SC&A S. COHEN & ASSOCIATES
AN EMPLOYEE-OWNED COMPANY

November 23, 2005

Mr. David Staudt
Centers 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 200-2004-03805, Task 5, Subtask 1, *Review of NIOSH/ORAU Special Exposure Cohort Evaluation Procedures*

Dear Mr. Staudt:

SC&A is pleased to submit our draft report, *Review of NIOSH/ORAU Special Exposure Cohort Evaluation Procedures*. This review, prepared pursuant to the Subtask 1 of Task Order No. 5 of the subject contract, is focused on OCAS-PR-004, *Internal Procedures for Evaluation of Special Exposure Cohort Petitions*, dated September 23, 2004.

If you have any questions regarding this report, please feel free to contact me.

Sincerely,

John Mauro, PhD, CHP
Project Manager

cc: P. Ziemer, PhD, Board Chairperson
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Draft

ADVISORY BOARD ON RADIATION AND WORKER HEALTH

National Institute of Occupational Safety and Health

REVIEW OF NIOSH/ORAU SPECIAL EXPOSURE COHORT EVALUATION PROCEDURES

Contract No. 200-2004-03805
Task 5: Subtask 1
SCA-TR-TASK5-0001

Prepared by

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November 23, 2005

Disclaimer

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S. COHEN & ASSOCIATES: *Technical Support for the Advisory Board on Radiation & Worker Health Review of NIOSH Dose Reconstruction Program*	Document No. SCA-TR-TASK5-0001 Effective Date: Draft - November 23, 2005 Revision No. 0 (Draft)
REVIEW OF NIOSH/ORAU SPECIAL EXPOSURE COHORT EVALUATION PROCEDURES	Page 2 of 35
Task Manager: _____ Date:_____ Arjun Makhijani	Supersedes: N/A
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TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS

ABRWH	Advisory Board on Radiation and Worker Health (also referred to as Advisory Board or Board)
AWE	Atomic Weapons Employer
CFR	*Code of Federal Regulations*
DOE	U.S. Department of Energy
DOL	U.S. Department of Labor
EEOICPA	Energy Employees Occupational Illness Compensation Program Act
HHS	U.S. Department of Health and Human Services
IAAP	Iowa Army Ammunition Plant
LOD	Limits of Detection
MAC	Maximum Allowable Concentrations
NIOSH	National Institute for Occupational Safety and Health
OCAS	Office of Compensation and Analysis Support
ORAU	Oak Ridge Associated Universities
POC	Probability of Causation
SC&A	S. Cohen and Associates
SEC	Special Exposure Cohort
TBD	Technical Basis Document
TIB	Technical Information Bulletin

1.0 EXECUTIVE SUMMARY

The Energy Employees Occupational Illness Compensation Program Act (EEOICPA) provides for the U.S. Department of Health and Human Services (HHS) to add certain classes of U.S. Department of Energy (DOE), Atomic Weapons Employer (AWE), contractor, or subcontractor employees to the Special Exposure Cohort (SEC) under specified conditions. The rules, described in Title 42, Part 83, of the *Code of Federal Regulations* (42 CFR 83), relate to the process for filing petitions for additions to the Special Exposure Cohort and the ways in which National Institute of Occupational Safety and Health (NIOSH) and its contractors would evaluate the petitions.

This report is a review of NIOSH procedures and guidelines to implement 42 CFR 83. SC&A prepared this review pursuant to a decision by the Advisory Board on Radiation and Worker Health (hereafter referred to as the Board) to review NIOSH procedures and guidelines for evaluating SEC petitions. The main procedures for implementing 42 CFR 83 are set forth in *Internal Procedures for the Evaluation of Special Exposure Cohort Petitions*, OCAS-PR-004, Rev. 0, dated September 23, 2004 (referred to hereafter as NIOSH SEC procedures or as OCAS-PR-004). This review is focused on OCAS-PR-004. It also covers the forms that petitioners must file (Forms A and B), and the instructions for filling out Form B. Finally, this review also addresses a few aspects of OCAS-IG-001 and OCAS-IG -002 to the extent that they affect the determination of the feasibility of dose reconstruction with sufficient accuracy as required under 42 CFR 83.

1.1 Principal Strengths

- OCAS-PR-004 provides a logical step-by-step procedure for following 42 CFR 83 and preparing the various documents and findings required under the rule.
- The NIOSH procedures provide for assistance to petitioners in completing petitions and providing additional information in order to facilitate the qualification of the petition for evaluation.
- The NIOSH procedures provide for splitting up the class into subclasses when NIOSH determines that it is not possible to do dose reconstructions for one or more sub-groups of the class, but that it is possible to do dose reconstructions for others.
- OCAS-PR-004 contains several hypothetical, qualitative examples that help clarify the directions given in the guidelines. The examples are rather schematic and simple, and would be expected to be helpful in very straightforward cases.
- The NIOSH procedures rely on completed and in-process dose reconstructions that are relevant to the class in its petition evaluation.
- The NIOSH SEC procedures make provision for dose reconstruction for non-SEC cancers in cases where the petition is granted in view of the fact that dose reconstruction for some cancers may still be possible.

- Appendix B to OCAS-PR-004, Rev. 0, provides a useful summary of the DOE request for monitoring and related records that is indicative of the type of information that would be considered in evaluating the feasibility of dose reconstruction.
- Appendix C provides a helpful evaluation report template comprising an evaluation summary, class definition proposed by the petitioners and petition basis, description of the data collection effort and its results, summary of radiological operations relevant to the initial class, evaluation of the feasibility of dose reconstruction, summary of feasibility findings, evaluation of health endangerment, and definition of the class or classes established on the basis of the analyses.

