-MAIL CORRESPONDENCE

[This document has been redacted in full.]

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# ATTACHMENT A-3: AMENDED NIOSH REFERRAL SUMMARY INFORMATION

• *		CLAIMANT ID # DOL BATCH # DOL D.O. # NIOSH/OCAS
2009 DEC 20 RM	DOL Case Number:	CAN
	racking Number:	

Summary of changes: ICD codes for lymphomas of right tonsil & left neck are incorrect. Also, employment dates were incorrectly reported. See changes for both below.

EE Full Name: [First, Middle,	
Last, Suffix]	
EE Gender: [M, F, U]	M
Date of Birth: [Month, Day, Year]	
Date of Death (If applicable): [Month, Day, Year]	N/A
EE Full Address (If applicable): [Street Address, City, State, Zip]	
EE Phone Number (If applicable): [Phone Number, Phone Type]	D

Medical and Employment Information:

# EE Covered Cancer Information [For each cancer, list the following information]:

Cancer Description / Type	lymphoma of the right tonsil	
Associated ICD-9 Code	202.81	
Date of Cancer Diagnosis		

Primary [x] or Secondary (Metast	tatic) []
Cancer Description / Type	lymphoma of the left neck
Associated ICD-9 Code	202.81
Date of Cancer Diagnosis	

Amended NIOSH Referral Summary Information

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# **ATTACHMENT A-4: NOTICE OF RECOMMENDED DECISION SHEET**



#### NOTICE OF RECOMMENDED DECISION

This is the Recommended Decision of the District Office concerning your claim for compensation under Part B of the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). The District Office **recommends denial** of your claim under Part B for employee benefits for the condition lymphoma of the left neck and right tonsil. The District Office defers determination of entitlement to benefits under Part E (formerly Part D) of the EEOICPA.

#### STATEMENT OF THE CASE

filed a Part B claim (EE-1) on 07/31/2001 seeking benefits pursuant to the EEOICPA as a covered employee for the condition of lymphoma.

Submitted an EE-3 indicating that he was employed with Genstar Mining Co. at Rock Island Dam from an unknown start date through and with Kaiser Engineers and JA Jones at the Hanford site from through through Jones The EE-3 indicates a dosimetry badge was worn while at Hanford but not while with the Genstar Mining Co.

The Department of Energy (I	DOE) confirmed that		was em	ployed with
JA Jones and Kaiser Engine	ers Hanford at the H	lanford facility	from	hrough
throug	h	through		
through	hrough , a	and the th	rough	. In
addition, DOE records indica	ited that	was a v	isitor at the l	Hanford site
from through reconstruction.	, and so thos	e dates were a	added during	the dose

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#### ATTACHMENT A-4: NOTICE OF RECOMMENDED DECISION SHEET (CONTINUED)

submitted a medical report from MD dated MD dated indicating a diagnosis of large B-cell lymphoma. Also submitted was a pathology report of the right tonsil and left neck dated with the basis for the diagnosis of lymphoma. This medical evidence is sufficient to document the diagnoses of cancer under the EEOICPA.

A copy of the case file and a National Institute for Occupational Safety and Health (NIOSH) Referral Summary was forwarded to NIOSH for dose reconstruction in February of 2002. On 3/21/2005, the Office received the "NIOSH Report of Dose Reconstruction under EEOICPA," dated 3/8/2005, which provided the estimates of dose to the primary cancer sites of the right tonsil and left neck.

NIOSH estimated annual doses totaling 6.765 rem (roentgen equivalent man) each for the left neck and right tonsil lymphomas. Based on these dose estimates, the calculation of probability of causation was completed using NIOSH-IREP (NIOSH-Interactive RadioEpidemiological Program), which is an interactive software program. The total probability of causation for the two primary cancers was determined to be 19.57 percent.

#### FINDINGS OF FACT

filed a Part B claim for employee benefits on 07/31/2001.

1.

- Was employed with JA Jones and Kaiser Engineers Hanford, a Department of Energy facility, contractor, subcontractor or vendor, at the Hanford facility.
- On was diagnosed with lymphoma of the right tonsil and left neck.
- The cancer diagnoses made after Department of Energy.
- 5. NIOSH reported annual dose estimates for the lymphomas from the date of initial radiation exposure at Hanford to the date of cancer diagnosis. A summary and explanation of information and methods applied to produce these dose estimates, possibly including involvement through an interview and review of the dose report, are documented in the "NIOSH Report of Dose Reconstruction under EEOICPA," dated 3/8/2005.

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#### ATTACHMENT A-4: NOTICE OF RECOMMENDED DECISION SHEET (CONTINUED)

6. Based on the dose reconstruction performed by NIOSH, the probability of causation (the likelihood that a cancer was caused by radiation exposure incurred by the employee while working at a DOE covered facility) was calculated for the two primary cancers. The probability of causation values were determined using the upper 99 percent credibility limit, which helps minimize the possibility of denying claims to employees with cancers likely to have been caused by occupational radiation exposures. It was shown that the termine lymphomas, did not meet the "at least as likely as not" (a 50% or greater probability) threshold, as required under the EEOICP that the cancer was caused by radiation doses incurred while employed at Hanford, as the total probability of causation was 19.57 percent.

