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March 30, 2009

Mr. David Staudt
Center for Disease Control and Prevention
Acquisition and Assistance Field Branch
Post Office Box 18070
626 Cochrans Mill Road – B-140
Pittsburgh, PA 15236-0295

Re: Contract No. 200-2009-28555, Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction: SCA-TR-TASK3-0011, *Review of OCAS-IG-004: The Use of Data from Other Facilities in the Completion of Dose Reconstructions under the Energy Employees Occupational Illness Compensation Program Act*

Dear Mr. Staudt:

SC&A is please to submit to NIOSH and the Advisory Board the Privacy Act-cleared version of our report titled, *Review of OCAS-IG-004: The Use of Data from Other Facilities in the Completion of Dose Reconstructions under the Energy Employees Occupational Illness Compensation Program Act*. The restricted version of this report was forwarded to you on March 2, 2009.

One minor change was made to clarify the language in item 7 on page 11 of this report, along with the appropriate revision to the disclaimer that appears at the bottom of each page and the removal of the word "draft" next to the date in the header. No other changes were made in this version of the subject report.

Should you have any questions, please contact me at 732-530-0104.

Sincerely,

John Mauro, PhD, CHP
Project Manager

cc: P. Ziemer, Board Chairperson
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Project File (ANIO2/003/03)

Draft Report

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

ADVISORY BOARD ON RADIATION AND WORKER HEALTH

REVIEW OF NIOSH/ORAUT PROCEDURES AND METHODS USED FOR DOSE RECONSTRUCTION

Review of OCAS-IG-004: The Use of Data from Other Facilities in the Completion of Dose Reconstructions Under the Energy Employees Occupational Illness Compensation Program Act

Contract No. 200-2009-28555
SCA-TR-TASK3-0011, Revision 0

Prepared by

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March 2009

Disclaimer

This document is made available in accordance with the unanimous desire of the Advisory Board on Radiation and Worker Health (ABRWH) to maintain all possible openness in its deliberations. However, the ABRWH and its contractor, SC&A, caution the reader that at the time of its release, this report is pre-decisional and has not been reviewed by the Board for factual accuracy or applicability within the requirements of 42 CFR 82. This implies that once reviewed by the ABRWH, the Board's position may differ from the report's conclusions. Thus, the reader should be cautioned that this report is for information only and that premature interpretations regarding its conclusions are unwarranted.

S. Cohen & Associates: ***Technical Support for the Advisory Board on Radiation and Worker Health Review of NIOSH Dose Reconstruction Program***	Document No. SCA-TR-TASK3-0011 Effective Date: Draft – March 2, 2009 Revision No. 0 – Draft
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Document Reviewer: _____ Date: _____ U. Hans Behling, PhD Project Manager: _____ Date: _____ John Mauro, PhD, CHP	Supersedes: N/A

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1.0 EXECUTIVE SUMMARY

Under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) and Title 42, Part 82, *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*, of the *Code of Federal Regulations* (42 CFR Part 82), the Advisory Board on Radiation and Worker Health (Advisory Board or Board) is mandated to conduct an independent review of the methods and procedures used by the National Institute for Occupational Safety and Health (NIOSH) and its contractors for dose reconstruction.

In its role as technical support contractor to the Advisory Board, one of SC&A's requirements is to "…evaluate whether methodologies and procedures are consistent with requirements of 42 C.F.R. Part 82 and whether there are sufficient procedures to achieve consistent application of the requirements in 42 C.F.R. Part 82." On this basis and others in its defined support role, SC&A was charged by the Advisory Board to conduct a critical review of OCAS-IG-004, Revision 0, entitled, *The Use of Data from Other Facilities in the Completion of Dose Reconstructions Under the Energy Employees Occupational Illness Compensation Program Act.*

SC&A's method for the review of NIOSH/OCAS procedures is described in our report entitled, *A Protocol for the Review of Procedures and Methods Employed by NIOSH for Dose Reconstruction*, which was approved by the Advisory Board in April 2004 (SC&A 2004). The objective of this particular review is to evaluate the degree to which OCAS-IG-004 meets the requirements of 42 CFR Part 82 and sound health physics practice. It is important to note that 42 CFR Part 83 (*Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort under EEOICPA of 2000*) provides direction on the use of data from other sites for the purpose of determining if it is feasible to estimate the level of radiation doses of individual members of the class with sufficient accuracy. This report does not address the application of OCAS-IG-004 with respect to implementing the provisions of Part 83, because OCAS-IG-004 appears to be intended to be used specifically as guidance for the performance of dose reconstructions performed in accordance with Part 82. If the Advisory Board would like SC&A to broaden its review to include consideration of the provisions of Part 83, we will supplement this report, as appropriate.