1.2 Principal Findings

SC&A has arrived at the findings below in light of the requirements of 42 CFR 83 for petition evaluation. Specifically, they are focused on the requirement that NIOSH demonstrate the feasibility of reconstructing doses with sufficient accuracy for all 22 SEC cancers and all members of the proposed class in the meaning of the term "sufficient accuracy" as defined in 42 CFR 83. As a general matter, SC&A notes that the requirements for assessing whether there are sufficient data to estimate "maximum radiation dose" that could have been incurred "in plausible circumstances by any member" (42 CFR 83.13(c)(1)) of the entire class of workers in a manner that is fair, uniform, and scientifically sound poses special challenges. Some of these challenges have been illustrated by the evaluations of the SEC petitions for IAAP and for the 1949–1957 period for Mallinckrodt. Those cases show the importance of using (1) complete or partial dose reconstructions that, together, would be representative of all members of the class, and all periods, processes, and radionuclides covered by the job types in question to illustrate NIOSH's ability to reconstruct doses with sufficient accuracy, and (2) data that have been sufficiently validated and shown to have the integrity needed to support the claims of ability to reconstruct maximum doses. The use of other documentation and data, such as site profiles and workbooks, should also be subjected to sufficient checks to ensure that there are no essential problems that would prevent dose reconstruction with sufficient accuracy for the members of the proposed class.

As a preface to these findings, SC&A would like to emphasize that we recognize that the final decision regarding whether a given petition meets the SEC acceptance criteria pertaining to the plausibility of performing a dose reconstruction for a given class of workers and the health endangerment provisions of the rule will include "judgment calls" that are specific to each petition. The findings below represent an attempt to assist NIOSH and the Board in developing guidelines that will help to ensure that these judgments explicitly address the full range of pertinent issues and are made in a scientifically valid, claimant-favorable, and consistent manner.

Finding 1: The NIOSH procedures need to provide more complete guidance to the Office of Compensation Analysis and Support (OCAS) staff and its contractors regarding acceptable methods for estimating the maximum dose for the class. Without guidelines to address the problem of constraining maximum dose estimation methods, it will be difficult to arrive at a result that simultaneously fulfills the criteria of scientific soundness and claimant favorability, and uniform and fair consideration for all members of the class, as required by 42 CFR 83.

Finding 2: NIOSH needs to provide a practical way to distinguish between the definition and use of "maximum radiation dose" under 42 CFR 83, and the definition and use of "highest reasonable possible value" of dose using "worst-case assumptions" used only to deny compensation under 42 CFR 82.10(k)(2) and (k)(3) using the definition in 42 CFR 82.5(r). The latter kind of dose estimate is used only for denial on the grounds that a higher dose estimate is not scientifically credible. This is expressed in the regulation by the statement that "[d]oses estimated using worst-case assumptions will not involve uncertainty" (42 CFR 82, paragraph O, pg. 22324). The main implication is that the dose estimate using worst-case assumptions under 42 CFR 82 should be greater than the maximum dose in plausible circumstances under 42 CFR 83. Yet, there is no constraint in the procedures that this inequality should apply.

Finding 3: NIOSH SEC procedures contain no guidelines for judging when data are or are not adequate for maximum dose estimates in plausible circumstances. For instance, they do not require creation of radionuclide lists applicable to different members of the class. Nor do they provide guidance on other critical issues, such as evaluation of data integrity or data needed to conclude that doses for unmonitored workers are (or are not) bounded by those for monitored workers.

Finding 4: NIOSH SEC procedures do not set forth specific guidelines for co-worker data that would ensure that the estimated doses bound those for all members of the class when individual monitoring data are not available. The examples provided are insufficient to ensure uniform and fair consideration in complex circumstances, such as when job types are not easily comparable. Just as examples are provided for the use of co-worker data for reconstructing doses for unmonitored or inadequately monitored workers, examples should be provided describing when it is not possible to reconstruct doses using co-worker data.

Finding 5: The procedures propose to use completed dose reconstructions, which is a strength, but do not require a them to be internally checked as representative of a class of workers. The procedures should provide guidelines that help to ensure that the cases are representative of members of the class or time periods under consideration in the SEC petition, so that the ensemble of dose reconstructions used enables a judgment about dose reconstruction feasibility under 42 CFR 83.

Finding 6: The discussion of the term "incident" in the NIOSH procedures follows 42 CFR 83. However, it is not sufficiently developed to ensure that workers with less than 250 days employment, and who may have worked in conditions of failure of radiological controls or experienced a serious incident, other than one similar to a criticality accident, receive comparable consideration in regard to a health endangerment as those who have 250 or more days of employment.

Finding 7: NIOSH guidelines do not address how issues of job types and incidents for proposed SEC classes that have very large proportions of survivor claimants might be addressed, particularly for petitions involving the early years (~first two decades after the start of the Manhattan Project). In this respect, survivor claimants who decide to become petitioners may find it considerably more difficult to provide the required information. The procedures make no special allowance for NIOSH assistance in such cases.

Finding 8: NIOSH SEC procedures provide for interviews with petitioners, but do not require that even one such interview be conducted. This could result in missed information or misinterpretation of the intent of the petitioners. It may also contribute to reduced confidence in case NIOSH rejects a petition.

Finding 9: NIOSH procedures do not provide guidelines for the selection of facilities or processes from other sites that could be used in SEC petition evaluations. This increases the risk of scientific misjudgments and inconsistencies.

Finding 10: NIOSH procedures do not contain any specific guidelines that may be needed to supplement OCAS-IG-001 and OCAS-IG-002, the guidelines for external and internal dose reconstruction, respectively, devised for use in individual dose reconstruction. Such supplementary guidelines are needed in several areas, some of which are identified in this review. Of particular concern is guidance for performing plausible maximum radiation doses for a class of workers.

Finding 11: NIOSH procedures provide no significant discussion of the contents of the evaluation plan that is to be presented to the Board under 42 CFR 83.12(c).

Finding 12: NIOSH procedures are not detailed enough about how the breadth of a class added under 42 CFR 83.14 (when Form A is filed) would be determined.

Finding 13: Part 83.13 requires that a dose reconstruction is considered feasible only if it is "based on some information from the site where the employee worked." The procedures need to present guidance or examples of what constitutes "some information," and how marginal information is to be distinguished from data that could be considered to be at least a partial basis for dose estimation. Our review of several dose reconstructions under 42 CFR 82 where the claimant was compensated found that NIOSH used bounding analyses that made no use of site-specific information other than, for example, the fact that uranium was handled at the site of interest, and it was also handled at the site(s) from which the surrogate data were used for dose reconstruction. It is questionable whether this approach, if used as a basis for determining that a dose reconstruction is feasible, meets the intent of Part 83.13 for use of site-specific data.

1.3 Suggestions for Improvement

Some of the following suggestions for improvement, such as use of dose reconstruction reviews and site profile reviews, derive from the fact that certain procedures and guidelines may have been difficult or impossible to put in place at the time OCAS-PR-004 was published (September 2004). Such suggestions should not be viewed as resulting from deficiencies, but rather as updates of the procedures that are needed.