#### CONCLUSIONS OF LAW

- does not qualify as a covered employee with cancer under Part B, as defined by 42 U.S.C. § 7384I(9)(B) of the EEOICPA.
- The dose reconstruction estimates were performed in accordance with 42 U.S.C. § 7384n(d) of the EEOICPA and 42 CFR.Part 82 §82.10.
- The Probability of Causation was completed in accordance with 42 U.S.C. § 7384n(c)(3) of the EEOICPA and 20 CFR 30.213, which references Subpart E of 42 CFR Part 81. Further, the calculation based on two primary cancer sites was completed in accordance with 42 CFR Part 81 §81.25.
- U.S.C. §§ 7384s(a)(1) and 7384n(b)of the EEOICPA.
- 5. Entitlement to Part E benefits under 42 U.S.C. is deferred at this time.

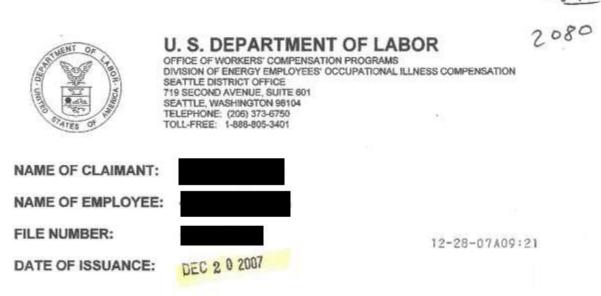
Please review the enclosed Notice of Recommended Decision and Claimant Rights that explains your rights regarding this Recommended Decision.

Examiner	Senior Examiner

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# **ATTACHMENT A-5: NOTICE OF RECOMMENDED DECISION**

NT



#### NOTICE OF RECOMMENDED DECISION

The District Office **recommends denial** of the claim for survivor benefits under Part B and Part E of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) for the conditions of lymphoma and bladder cancer.

#### STATEMENT OF THE CASE

filed a Part B claim on 07/31/2001 and a Part E claim on 07/16/2003 seeking benefits as a covered employee under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA or the Act). He indicated on each application form that he had been diagnosed with lymphoma as the result of his employment at the Department of Energy's Hanford facility. All also submitted an employment history on Form EE-3 indicating that he was employed at the Hanford facility from the to the second secon	
filed a claim for survivor benefits on 07/31/2006 seeking benefits under the EEOICPA as the surviving spouse of the surviving	
The Department of Energy (DOE) confirmed that was employed at the Hanford facility by J.A. Jones and Kaiser Engineers Hanford, both DOE subcontractors, from to	

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#### **ATTACHMENT A-5: NOTICE OF RECOMMENDED DECISION (CONTINUED)**

In support of the claim, the District Office received medical evidence which included a surgical pathology report from the diagnosed B cell lymphoma on the diagnosis from the diagnosis from the diagnosed a post operative diagnosis from the diagnosed and the diagnosed a bladder tumor on the diagnosed, and a medical report from MD which reported a history of bladder cancer.

On 02/07/2007, the District Office referred the file to the District Medical Consultant for a determination of whether the cancer reported in the neck and tonsil supported a diagnosis of two primary cancers or only a single primary lymphoma.

On 05/17/2007, the District Office received the report of the District Medical Consultant, who opined that "lesions to the tight tonsil and to the left sided neck mass represent one singular primary cancer, a B cell lymphoma".

In 05/2007 a copy of the case file, along with a National Institute for Occupational Safety and Health (NIOSH) Referral Summary, was forwarded to NIOSH for dose reconstruction for lymphoma and bladder cancer. On 11/09/2007, the District Office received the "NIOSH Report of Dose Reconstruction under EEOICPA," dated 10/01/2007, which provided the estimated dose of radiation to the primary cancer sites of the bladder and lymphoid tissue.

Based on these dose estimates, the District Office calculated the probability of causation by entering this claim's specific information into a computer program called NIOSH-IREP. The probability of causation values were determined using the "upper 99% credibility limit," which helps minimize the possibility of denying claims to employees with cancers likely to have been caused by occupational radiation exposures. The probability of causation for the two primary cancers was determined to be 33.98 percent. This calculation took into account the fact that there was more than one primary cancer, and the resulting probability of causation applies to each of those cancers.

Under Part E of the Act, § 7385s requires us to determine that the death of the covered DOE contractor employee was due to a covered illness as a result of exposure to a toxic substance. The Act requires a finding that it is "at least as likely as not" that such exposure occurred at a covered facility during a covered time period and that the toxic substance was a significant factor in aggravating, contributing to, or causing both the employee's illness and death.

The employee's autopsy report, signed by a medical doctor, indicates that in and and and caused or contributed to his death, not lymphoma or bladder cancer. It must be shown that the claimed conditions were at least as likely as not a significant factor in causing, contributing to, or aggravating the employee's death.

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# ATTACHMENT A-6: COVER PAGE OF REVISED DR

NIOSH				OCAS
	nployees O	Dose Reconstructional II am Act (EEOI	Iness Com	
NIOSH ID:		Social Security No.	DOL District Office Seattle	
Energy Employee Name:	Last	Fest	Mahlle	Daw of Hirsh
Covered Employment:	employment) dose reconstruc	(added during	Hanford Site Richland, WA	
Cancer:	Malignant neop Lymphoma, lyn left neck	olasm, bladder nph node, right tonsil,	188.2 202.01 RCD Cede	Date of Diagrams
Calculations Perfo	ormed By:	Michael B. M	loyer	09/26/07
Peer Review Completed By:		Sallie D. Robinson		09/27/07
Dose Reconstruction Approved By:		F.C. Crawford		10/01/2007