SC&A's review of OCAS-IG-004 is divided into four parts. The first part describes the provisions of Part 82 with respect to the use of data from other sites. The second part addresses NIOSH's discussion of the use of data from other sites as a precedent for application to dose reconstructions performed under Part 82. Based on the provisions of Part 82, the third part of this report addresses the substance of OCAS-IG-004, in terms of the degree to which the criteria meet or exceed the provisions of Part 82 and good health physics practice. Part 4 discusses OCAS-IG-004 with respect to the draft criteria issued by the Advisory Board's work group for the use of surrogate data.

SC&A's review of OCAS-IG-004 resulted in the following findings:

(1) Part 82 has no explicit language permitting the use of data from other sites for the purpose of performing dose reconstructions. However, Part 82.17, entitled "What types

of information could be used to supplement or substitute for individual monitoring data," provides guidance that is relevant to the subject of this report. Part 82.17 could be interpreted to preclude the use of data from other sites. However, consultation with a NIOSH representative indicated that it interprets these and other provisions of Part 82 of the rule to allow for the use of data from other sites in the performance of dose reconstructions. SC&A recognizes that it is NIOSH's position that interpretation of the regulations is outside the purview of SC&A's technical support mandate, and SC&A acknowledges, respects, and accepts that position. Nevertheless, we believe that this ambiguity in Part 82 should be brought to the attention to the Board because the manner in which Part 82 is interpreted with respect to this matter has profound implications with respect to SEC petition/evaluation reports, site profiles, and dose reconstructions.

(2) In addition to the interpretation of Part 82, OCAS-IG-004 establishes the precedent for the use of data from other sites, as employed in other venues, as part of the rationale for using data from other sites in dose reconstructions. SC&A finds some of these arguments inappropriate, such as those dealing with the use of data from other sites in epidemiological investigations, because of fundamental differences in the objectives of epidemiological studies and dose reconstructions.

(3) Assuming that Part 82 allows data from other sites to be used in dose reconstructions, the criteria set forth in OCAS-IG-004 are technically sound. However, SC&A believes that implementation of these criteria for some facilities might be difficult, due to limited information regarding the characteristics of the source term (e.g., the types, quantities and chemical forms of the radionuclides), the design of the facility (e.g., facility layout and building ventilation system), and health physics practices (e.g., time, distance, shielding, and good housekeeping) at the facility of concern. In addition, obtaining data from a surrogate facility for time periods that are applicable to the facility of interest will be challenging. OCAS-IG-004 would allow the use of surrogate data from other time periods under some circumstances. However, such use would be in conflict with the Board's draft criteria for surrogate data, which would restrict the use of surrogate data to the same time period.

(4) SC&A finds that the description of the criteria set forth in Sections 3.2 and 3.3, dealing with Source Terms and Facility and Process Similarities, heavily emphasize Atomic Weapons Employer (AWE) facilities and the handling and processing of uranium. It seems that the original intent of OCAS-IG-004 was for it to apply to all types of facilities. However, the actual text appears to limit its scope to AWE facilities. It should also be noted that, with respect to scope, if OCAS-IG-004 is primarily intended to be applicable to AWE facilities, it may not be needed in light of TBD-6000, -6001, and their appendices.[1] These TBDs appear to provide more comprehensive guidance on the use of data from other sites in support of dose reconstruction for AWE facilities. At a minimum, TBD-6000 and TBD-6001, and perhaps other guidelines, should be cross referenced, and there should be an explicit effort to ensure consistency between these documents and OCAS-IG-004.

[1] SC&A has reviewed TBD-6000 and -6001 and two of its appendices, and has identified numerous issues with regard to these documents.

(5) SC&A is in agreement with the provisions of Sections 3.6 (Data Evaluation) and 3.7 (Review of Bounding Exposure Models) of OCAS-IG-004.

(6) SC&A is in agreement with Section 4 (Examples) of OCAS-IG-004; however, the section would benefit from a discussion that addresses off-normal conditions, unique work practices, and accidents. In addition, the discussion of external exposures in Section 4.2 of OCAS-004 would benefit from a discussion of using other site film badge data as a means to reconstruct external exposure to non-penetrating and penetrating radiation, especially neutron exposure.

(7) The criteria set forth in OCAS-IG-004 are consistent with the four draft criteria developed by the Work Group on the Use of Surrogate Data except on the question of time periods. In some instances, however, the draft criteria developed by the work group seem to be somewhat more explicit and stricter in establishing a threshold of acceptability (see the comparisons provided in Section 6). On the other hand, OCAS-IG-004 adopts the concept of "plausibility," which is not explicitly addressed in the draft criteria developed by the work group.

2.0 SUMMARY OF THE PROVISIONS OF PART 82 WITH RESPECT TO THE USE OF DATA FROM OTHER SITES FOR DOSE RECONSTRUCTIONS

42 CFR Part 82 provides direction and guidance for determining a reasonable estimate of the radiation dose received by a covered employee with cancer under EEOICPA, through the completion of a dose reconstruction that may be based on a hierarchy of data/methods. Appendix A presents selected excerpts contained in these regulations that are considered most relevant to guidance contained in OCAS-IG-004 regarding the use of data from other facilities in the completion of dose reconstruction. As indicated, it appears that the provisions of Part 82 are silent regarding the use of data from other sites, and neither explicitly precludes nor allows for the use of data from other sites for the purpose of dose reconstruction.