(1) The procedures should be updated to reflect the experience of the Iowa Army Ammunition Plant SEC evaluation, keeping the potential for similar cases in view. Specifically, the procedures should include explicit constraints on plausible circumstances used to make maximum dose estimates to ensure that the results are fair to

and uniform for all members of the proposed class, even when they are based on assumptions not related to working conditions at the plant.

(2) The procedures should include examples of cases where NIOSH found that it was not possible to perform dose reconstruction, and incorporate the rationale used in these determinations into guidelines that can be used to determine when a dose reconstruction cannot be performed.

(3) The procedures should address timeliness issues; i.e., guidance that addresses conditions where it does not appear plausible to reconstruct doses in a timely manner. The timeliness guideline should be linked to technical feasibility. If the petition evaluation determines that a set of technical methods exists to reconstruct doses with sufficient accuracy, the evaluation should also address whether the methods can be applied to the claimants who are members of the proposed class within a reasonable time frame.

(4) NIOSH SEC procedures should explicitly constrain maximum doses under 42 CFR 83 to be less than highest reasonable dose using worst-case assumptions under 42 CFR 82 in those cases where a petition is denied. In some cases where NIOSH's worst-case assumptions are not related to facilities or radionuclide lists that are similar to the site or facilities under consideration, this might require NIOSH to revisit the worst-case assumptions it is using under 42 CFR 82. One example may be NIOSH's use of the Hanford radionuclide lists as worst-case assumptions for Mallinckrodt workers compared to the approaches developed during the Site Profile Review process (ORAUT-OTIB-0002, 2004; SC&A 2005a; SC&A 2005b). In other words, the following inequality should be made a part of the procedures for transition between 42 CFR 83 and 42 CFR 82 in cases where NIOSH proposes to deny the petition on grounds of feasibility of dose reconstruction:

$$D_{82worstcase} \geq D_{83max}$$

where $D_{82worstcase}$ is the highest reasonable value of dose using worst-case assumptions under 42 CFR 82, and

D_{83max} is the maximum dose in plausible circumstances using the methods proposed in a 42 CFR 83 petition evaluation that recommends a denial of the petition.

(5) NIOSH procedures should explicitly require that the data and other information used for evaluating petitions be appropriately verified, by sampling for instance, and checked for correctness, as applied to a given class of workers, and that the completed dose and partial dose reconstructions used for determining feasibility of dose reconstruction with sufficient accuracy should cover or bound all job types and periods for all members of the proposed class.

(6) NIOSH procedures should require at least one interview with one petitioner as part of the evaluation process. One or more interviews may be conducted under current procedures, but they are optional. At least one interview is needed to ensure a thorough evaluation process and to increase petitioner confidence in case the SEC petition is denied.

(7) A more inclusive statement of health endangerment in cases where a member of the proposed class has worked for less than 250 days is needed. Specifically, while the current guidelines regarding high-exposure incidents provide adequate guidance for extreme conditions, there are other conditions involving failure of radiological controls that could result in health endangerment as defined, for instance, by a probability of causation of 50% or more that may be unfairly excluded under the current procedure.

(8) NIOSH should make explicit provisions to provide additional assistance to survivors who wish to become petitioners in completing Form B, especially for the early periods, since many or most employees may no longer be available to provide assistance and expertise to survivors in such cases.

(9) NIOSH should supplement the guidelines in OCAS-IG-001 and OCAS-IG-002 to address the specific requirements of SEC petition evaluations in regard to maximum dose estimates in plausible circumstances.

(10) NIOSH procedures should be updated to include detailed guidelines for determining members of the class in cases where Form A is filed (i.e., where NIOSH has determined it cannot complete a dose reconstruction).

(11) The NIOSH SEC petition evaluation plan that it is required to present to the Board should include the documentary basis for the evaluation, dose reconstruction that it might use in the process, and other details that it has decided on at the initial stage. As NIOSH adds documentation, dose reconstructions, analyses of data, and other elements to its petition evaluation process, it should inform the Board in a prompt manner, and make the documents and analyses available to the Board. Such a process would facilitate timely Board consideration of SEC petition evaluations when they are completed.

2.0 INTRODUCTION

The Energy Employees Occupational Illness Compensation Program Act (EEOICPA) provides for the U.S. Department of Health and Human Services (HHS) to add certain classes of U.S. Department of Energy (DOE), Atomic Weapons Employer (AWE), contractor, or subcontractor employees to the Special Exposure Cohort (SEC) under specified conditions. HHS has set forth the regulations for designating these classes in Title 42, Part 83 of the *Code of Federal Regulations* (42 CFR 83, *Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000*, May 28, 2004). The rules described in 42 CFR 83 include a process for employees, survivors, or certain of their representatives to file petitions for inclusion in the SEC, as well as a process by which the National Institute of Occupational Safety and Health (NIOSH) and its contractors would evaluate the petitions that are being developed for the addition of employees of other DOE facilities and AWEs to the SEC. This report is a review of NIOSH procedures and guidelines to implement 42 CFR 83. SC&A prepared this report pursuant to a decision by the Advisory Board on Radiation and Worker Health (the Board) to review NIOSH procedures and guidelines for evaluating SEC petitions. The main procedures for implementing 42 CFR 83 are set forth in *Internal Procedures for the Evaluation of Special Exposure Cohort Petitions*, OCAS-PR-004, dated September 23, 2004 (referred to hereafter as SEC procedures or as OCAS-PR-004).

Addition to the SEC depends on two criteria under 42 CFR 83:

> *HHS determines that (1) it is not feasible to estimate with sufficient accuracy the radiation dose that the class received; and (2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class.*

Claimants choosing to petition for addition to the SEC must submit a petition to the U.S. Department of Labor (DOL). 42 CFR 83 divides petitions into the following two main categories:

(1) **Petitions under 42 CFR 83.9(b) in which NIOSH has already determined that a dose reconstruction cannot be completed under 42 CFR 82:** These petitioners only need to cite NIOSH's finding that a dose reconstruction is not possible. Petitioners are not required to provide any additional information other than basic identification information.

(2) **Petitions for all cases where NIOSH has not made a finding that dose reconstruction cannot be completed**: The requirements for specification of the class and other information to be included in the petition are set forth in 42 CFR 83.9(c). The requirements in 42 CFR 83 for the content of petitions have the stated intention "to ensure that petitions are submitted by authorized parties, are justified, and receive uniform, fair, scientific consideration." While EEOICPA itself specifies inability to do dose reconstruction with "sufficient accuracy" as the criterion for addition to an SEC, 42 CFR 83 specifies the overarching criterion for this as maximum dose estimation in "plausible circumstances." This is specified in 42 CFR 83.13(c)(1)(i) as follows:

> *Radiation doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose, for every type of cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any member of the class, or if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose.* (42 CFR 83.13(c)(1)(i))

2.1 Statement of Purpose and Scope of the Review

SC&A reviewed selected NIOSH documents to evaluate their consistency with 42 CFR 83, and with the dose reconstruction procedures in 42 CFR 82 and related guidelines in so far as they apply to 42 CFR 83. Specifically, minimum dose reconstruction guidelines in 42 CFR 82 are not relevant. Efficiency procedures for maximum dose specifically designed to shorten the dose reconstruction effort are also not relevant. The procedures and guidelines that SC&A reviewed are as follows:

(1) SEC Petition Forms A and B.

(2) SEC Petition Form B Instructions.

(3) *Internal Procedures for the Evaluation of Special Exposure Cohort Petitions*, OCAS-PR-004, September 23, 2004.

(4) Office of Compensation Analysis and Support (OCAS) and Oak Ridge Associated Universities (ORAU) procedures guidelines for dose reconstruction. This portion of the review relied largely on work already completed by SC&A under Task 3.

The last item in the above list has largely been covered in SC&A's review of guidelines and procedures under Task 3 (SC&A 2005d) submitted to the Board in January 2005. Under the current task, SC&A incorporates by reference those parts, if any, of the Task 3 review that are relevant to SEC petition evaluations.

2.2 SC&A's Approach to Reviewing Documents

The SC&A review of the procedures and other documents focuses on the extent to which they are suitable for allowing NIOSH to have a sufficient and scientifically sound basis in data and analytical approach to evaluate petitions so that they "receive uniform, fair, and scientific consideration," as required by 42 CFR 83.1. So far as ability to reconstruct doses is concerned, SC&A's review of procedures and guidelines focuses on the 42 CFR Part 83 definition of "sufficient accuracy;" that is, on maximum dose estimates under "plausible circumstances" or dose estimates more precise than the maximum.

2.3 Structure and Organization of the Report

- Section 1 is the Executive Summary
- Section 2 is the Introduction
- Section 3 covers the SEC Petition Forms A and B, and SEC Petition Form B Instructions
- Section 4 reviews the strengths of OCAS-PR-004
- Section 5 discusses SC&A Findings relating to OCAS-PR-004 and specific issues in NIOSH dose reconstruction guidelines OCAS-IG-001 and OCAS-IG-002 as they relate to SEC petition evaluation

3.0 SPECIAL EXPOSURE COHORT PETITION FORMS A AND B

3.1 SEC Petition Form A (OMB Number: 0920-0639)

Form A is for claimants who have been informed by NIOSH that it cannot reconstruct a claimant's dose. In effect, Form A allows the claimant to become a petitioner as well. This enables the claimant to receive compensation, because NIOSH cannot reconstruct the employee's dose. At the same time, it allows NIOSH to proceed with defining a class of employees that would fit the same criteria for identification.

SC&A finds the procedure specified in Form A appropriate for claimants whose doses NIOSH has found it cannot reconstruct. Under 42 CFR 83.14, NIOSH constructs the class corresponding to these cases using criteria specified in 42 CFR 82.13. The review of OCAS-PR-004 in Section 5 of this report covers the question of the guidelines in relation to the definition of the Class for those cases where the petitioner has filed Form A.

NIOSH procedures provide for addition of an entire class to the SEC in such cases, using the rules under 42 CFR83.13. However, the NIOSH SEC procedures do not provide detailed guidelines on how this might be done, leading to a risk of inconsistency across petitions.

3.2 SEC Petition Form B and Instructions (OMB Number: 0920-0639)

Form B is more elaborate than Form A, because it is for use by petitioners who are expected to provide some basis regarding the infeasibility of dose reconstruction with sufficient accuracy for the proposed class. Petitioners can be claimants, but they do not have to be. There is provision in 42 CFR 83 for representatives of claimants to be petitioners. Form B makes provisions for petitioners to supply information regarding radiation dose records, working conditions, incidents, and other issues relating to the feasibility of dose reconstruction. Affidavits by employees or former employees, as well as expert reports by health physicists, can be filed together with the form. The provisions of Form B, therefore, correspond to 42 CFR 83.9(c), which specifies the documentation and information that should accompany the petition.

NIOSH has also published line-by-line instructions for completing Form B. These instructions are useful and can be expected to assist petitioners in filling out the form.

There are no regulatory issues relating to Form B and the accompanying instructions. Since survivors may take the assistance of representatives of labor organizations or of health physicist experts in preparing the petition, and since representatives of labor organizations can themselves be petitioners, the problem of uniform and fair consideration appears to be considerably less difficult than the corresponding problem in interviews, which SC&A discussed in its Task 3 report (SC&A 2005d, Section 5). Finally, NIOSH also makes provisions for assisting petitioners to provide missing documentation after it receives the petition. This is part of NIOSH's procedure for deciding which petitions it is going to take up for evaluation.

Despite these features of Form B and the accompanying instructions and NIOSH process, the hurdles are higher for survivor petitioners who want to file Form B than they are for employee

petitioners. One large area of difference is that survivor petitioners cannot be expected to know about incidents. Secrecy and work culture often led to employees not discussing details of their work with family members. It was often a requirement of the classification status of the work to keep the nature of the work secret. Under the circumstances, employee petitioners would be far more likely to remember incidents in which high exposures could have occurred. The issue of incidents is even more important in case of SEC petitions than it is for dose reconstructions for the following reasons:

- SEC petitions involve situations where petitioners believe that records are incomplete, non-existent, or deficient in some other fundamental way so as to prevent dose reconstruction.
- A finding of health endangerment can occur without a 250-day minimum work time if the class was exposed to an incident with sufficiently high radiation levels or failure of radiation controls.