The provisions of Part 82 that appear to SC&A to be most directly applicable to the use of data from other sites are contained in §82.17, as given below:

> ***§ 82.17 What types of information could be used to supplement or substitute for individual monitoring data?***
>
> *Three types of information could be used:*
>
> *(a) Monitoring data from co-workers, if NIOSH determines they had a common relationship to the radiation environment; or,*
>
> *(b) A quantitative characterization of the radiation environment in which the covered employee worked, based on an analysis of historical workplace monitoring information such as area dosimeter readings, general area radiation and radioactive contamination survey results, air sampling data; or,*
>
> *(c) A quantitative characterization of the radiation environment in which the employee worked, based on analysis of data describing processes involving radioactive materials, the source materials, occupational tasks and locations, and radiation safety practices.*

It would seem that paragraph (a), which deals with coworker data, would only apply to coworkers at the same facility as the person for which dose reconstruction is being performed. Hence, use of coworker data from workers at another site does not seem to be encompassed by this paragraph. In addition, when SC&A first reviewed paragraphs (b) and (c), it was our interpretation that "the radiation environment" referred to the facility and site in which the employee worked. However, discussions with the NIOSH Project Officer[2] indicate that any interpretation of existing regulations on the part of SC&A is beyond the purview of SC&A's technical support role to the Advisory Board, and that it is NIOSH's interpretation of the rule that these provisions allow for the use of data from other sites in dose reconstructions. SC&A would like to bring this interpretation of Part 82 to the attention of the Advisory Board and its Work Group on the Use of Surrogate Data, since it does go to the heart of subject of this review.

[2] Ted Katz, who as NIOSH Project Officer for the SC&A contract, has provided preliminary comments on these issues.

In the sections that follow, SC&A proceeds with our review of OCAS-IG-004 from a purely technical basis, assuming that Part 82 allows for the use of data from other sites in the performance of dose reconstructions.

3.0 COMMENTARY ON THE SECTION OF OCAS-IG-004 DESCRIBING PRECEDENCE FOR THE USE OF SURROGATE DATA

To help justify the use of surrogate data for dose reconstruction in a compensation program, Section 2.0, "Precedence for the Use of Surrogate Data," in OCAS-IG-004 cites and describes the following three conditions in which surrogate data have been employed, along with references:

(1) Epidemiologic Studies
(2) Radiation Compensation Programs
(3) General Exposure Modeling

As indicated in the following discussion, SC&A believes that the examples of the use of data from other sites described in this section are not applicable to dose reconstructions performed under the EEOICPA. SC&A believes that the criteria set forth in OCAS-IG-004 stand on their own technical merit and do not need to be justified using the precedents cited in this section.

3.1 EPIDEMIOLOGIC STUDIES

In support of surrogate data, Section 2.1 of OCAS-IG-004 introduces this topic with the following statement:

> *Surrogate data has* [sic] *been used in epidemiological studies to estimate exposure to individuals in the workplace. . . .*

NIOSH cites the following six references from the scientific literature:

(1) Eheman, C.R. and P.E. Tolbert (1999). "Estimating occupational radiation doses when individual dosimetry is not available: a job exposure matrix," *Amer. J. Ind. Med.* **36**, 348-359.

(2) Hornung, R.W., A.L. Greife, L.T. Stayner, N.K. Steenland, R.F. Herrick, L.J. Elliott, V.L.Ringenburg, and J. Morawetz (1994). "Statistical model for prediction of retrospective exposure to ethylene oxide in an occupational mortality study," *Amer. J. Ind. Med.* **25**, 825-836.

(3) Kauppinen, T.P. (1994). "Assessment of exposure in occupational epidemiology," Scand. *J. Work. Environ. Health* **20,** 19-29.

(4) Seixas, N.S. and H. Checkoway (1995). "Exposure assessment in industry specific retrospective occupational epidemiology studies," *Occup. Environ. Med.* **52**, 625-633.

(5) Simon, S.L., R.M. Weinstock, M.M. Doody, J. Neton, T. Wenzl, P. Stewart, A.K. Mohan, R.C. Yoder, M. Hauptmann, and M. Linet (2006). "Estimating historical radiation doses to acohort of U.S. radiologic technologists," *Radiat. Res.* **166**, 174-192.

(6) Stewart, P.A., R.F. Herrick, C.E. Feigley, D.F. Utterback, R. Hornung, H. Mahar, R. Hayes, D.E. Douthit, andA. Blair (1992). "Study design for assessing exposures of embalmers for a case-control study. Part 1. monitoring results," *Appl. Occup. Environ. Hyg.* **7(8)**, 532-540.

This above-quoted statement suggests that it is the purpose of epidemiological studies to estimate the magnitude of exposures to individuals to a specific agent. This is clearly not the objective of epidemiologic studies. In classical terms, the objective of epidemiologic studies is the measurement of the occurrence of diseases and its relationship to a suspected etiological agent (e.g., a chemical, physical, or biological agent). Imperative to establishing the causal role of a suspect agent and the disease is an understanding of the dose-response relationship, which in turn defines the risk coefficient. It is for this reason that a quantitative assessment of exposure to members of a study cohort is essential. There are numerous statements in the references cited in OCAS-IG-004 that establish the differences between dose reconstruction intended to support epidemiological studies and those performed in support of compensation decisions under the EEOICPA. The following are particularly relevant quotes from the citations:

- From Reference #1 – Eheman and Tolbert 1999 (from page 348):

  A job exposure matrix (JEM) was developed for a population based case control study to assess the possible relation between occupational radiation and non-Hodgekin's lymphoma.

- From Reference #5 – Simon et al. 2006 (pages 174–175):

  Quantitative dose-response data are limited for populations exposed to chronic fractionated low to moderate levels of ionizing radiation.

  > …*The impetus for the detailed dosimetry described here is to support mortality and cancer risk analysis from data collected on the USRT* [U.S. Radiologic Technologist] *cohort. In particular, estimated doses will allow for estimation of the dose-response.*

Unfortunately, for the majority of epidemiologic studies, an assessment of exposure is hampered by the fact that the exposed population was either inadequately monitored or not monitored at all. Due to the fact that an exposure assessment is essential and at the core of any epidemiologic study, the absence of monitoring data offers no choice for the epidemiologist but to assign estimates of exposure by any available means. Rather than assigning doses to individuals, epidemiological investigations often have little choice than to assign a mean and standard deviation to a group of individuals and attempt to establish a statistical relationship between the radiological exposures of different groups and the incidence of a given biological endpoint within each group. As such, it is often not possible to reconstruct the doses to real individuals when performing epidemiologic studies. However, reconstructing individual exposures is essential for dose reconstruction under the EEOICPA.

SC&A carefully reviewed each of the six references in context with Section 2.1 of OCAS-IG-004 and concludes the following:

(1) A central objective of any retrospective epidemiologic study is the ability to demonstrate either a positive or negative relationship between a suspected agent and the exposed study cohort.

(2) Causality is best demonstrated by a positive dose response relationship between the suspected agent and the disease under study.

(3) A dose response can only be demonstrated if the exposure can be "quantified."

(4) In instances of inadequate or the complete absence of monitoring data, the epidemiologist has few options and may require the assignment of purely subjective and highly uncertain estimates of exposures to the study cohort.

(5) To demonstrate a positive dose response, the need for accuracy, however, is of limited significance as long as any systemic error in the assigned doses is applied consistently to all subpopulations of the exposed population under study. For example, if a radiological study cohort is divided into four groups with assigned exposures of 0–20, 21–40, 41–60, and 61–80 rem, it would make little difference to the ability to demonstrate a positive dose response to the induction of leukemia, even if the actual doses were in error by ± 50%. (Note: The impact of dose uncertainty is the accuracy of the leukemia risk coefficient. A classic example of this is the historical revisions to doses assigned to the A-bomb survivor cohort and the associated cancer risk coefficients cited in the NAS/BEIR Reports I, III, V, and VII.)

(6) In brief, the need to assign and quantify exposures in behalf of a retrospective epidemiological study is a requirement and not an option; and when monitoring data are either inadequate or totally lacking, the use of surrogate data represents the only available option.

(7) Under EEOICPA, the dividing line between compensation and denial of a claim rests with a DOL determination of whether or not the claim meets the "at least as likely as not" probability of causation (POC) threshold of 50% or more. Sometimes this determination utilizes a "best-estimate" dose reconstruction as one component of the DOL decision. Where there is insufficient data to estimate the radiation doses of the covered worker with sufficient accuracy, a determination to add a class of employees to the SEC under 42 CFR Part 83 can be made by the HHS Secretary.

It is SC&A's opinion that the objectives of dose reconstruction and the need for accuracy in epidemiologic studies and in a compensation program differ both qualitatively and quantitatively. SC&A believes that epidemiological investigations should not be used as a basis for justifying the use of surrogate data in dose reconstructions under the EEOICPA.

3.2 COMPENSATION PROGRAMS

In Section 2.2 of OCAS-IG-004, NIOSH states that the use of surrogate data has also been employed in the evaluation of worker exposures under the (1) Radiation Exposure Compensation Act (RECA), and (2) Nuclear Test Personnel Review (NTPR) program formerly administered by the U.S. Department of Veterans Affairs (VA). (Note: Currently, the Defense Threat Reduction Agency (DTRA) has the primary responsibility for the administration of the program, while the VA's role is limited to determining eligibility for compensation.)