NIOSH does provide assistance to petitioners in completing the forms and enhancing the information provided. However, the application process should specifically assist survivors who wish to become petitioners in regard to matters such as job types, exposure periods, and incidents. This would help to reduce any inequities between petitioners who are survivors and petitioners who are former workers.

3.2.1 Miscellaneous Comments on Form B

(1) The words "An authorization," which appear at the bottom of page 1, do not appear to be connected to any other words.

(2) In the black IMPORTANT section at the top of Page 2 of 10, the definition of “Class” should include the time period.

(3) C.7b, Dates of Employment, and C7d, Work Site Location, on page 2, are redundant to information requested in Section E.

(4) Reference is made on page 6 and in Section F (p. 8) to the General Accounting Office. The name of this office has been changed to the Government Accountability Office.

(5) Section F does not provide for explanations of suggested evidence about cases where monitors were not functional or were inadequately calibrated to the point that dose reconstruction might be significantly affected or compromised.

4.0 INTERNAL PROCEDURES FOR THE EVALUATION OF SPECIAL EXPOSURE COHORT PETITIONS (OCAS-PR-004) - STRENGTHS

SC&A reviewed the NIOSH procedures (OCAS-PR-004, Rev. 0, September 23, 2004) to evaluate compliance with the provisions of 42 CFR 83, primarily those related to dose reconstruction, rather than to administrative or procedural matters, undertaken by NIOSH, its contractors, or other offices under HHS. The document contains a careful, logical, step-by-step procedure for meeting the requirements of 42 CFR 83.

4.1 Procedural Strengths

The guidelines contain a step-by-step procedure for determining whether NIOSH can perform dose reconstructions for the entire class of employees that are the subject of the petition. The step-by-step format of the NIOSH guidelines is seen in several subsections of Section 6, which contain directions of the form, "If … go to step …." The evaluator can follow the instructions from subsection to subsection until the appropriate methodology for the petition being reviewed is fully executed.

The procedure also provides for splitting up the class into subclasses when NIOSH determines that it is not possible to do dose reconstructions for one or more sub-groups of the class, but that it is possible to do dose reconstructions for others. This division of claimants addresses the directions of 42 CFR 83.13(2)(d)(2)(ii), which require "the identification of any group of employees who were identified in the original petition(s) who should constitute a separate class of employees." Two examples of defining sub-groups where dose reconstruction may be feasible are taken from Section 6:

> *If one or more dose reconstructions have been completed or initiated and they demonstrate feasibility only for a subgroup of the petitioning class of employees, as appropriate under 6.3.2, define the two separate classes of employees accordingly (one class of employees for which dose reconstruction is feasible, and one class for which feasibility must still be determined). Go to step 6.3.9 for the class for which dose reconstruction is feasible and go to step 6.3.4 for the class for which the feasibility of dose reconstruction must still be determined.* (§6.3.3.2)

> *If the personnel and/or area monitoring data are available and adequate to conduct dose reconstructions only for a subgroup of the class of employees considered in this step, as appropriate under 6.3.2, define two separate classes of employees accordingly (one class of employees for which dose reconstruction is feasible, and one class for which it is not). Go to step 6.3.9 for the class for which dose reconstruction is feasible and go to step 6.3.5 for the class for which personnel and/or area monitoring data are not available and adequate.* (§6.3.4.2)

4.2 Examples, Notes, and Discussions

The NIOSH guidelines contain several hypothetical, qualitative examples in Sections 6.3 (Evaluate a petition qualifying for evaluation under §83.13) and 6.4 (Evaluate the petition qualifying for evaluation under §83.14, for a claimant for whom OCAS was unable to complete a dose reconstruction). These examples are set off from the main text by boxes and help clarify the procedures. An illustration is taken from Section 6.4.4:

> ***Example**: OCAS found that it could not complete a dose reconstruction for employee John Q. Public. Mr. Public was exposed to radiation during an incident, for which there any no monitoring data and inadequate source term and process data.…* (§6.4.4)

Several helpful notes also appear at the beginning of major sections to inform the reader of the purpose of a particular section. For example, the note in Section 6.1 begins as follows:

> *Note: The steps and procedures under 6.0 are intended to provide guidance for determining whether a petition meets the requirements specified under 42 CFR Part 83 to qualify for evaluation by NIOSH, the Advisory Board on Radiation and Worker Health ("the Board"), and the Secretary of HHS.* (§6.1)

The procedures also include boxed discussions to clarify certain points. The following is taken from a section dealing with evaluation of petitions against requirements of 42 CFR 83.9(c)(2) and (3):

> *Discussion: "Adequacy" and "credibility" are not judgments subject to any rigid criteria; because each case is likely to be unique, "adequacy" and "credibility" will be determined on a case-by-case basis, based on a totality of the circumstances.* (§6.1.5.1.1)

4.3 Completed Dose Reconstructions

The NIOSH procedures use completed dose reconstructions, when applicable, as part of the process of making judgments of feasibility of dose reconstruction for all or parts of the class. This practice should facilitate petition evaluations and promote review consistency. An illustration can be taken from the section presenting guidelines for evaluating petitions under 42 CFR 83.13:

> *Determine whether one or more dose reconstructions have been completed and/or initiated that demonstrate that dose reconstructions are feasible for the class of employees identified in the petition, or, if appropriate under 6.3.2, for a subgroup thereof, in light of the information provided in the petition concerning the feasibility of estimating radiation doses for the class of employees identified in the petition.* (§6.3.3)

4.4 Partial Reconstructions

Section 6.3.10 contains the appropriate caution that a determination that NIOSH cannot reconstruct doses for all members of the class and the 22 cancers in the SEC list does not mean that NIOSH cannot reconstruct some doses for *some* cancers for *some* members of the class. NIOSH applies this caution specifically to non-SEC cancers. As such, it is a necessary (but not sufficient) part of the procedure that would enable next steps in regard to estimation of doses for non-SEC cancers.

> *Include the following statement: "The determination by NIOSH that it cannot estimate radiation doses with sufficient accuracy for members of this class does NOT necessarily mean that NIOSH cannot estimate ANY radiation doses with sufficient accuracy for ALL members of this class." In a case in which a member of this class incurred a cancer not included among the 22 specified cancers covered by EEOICPA and hence requires a dose reconstruction (or would otherwise be left without a remedy), it is possible that NIOSH could reconstruct some or all of the radiation doses relevant to the individual's cancer in conformance with 42 CFR Part 82.* (§6.3.10.2(5))

4.5 Data Lists

Appendix B to OCAS-PR-004 provides a useful summary of the DOE request for monitoring and related records that is indicative of the type of information that would be considered in evaluating the feasibility of dose reconstruction.