For RECA, NIOSH cites the graded approach used for demonstrating compensable radon exposure (i.e., in excess of 40 working level months) to miners when mine-specific radon measurements are unavailable and the use of surrogate data from other mines is employed. For NTPR military personnel exposed to fallout from nuclear weapon tests, NIOSH cites the use of surrogate resuspension factors for modeling inhalation exposures as its example.

SC&A has concerns with OCAS-IG-004 in its use of dose reconstruction protocols adopted under RECA and the NTPR program as applicable dose reconstructions performed under the EEOICPA. The RECA is a program that is independent of the EEOICPA and is defined by regulations under 28 CFR Part 79 and 38 CFR Part 3. It is reasonable to assume that regulations developed in behalf of RECA were based on a clear understanding of the limited availability of personnel monitoring data involving miners (and other covered personnel). Thus, regulators anticipated the need for and use of surrogate data, and incorporated this provision in 28 CFR 79.

NIOSH's example of "surrogate" resuspension factors for modeling inhalation exposures in behalf of military personnel under the NTPR/DTRA compensation program does appear to be useful in defending the use of surrogate data for dose reconstructions under the EEOICPA. However, SC&A sees a substantive difference between using generic default modeling assumptions, such as resuspension factors, dust loadings, soil ingestions rates, etc., and other site data, such as air sampling, bioassay, and external dosimetry data. We believe it is the latter type of data that is at issue in OCAS-IG-004, not the former. Hence, reference to such data is of limited use as precedent for use of other site data under the EEOICPA.

3.3 GENERAL EXPOSURE MODELING

For its third category of precedential use of surrogate data, NIOSH cites a computer code [i.e., RESRAD-BUILD (Yu et al. 1994)]. This code is used to model expected annual doses for future occupants of formerly NRC-licensed facilities that have been remediated and are awaiting release for unrestricted use. The objective of running this model is to determine if potential/future total effective dose equivalents (TEDEs) to members of the public are in compliance with dose limits defined in 10 CFR 20, Subpart E.

By design, the need to predict future exposures can only be done by use of models for which parameter values must be assigned. (There is no choice.) The objectives of RESRAD-BUILD (and other codes) have little in common with dose reconstruction, as defined under EEOICPA.

4.0 ASSESSMENT OF SECTION 3.0 OF OCAS-IG-004: CRITERIA FOR USE OF SURROGATE DATA

4.1 GENERAL OBSERVATIONS

Key statements contained in the introduction to OCAS-IG-004 include the following:

Statement #1:

> *The basic principle of dose reconstruction is to characterize the radiation environments to which workers were exposed and then place each worker in time and space within this exposure environment.*

Statement #2:

> *When personnel monitoring data are unavailable or limited in number as to be unrepresentative, workplace measurements, such as air samples or area measurements of external dose may be used. Lacking the above, information about the sources and types of radiation present at a facility and the process operations involving the radioactive materials may be used to construct a model to estimate worker exposure.*

Statement #3:

> *When the source term and process information (hierarchy #4)[*] for a particular facility need to be supplemented to adequately characterize the workplace exposure conditions, it may be necessary to rely on data from another facility to completely develop an exposure model. The data, which could be obtained from any of the first three sources listed in Table 1, are referred to as surrogate data in this implementation guide.*

Statement #4:

> *Table 1* [of OCAS-IG-004] *provides a listing of the hierarchical approach to data source usage that is prescribed in NIOSH's dose reconstruction regulation (USHHS 2002).* [Emphasis added.]
>
> (Note: USHHS 2002 is 42 CFR Part 82.)

The use of the hierarchical data is clearly endorsed by 42 CFR 82 (see §82.2, as reproduced in Appendix A). However, when an exposure model is based on source term and process information, it is conditional, inasmuch as the model must incorporate a substantial body of facility-specific data [e.g., chemical form of radionuclide(s), particle size distribution, level of

[*] Note: Table 1 of OCAS-IG-004 lists the following sources for dose reconstruction in hierarchical order; (1) individual monitoring data, (2) monitoring data of coworkers at a site, (3) workplace monitoring data, and (4) source term data and process information.

containment, likelihood of dispersion, etc]. Furthermore, while § 82.2 does permit a combination of hierarchical data for dose reconstruction, it is not apparent that consideration was given to the use of data from other sites at the time that the rule was promulgated. Nevertheless, in the opinion of SC&A, it is not unreasonable to use data from other sites to supplement site-specific data in the performance of dose reconstruction if done so in a scientifically sound and claimant-favorable manner.