4.6 Report Format

Appendix C provides a helpful evaluation report template comprising an evaluation summary, class definition proposed by the petitioners and petition basis, description of the data collection effort and its results, summary of radiological operations relevant to the initial class, evaluation of the feasibility of dose reconstruction, summary of feasibility findings, evaluation of health endangerment, and definition of the class or classes established on the basis of the analyses.

5.0 INTERNAL PROCEDURES FOR THE EVALUATION OF SPECIAL EXPOSURE COHORT PETITIONS (OCAS-PR-004) - FINDINGS

In evaluating the NIOSH SEC procedures, SC&A considered the implications of the individual dose reconstruction regulation, 42 CFR 82, the SEC regulation, 42 CFR 83, and their relationship to each other. This relationship is discussed in a general way in 42 CFR 83, and has significant implications for the petition evaluation guidelines that the NIOSH procedures should contain.

Section I.C of the Final Rule to 42 CFR 83 identifies the "Purpose of the Rule," and states the following:

> *The purpose of this rule is to establish procedures by which the Secretary of HHS will determine whether to add to the cohort new classes of employees from DOE and AWE facilities. The procedures are intended to* ***ensure*** *that petitions for additions to the Cohort are given* ***uniform, fair, scientific consideration****, that petitions and interested parties are provided the opportunity for appropriate involvement in the process…*
>
> *42 CFR Part 82 provides the methods by which NIOSH is conducting dose reconstructions to estimate the radiation doses incurred by individual covered employees who have incurred cancer. These estimates are required by EEOICPA for DOL to adjudicate a cancer claim for an employee who is* ***not*** *a member of the Cohort or whose claim is not covered by provisions of EEOICPA for compensating members of the Cohort. The methods to arrive at these estimates,* ***however, will be directly considered*** *by HHS in reviewing petitions to add classes of employees to the Cohort. In particular, HHS will consider these methods in determining for a petitioning class of employees, as required by EEOICPA, whether ''it is not feasible to estimate with* ***sufficient accuracy*** *the radiation dose that the class received.''* [42 CFR 83, Section I.C, Federal Register, Vol. 69, No. 104, May 28, 2004, pp. 30764-30765, Emphasis added.]

Regulatory requirements for adding new classes to the cohort are defined in 42 CFR Part §83.13(c), which states how NIOSH will evaluate records and information to make critical determinations about the following question:

> *Is it feasible to estimate the level of radiation doses of individual members of the class with sufficient accuracy?*
>
> *(i) Radiation doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the* ***maximum radiation dose, for every type of cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any member of the class, or if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose.*** *NIOSH must also determine that it has information regarding monitoring, source, source term, or*

> *process **from the site where the employees worked to serve as the basis for a dose reconstruction. This basis requirement does not limit NIOSH to using only or primarily information from the site where the employee worked, but a dose reconstruction must, as a starting point, be based on some information from the site where the employee worked**.*
>
> *(ii) In many circumstances, to establish a positive finding under paragraph (c)(1)(i) of this section would require, at a minimum, that NIOSH have access to reliable information on the identity or set of possible identities and maximum quantity of **each radionuclide** (the radioactive source material) to which members of the class were potentially exposed without adequate protection. Alternatively, if members of the class were potentially exposed without adequate protection to unmonitored radiation from radiation generating equipment (e.g., particle accelerator, industrial x-ray equipment), in many circumstances, NIOSH would require relevant equipment design and performance specifications or information on maximum emissions.*
>
> *(iii) In many circumstances, to establish a positive finding under paragraph (c)(1)(i) of this section would also require information describing the process through which the radiation exposures of concern may have occurred and the physical environment in which the exposures may have occurred.* [Emphases added.]

SC&A interprets these statutory requirements to include the following:

(1) Guidance and procedural documents currently employed to adjudicate claims under 42 CFR 82 are potentially also applicable for the evaluation of SEC Petitions under 42 CFR 83.

(2) Denial of a Petition for SEC status requires that, at a minimum, "radiation doses can be estimated with **sufficient accuracy** if NIOSH has established that it has access to **sufficient** information to estimate the **maximum** radiation dose, for **every** type of cancer … that could have been incurred in **plausible** circumstances by **any** member of the class." [Emphasis added.]

(3) Denial of a Petition also requires that NIOSH "… has [at least some] information regarding monitoring, source, source term, or process **from the site where the employees worked**." [Emphasis added.]

(4) Lastly, denial of a Petition requires "… that NIOSH have access to **reliable** information on the **identity** or set of possible identities and **maximum quantity** of **each** radionuclide (the radioactive source material) to which members of the class were potentially exposed without adequate protection." [Emphasis added.]

The findings below discuss various aspects of these requirements. As a general matter, SC&A notes that assessing whether there are sufficient data to estimate maximum doses for an entire class of workers in a manner that is fair, uniform, and scientifically sound poses special

challenges. Some of these challenges have been illustrated by the evaluations of the SEC petitions for IAAP and for the 1949–1957 period for Mallinckrodt. Those cases show the importance of using (1) complete or partial dose reconstructions that, together, would be representative of all members of the class, and all periods, processes, and radionuclides covered by the job types in question to illustrate NIOSH's ability to reconstruct doses with sufficient accuracy, and (2) data that have been sufficiently validated and shown to have the integrity needed to demonstrate the feasibility of dose reconstruction for a class of workers. The use of other documentation and data, such as site profiles and workbooks, should also be subjected to sufficient checks to ensure that there are no essential problems that would prevent dose reconstruction with sufficient accuracy for the members of the proposed class.

5.1 Issue 1: Maximum Dose Estimates in Plausible Circumstances

Requirements have been established in 42 CFR 83.13 for claims where NIOSH has not previously determined that it could not complete a dose reconstruction for a claimant under 42 CFR 82 regulations. Section 83.13 asks: "How will NIOSH evaluate petitions, other than petitions by claimants covered under §83.14?" Section 83.13(c)(1) discusses the issue of feasibility by asking: "Is it feasible to estimate the level of radiation doses of individual members of the class with sufficient accuracy?" As noted above, 42 CFR 83.13(c)(1)(i) states the regulation's requirements for estimating doses with "sufficient accuracy" in terms of maximum dose that could have been incurred in plausible circumstances by any member of the proposed SEC class.