In Subsection 3.1 of Section 3.0 of OCAS-IG-004, NIOSH states the following:

> *In situations where NIOSH lacks personal and/or area monitoring data, the dose reconstruction regulation (USHHS 2002, 42 C.F.R. § 82.14 (h)(1) thru (5)) provides for the use of source-term and process data to complete reconstructions. Specifically, in section 82.2(c), it states:*
>
> > *If neither adequate worker nor workplace monitoring data are available, the dose reconstruction may rely substantially on process description information to analytically develop an exposure model.*
>
> *Because NIOSH has encountered a number of facilities where radiation monitoring data are sparse, models that incorporate non-facility-specific data to provide actual or bounding estimates of exposure are necessary to complete some dose reconstructions. These models may be needed to reconstruct dose for each type of exposure that is evaluated under EEOICPA (i.e., internal, external, environmental, and medical). To the extent possible, facility-specific data should be used in any dose reconstruction; however, data from other facilities should be used when necessary, according to the criteria outlined in this Implementation Guide.*

SC&A believes that, from a purely technical perspective, the concepts described in the introduction to OCAS-IG-004 are generally scientifically sound. The challenge will be to ensure that sufficient information is available characterizing the facility of interest such that informed judgments can be made when data and other information from other sites are either directly applicable or reasonably bounding[3] to the worker and the site of interest. In addition, when using data from other sites, it is important not to lose site of the hierarchy of data when integrating site-specific data with the data from other sites.

Subsections 3.2, 3.3, 3.4, 3.5, and 3.6 of OCAS-IG-004 describe the conditions and criteria under which surrogate data from other sites can be used, including the source term, facility and process similarities, temporal considerations, data quality, and models used to bound doses. The following sections provide commentary on each section.

[3] SC&A believes that the subject of "bounding" and/or "worst case" assumptions are important concepts that require a discussion of their own, and is not addressed in this report.

4.2 SOURCE TERM

It is self-evident that some site-specific information is needed regarding the types and quantities of material being processed at a facility before a surrogate facility can be found and used to supplement the information at the facility where a dose reconstruction is performed. The question is, how much and what type of information regarding the source term is needed to have confidence that a given facility can be used as a surrogate for another facility? Section 3.2 of OCAS-IG-004 goes on to state that knowledge that a facility processed uranium and thorium constitutes sufficient information, but then qualifies this statement by indicating that "for practical purposes, additional process information would be needed as well." SC&A believes that more information is needed regarding the source term than simply the knowledge that a given radionuclide was handled or processed at a facility. Section 3.2 of OCAS-IG-004 goes on to identify one piece of information that is important, at least with regard to uranium and thorium processing facilities. Specifically, Section 3.2 of OCAS-IG-004 states that consideration must also be given to the degree to which progeny of uranium and thorium are present at a site that processed uranium and thorium.

SC&A believes that OCAS-IG-004 needs to give more consideration to other factors related to the source term. For uranium and thorium processing facilities, the physical and chemical forms and the quantity of the material handled are needed. For instance, in the case of ores, the grade of ore is needed. As another example, it is important to know whether metal or salts are being handled, and whether the processes involve the potential for generation and suspension of fine particles in the workplace environment.

Another concern we have with this section is that although the title of OCAS-IG-004 would indicate that it applies to the use of other site data for all types of facilities, the discussion in Section 3.2 is limited to uranium and thorium processing facilities. The write-up in Section 3.2 regarding source term seems to be rushed. If OCAS-IG-004 was intended primarily for uranium facilities, it would have done well to reference TBD-6000 and -6001 and its various attachments, where a great deal of careful consideration is given to the source term. If OCAS-IG-004 was developed primarily for uranium facilities, there is some question whether it is actually needed, given TBD-6000 and -6001. There is no comparison in OCAS-IG-004 between the methods suggested there and those in TBD-6000 and -6001. This observation also applies to the other criteria.

4.3 FACILITY AND PROCESS SIMILARITIES

Section 3.3 of OCAS-IG-004 presents a general discussion of the importance of facility and process similarities, and provides several important considerations that are especially applicable to uranium and thorium handling and processing facilities. Consideration of breathing zone versus general air versus process samples, and the ventilation system design, is certainly especially important. However, again, this section seems to apply primarily to uranium and thorium handling and processing facilities. If this guide is intended to have broader applicability, substantially more guidance is needed. For example, for plutonium processing facilities, consideration needs to be given to whether high-fired plutonium was handled. We note that OCAS-IG-004 does not have an explicit discussion of why a particular site might be used for

surrogate data rather than another site where similar processes were carried out in the same general time period. Some discussion of a claimant-favorable process in this regard would be useful.

The general guidelines provided in Section 3.2 are certainly appropriate. However, OCAS-IG-004 would benefit from a more thorough and detailed treatment of the various facility designs and processes that need to be taken into consideration for a broad range of types of facilities, or to at least refer the reader to other guidelines, such as ORAUT-OTIB-0054 for reactors. Also, if breathing zone and process air samples are available from a surrogate facility, the processes that resulted in the production of aerosols at the surrogate facility and at the facility of concern are of considerable importance.

4.4 TEMPORAL CONSIDERATIONS

SC&A is in agreement with this section of OCAS-IG-004, insofar as it concerns the use of surrogate data from the same time period is concerned. SC&A points out that OCAS-IG-004 allows the use of data from other time periods, and that this is not in conformity with the Board's draft criteria. Given the evolution of production processes, as well as industrial hygiene and monitoring practices, SC&A finds that it is likely to be very difficult to provide convincing evidence of claimant favorability of surrogate data from later time periods extrapolated back in time to another facility.

4.5 DATA EVALUATION

SC&A is in agreement with this section of OCAS-IG-004.

4.6 REVIEW OF BOUNDING EXPOSURE MODELS

SC&A is in agreement with this section of OCAS-IG-004.

5.0 ASSESSMENT OF SECTION 4.0 OF OCAS-IG-004: EXAMPLES

Section 4 of OCAS-IG-004 presents examples of conditions under which surrogate data and information may be used to reconstruct internal and external doses. For internal exposures, Section 4.1 refers to the vast amount of air sampling, bioassay, and process data and information pertaining to uranium handing and processing facilities that operated during the early years when commercial facilities were under contract with the Atomic Energy Commission. SC&A has reviewed AWE records and documents in support of the review of numerous site profiles, exposure matrices, procedures, and dose reconstructions, and we concur that there is a vast amount of information available that can be used as surrogate data. However, we would like to reiterate that the challenge is to carefully select those datasets that apply to or that reasonably bound the conditions at the facility of interest, taking into consideration off-normal conditions, unique work practices, and accidents. This is the aspect of the use of surrogate data that is most challenging.

Section 4.2 presents examples of deriving external exposures using surrogate data. SC&A believes that successfully reconstructing exposures from surrogate data and using models can be much more readily achieved when reconstructing external exposures, as compared to reconstructing internal exposures. As indicated in Section 4.2, if the source term and geometric configuration of the external source of exposure is known, conventional external dosimetry computer codes, such as MicroShield and MCNP, and also hand calculations, can be used to place a plausible upper bound on exposures by using reasonably conservative assumptions regarding proximity to the source and duration of exposure. Hence, we concur with this aspect of Section 4 of OCAS-IG-004. However, this section would benefit from a discussion of using other site film badge data as a means to reconstruct external exposure to penetrating and non-penetrating radiation and neutron exposure.

6.0 COMPARISON OF THE CRITERIA IN OCAS-IG-004 WITH THE DRAFT CRITERIA DEVELOPED BY THE ADVISORY WORK GROUP ON SURROGATE DATA

The following table compares the four draft criteria developed by the Board's Work Group on Surrogate Data with the criteria delineated in OCAS-IG-004.

Table 1. Comparison of Working Group Draft Criteria and NIOSH Criteria for Use of Surrogate Data as Presented in OCAS-IG-004

Working Group Draft Criterion	NIOSH OCAS-IG-004 Criterion
Hierarchy of Data – It should be assumed that the usual hierarchy of data would apply to dose reconstructions for that site. Individual worker monitoring data are preferable to workplace monitoring data, etc. The use of surrogate data should also follow this hierarchy.	Hierarchy of Data – The comparable hierarchical approach is presented in Table 1 (p. 3)
Exclusivity Constraints – In some cases, there are no or very little monitoring data available. In those cases, the use of the surrogate data as the basis for individual dose reconstruction would need to be very stringently justified. This judgment needs to take into account not only the amount of surrogate data being relied on relative to data from the site, but also the quality of the surrogate data relative to data available for the site in question.	Data Evaluation (p. 8) – As with any data used in reconstructing doses, it is important to evaluate the quality of the data used in the development of an exposure model. The overall uncertainty of the model should reflect the uncertainty of that data used in its generation.
Site or Process Similarities – One of the key criteria for judging the appropriateness of the use of surrogate data would be the similarities between the site (or sites) where the data were generated and the site where the surrogate data are being utilized. The application of any surrogate data to an individual dose reconstruction at a site should include a careful review of the rationale for utilizing that source of data (why that site(s) - similarity of the production processes, monitoring methods, factors affecting exposures, etc.).	Facility and Process Similarities (p. 7) – For an exposure model to be sufficiently accurate, it must be based on a process that is substantially similar to the one being reconstructed. For example, operations that involve grinding, welding, or cutting have a high potential for generating airborne particulate and would be inappropriately modeled using data from a facility that performed solvent extraction operations.
Temporal Considerations – Consideration also needs to be given to the period in question, since working conditions and processes varied in different periods. Surrogate data should belong in the same general period as the period for which doses are sought to be reconstructed.	Temporal Considerations (p. 8) – Because building design and processes change over time, it is important to consider matching the surrogate facility time period of operation with the facility being modeled. If the era of operation of the surrogate facility differs substantially from the time period of operation for the facility being modeled, the appropriateness of the use of such data should be justified.
N/A	Plausibility (p.9) – When a bounding exposure model is developed using surrogate data, the upper bound must be plausible. That is, it must be realistically possible given the nature of operations at the facility being modeled and other relevant factors. While it is not possible to provide fixed criteria for evaluating plausibility, certain reasonableness tests can be applied. Each model should be evaluated for plausibility in light of the known conditions in existence at the facility.