SC&A notes that OCAS-PR-004 and the general references in the guidelines to 42 CFR 82, OCAS-IG-001, and OCAS-IG-002 are not sufficient to provide adequate guidance to the OCAS staff and its contractors as to how much conservatism to employ in developing maximum dose estimates, or how such methods are to be constrained either between different petitions or for members of the class proposed in the petition. In a sense, this problem might be viewed as a lack of guidelines in the procedures for assessing when the method for maximum dose estimation can be considered to possess sufficient accuracy. Without explicit guidance on this point, different evaluators may employ different degrees of claimant-favorable conservatism in compensating for deficiencies in the data and reach different conclusions for the same or similar cases. This question becomes even sharper if NIOSH uses different methods for estimating maximum dose for members of the class in circumstances not relating to the nature of the work**.**

The process for evaluating the IAAP SEC petition illustrates the potential problem. NIOSH prepared a TBD, which was used, in part, to recommend a denial of the IAAP SEC petition. The method resulted in a sudden decline in dose estimates in 1963 created by issues relating to the need to protect pre-1963 classified data. The reduction in the dose estimate did not relate to a change in working conditions in 1963, and derived principally from the change from a model based on classified data to one based on dose measurements. This made both the uniformity and fairness issues acute in the case of IAAP (SC&A 2005c).

Further, the review of the methods proposed by NIOSH to estimate a maximum dose for IAAP workers prior to 1963 also raised the issue of whether there was a procedure to bound the maximum doses when the estimation procedures were not related to working conditions, but

rather to the need to protect classified data. The proposed method to estimate maximum doses for the pre-1963 workers yielded values that were an order of magnitude higher than those estimated using measurements for the period covering 1963 until the close of production.

Therefore the guidelines need to be more explicit regarding the methods for maximum dose estimation in "plausible circumstances," with specific reference to the requirement of 42 CFR 83.1 that SEC petitioners be given uniform and fair consideration. In summary, NIOSH SEC procedures do not address the problem of constraining maximum dose estimation methods in order to arrive at a result that simultaneously fulfills the criteria of scientific soundness, claimant favorability, and uniform and fair consideration for all members of the class. This gap also raises a question of uniformity of evaluation across petitions.

5.2 Issue 2: Relation of 42 CFR 83 to 42 CFR 82

The problem of uniform and fair consideration also relates to how maximum dose estimates are developed under 42 CFR 83 to justify denial of an SEC petition and the highest reasonable dose estimates using worst-case assumptions under 42 CFR 82 for the purpose of denying a claim.

42 CFR 83 distinguishes the approach for developing maximum dose estimates under 42 CFR 83 from the efficiency approach for maximum dose estimates that are used only for denial of claims under 42 CFR 82 as follows:

> *The dose reconstruction rule very specifically restricted the condition on the use of worst-case assumptions to the case when they are used as an efficiency measure to limit time-consuming and resource-consuming additional research and analysis. This narrow restriction is stated in the dose reconstruction rule as follows (emphasis added):*
>
> > *At any point during steps of dose reconstruction described [above], 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: * * **
> > *(2) Dose is determined using worst-case assumptions related to radiation exposure and intake, **to substitute for further research and analysis**; * * **
> > *** * 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.'' 42 CFR Part 82.10(k)* (40 CFR 83)

> *In contrast, this Cohort rule implies the use of worst-case assumptions for dose reconstructions in essentially the opposite situation, to estimate maximum radiation doses in cases in which NIOSH lacks extensive information that could be used to conduct ''further research and analysis,'' rather than as an efficient substitute for such further research and analysis.* (42 CFR 83, pg. 30769}

Maximum dose estimates methods developed under 42 CFR 83 are not "worst-case" estimates and may be used for compensation and denial (once an SEC petition is rejected on the basis of demonstration of the feasibility dose reconstruction with sufficient accuracy). One implication of the above contrast is that the dose estimate using worst-case assumptions under 42 CFR 82 that is used for denial only should be greater than the maximum dose in plausible circumstances under 42 CFR 83. Yet, there is no constraint in the procedures that this inequality should apply.

That this could be a problem in terms of fairness of compensation as indicated by the evaluation of the Mallinckrodt SEC petition for the group of employees who worked there from 1949 to 1957. In attempting to define methods to estimate maximum doses in plausible circumstances for the class, NIOSH developed a method to compare a maximum dose that might have been incurred by a group of workers exposed to U-238, U-235, and the radionuclides in their decay chains (including Th-230, Ra-226, Pa-231, and Ac-227) with a maximum dose for a group of workers exposed mainly to Th-230, but not to significant amounts of Ra-226 or uranium isotopes (see attachments to SC&A 2005b, where the methods developed by NIOSH are reproduced).

SC&A evaluated NIOSH's suggested approaches and compared them with one maximum dose approach that had been used to deny Mallinckrodt claimants under 42 CFR 82, using worst-case assumptions. NIOSH used the radionuclide lists from Hanford for internal dose estimation, even though the list had little if any relation to the radionuclide list at Mallinckrodt. SC&A Site Profile reviews raised the possibility that the worst-case procedure used by NIOSH under 42 CFR 82 would yield estimates less than those under maximum dose estimation procedures suggested by NIOSH under 42 CFR 83 (see SC&A 2005a, Finding 16; SC&A 2005b, Section 1.3 and attachments).

In the absence of any constraints in the guidelines, a similar problem could arise in creating very high maximum dose estimates while recommending denial of SEC petitions. In case the petition is actually denied, the problem of a lack of a fair and uniform approach to compensating or denying claims could become acute. As in the case of changes in dose estimates between members of the class not related to working conditions, the lack of specificity in the SEC procedures regarding the transition between 42 CFR 83 and 42 CFR 82 dose reconstruction could lead to methods that lack sufficient accuracy to simultaneously meet the test of uniform, fair, and scientific consideration.