From the comparison provided in Table 1, it can be seen that the work group draft criteria are embraced by OCAS-IG-004. Although the "Exclusivity Constraints" criterion is not explicitly included in OCAS-IG-004, the concept seems to be adequately covered by NIOSH.

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APPENDIX A: COMMENTARY ON THE PROVISIONS OF PART 82 THAT APPEAR TO APPLY TO THE USE OF DATA FROM OTHER SITES FOR DOSE RECONSTRUCTION

Subpart A - Introduction

§ 82.2 What are the basics of dose reconstruction?

The basic principle of dose reconstruction is to characterize the radiation environments to which workers were exposed and to then place each worker in time and space within this exposure environment. Then methods are applied to translate exposure to radiation into quantified radiation doses at the specific organs or tissues relevant to the types of cancer occurring among the workers. A hierarchy of methods is used in a dose reconstruction…

(b) If individual monitoring data are not available or adequate, dose reconstructions may use monitoring results for groups of workers with comparable activities and relationships to the radiation environment. Alternatively, workplace area monitoring data may be used to estimate the dose. As with individual worker monitoring data, workplace exposure characteristics are used in combination with workplace monitoring data to estimate dose.

(c) If neither adequate worker nor workplace monitoring data are available, the dose reconstruction may rely substantially on process description information to analytically develop an exposure model. For internal exposures, this model includes such factors as the quantity and composition of the radioactive substance (the source term), the chemical form, particle size distribution, the level of containment, and the likelihood of dispersion. …If radiation exposures in the workplace environment cannot be fully characterized based on available data, default values based on reasonable and scientific assumptions may be used as substitutes. For dose reconstructions conducted in occupational illness compensation programs, this practice may include use of assumptions that represent the worst case conditions. . . .

These provisions of the rule establish that dose reconstruction may involve the hierarchical use of data. Use of coworker data, however, is conditional and requires that the radiological conditions to which the unmonitored claimant was exposed are comparable (in time and space) to that of "coworkers for whom exposure data exists." The "substantial" use of source term and process description for dose reconstruction must consider a host of variables that affect external and internal exposure. In addition, the regulations cite the use of ". . . default values [that are] based on reasonable and scientific assumptions," as well as ". . . assumptions that represent the worst case conditions."

This part of the rule does not explicitly state that surrogate data can be used in dose reconstruction, nor does it explicitly state that such data cannot be used. It is our understanding that NIOSH interprets these provisions to include the use of data from other sites.

Subpart B - Definitions

§ 82.5(r):

(r) Worst-case assumption is a term used to describe a type of assumption used in certain instances for certain dose reconstructions conducted under this rule. It assigns the highest reasonably possible value, based on reliable science, documented experience, and relevant data, to a radiation dose of a covered employee.

When a worst-case assumption is employed in dose reconstruction, there are nevertheless constraints that limit the assignment of a quantitative value for a "worst-case" assumption. These provisions of the rule do not preclude the use of data from other sites as a means to assign worst-case assumptions for the purpose of dose reconstruction.

Subpart C – Dose Reconstruction Process

§82.10 (i)

(i) As necessary, NIOSH will characterize the internal and external exposure environments for parameters known to influence the dose. For internal exposures, examples of these parameters include the mode of intake, the composition of the source term (i.e., the radionuclide type and quantity), the particle size distribution and the absorption type. When it is not possible to characterize these parameters, NIOSH may use default values, when they can be established reasonably, fairly, and based on relevant science.

§82.10 (k)

(k) At any point during steps of dose reconstruction described in paragraphs (f) through (j) of this section, NIOSH may determine that sufficient research and analysis has been conducted to complete the dose reconstruction. Research and analysis will be determined sufficient if one of the following three conditions is met:

(1) From acquired experience, it is evident the estimated cumulative dose is sufficient to qualify the claimant for compensation (i.e., the dose produces a probability of causation of 50% or greater);

(2) Dose is determined using worst case assumptions related to radiation exposure and intake, to substitute for further research and analyses; or,

(3) Research and analysis indicated under steps described in paragraphs (f)–(j) of this section have been completed. Worst-case assumptions will be employed under condition 2 to limit further research and analysis only for claims for which it is evident that further research and analysis will not produce a compensable level of radiation dose (a dose producing a probability of causation of 50% or greater), because using worst-case assumptions it can be determined that the employee could not have incurred a compensable level of radiation dose.

In instances of unknowns, default values may be employed in dose reconstruction leading to either compensation or denial of the claim. The use of worst-case assumptions, at least as defined here, is restricted to non-compensable claims.