It is important, therefore, for the SEC evaluation procedures to provide a specific guide as to the relationship of the worst-case assumptions used to deny claims under 42 CFR 82, and the constraints that might be applicable in determining maximum dose estimated in plausible circumstances under 42 CFR 83. SC&A suggests that the procedures specify that the following inequality should be maintained in the transition between 42 CFR 83 and 42 CFR 82:

$$D_{82worstcase} \geq D_{83max}$$

where $D_{82worstcase}$ is the highest reasonable value of dose using worst-case assumptions under 42 CFR 82, and

D_{83max} is the maximum dose in plausible circumstances using the methods proposed in a 42 CFR 83 petition evaluation that recommends a denial of the petition.

5.3 Issue 3: Adequacy of Data for Maximum Dose Reconstruction

Additional guidance is needed regarding when data are or are not adequate for maximum dose estimates in plausible circumstances. For instance, no guidelines are provided regarding radionuclide lists and their connection to job types performed by members of the class. This was a major issue in the Mallinckrodt SEC Petition, 1949–1957. Guidelines or checklists for other critical issues would be useful in making the considerations of petitions fair, uniform, and scientifically sound, including the following:

- Investigation of data integrity questions, which were alleged in the context of the Mallinckrodt petition[1]
- Validation of the data, as necessary, using appropriate sampling procedures
- Data needed to conclude whether unmonitored workers were at lower risk than monitored workers
- Guidelines for extrapolating backwards or forwards in time from a given set of data for a particular group of workers

Development of specific guidelines is important for such issues. For instance, data falsification has been alleged in at least one SEC petition (Mallinckrodt). These issues may come up not only as part of allegations in SEC petitions, but also in the course of Site Profile reviews, or NIOSH's own review of available data. Guidelines for evaluating data integrity issues might include the following:

(1) Review of available documentation to examine whether there is any evidence that radiation doses in high-exposure areas were not recorded (due to workers not wearing their dosimeters, for instance), problems with instrumentation that might result in systematic underestimation of doses, the use of unwarranted adjustment factors prior to recording dose, and fabrication of data, such as entering zeros in dose records when the badges were not turned in or were not available.

(2) Interviews with personnel, such as site experts, petitioners, members of the class, and co-workers of members of the class.

[1] SC&A review of the documentation in the context of the series of reports on the Mallinckrodt Site Profile determined that there did not appear to be significant data integrity issues in terms of data falsification that would affect the feasibility of dose reconstruction.

(3) Review of historical documentation and archives, Congressional hearings, and lawsuit documentation records (if any are available).

The first two of these items should be a mandatory part of the procedure for SEC petition evaluation when (1) the petition alleges that data integrity problems exist, (2) NIOSH determines that such problems may exist, or (3) a Board review or a Board-commissioned review indicates that such problems may exist.

Some of the gaps in the procedures are also discussed in the sections below on OCAS-IG-001 and OCAS-IG-002, which are the guidelines for external and internal dose, respectively, referred to in the NIOSH SEC procedures.

NIOSH SEC procedures provide no more than a general comment that site profiles "will provide an important resource of information to assist in evaluating feasibility (recognizing, however, that petitions may raise issues not yet identified through the site profile development process)" (§6.3.1(3)). There is no substantive guidance on the use of site profiles. SC&A recognizes that site profiles are not part of the regulations and that, in light of this, NIOSH may choose not to rely on the information contained in them. However, in cases where NIOSH does use the information, a more specific set of guidelines for the use of information in the site profiles that is relevant to SEC petition evaluations could provide for more uniform consideration of SEC petitions. They could also provide insights into whether and how the 42 CFR 83 dose estimation procedures are used in specific cases. This would ensure that problems of uniformity and fairness do not arise in the transition from a denial of an SEC petition, because maximum doses in plausible circumstances can be estimated, to actual dose reconstructions under 42 CFR 82.

5.4 Issue 4: Co-Worker Data

Section 6.3 of the NIOSH SEC procedures provides guidelines on how to comply with the requirements of 42 CFR 83.13 (i.e., where NIOSH has not already determined that it cannot complete a dose reconstruction for a particular claimant). The section includes examples where co-worker data could be used to conclude that NIOSH can do dose reconstruction for the petitioning class or some sub-groups of the class. However, the section lacks quantitative guidance on the procedure or set of steps that relate the co-worker data to the class or sub-group of employees in the SEC petition. Essential elements required for comparability of claimant and co-worker data, such as time periods worked and job-type details, are not specified. An illustration of what starts out as a helpful example, but does not provide sufficient guidance, may be found in Section 6.3.2 ("Procedures for determining the extent and specificity of evaluations supporting positive determinations"):

> ***Example 1:*** *The petition asserts that personnel monitoring was not conducted for a group of maintenance workers when they were engaged in a particular operation. An examination of records shows that maintenance workers were not monitored while engaged in the particular operation but that another group of maintenance workers were monitored while engaged in the same operation involving comparable exposure conditions at another location at the facility.*

> *This information may be sufficient to determine that dose reconstruction is feasible for the group of maintenance workers covered by the petition, while engaged in the particular operation. It would not be necessary to evaluate the availability and adequacy of records concerning the work of the group of maintenance workers while engaged in other operations not addressed by the petition.* (OCAS-PR-004, §6.3.2)

Cases that are similar to the above straightforward example can, of course, be addressed by co-worker data. More complex issues arise when a whole group of workers, such as support workers at Y-12, is unmonitored for certain time periods. In that case, the analysis is more difficult, because it must be shown that job descriptions of monitored workers exist that can be demonstrated to bound the doses of unmonitored workers. The procedures would benefit from additional examples of when it is not feasible to use co-worker data. SC&A believes that there may be conditions where it is not plausible to use co-worker data as the basis for determining that a dose reconstruction for a given class of workers can be performed. NIOSH should provide guidance for determining when these conditions exist, along with examples drawn from past dose reconstructions where this determination was made, if such dose reconstructions are available.

5.5 Issue 5: Use of Completed Dose Reconstructions

OCAS-PR-004 appropriately refers to completed dose reconstructions as one of the ways that can help to determine the feasibility of dose reconstruction under 42 CFR 83. Section 6.3.3 of the guidelines discusses use of existing dose reconstructions to inform the SEC feasibility assessment:

> *Determine whether one or more dose reconstructions have been completed and/or initiated that demonstrate that dose reconstructions are feasible for the class of employees identified in the petition, or, if appropriate under 6.3.2, for a subgroup thereof, in light of the information provided in the petition concerning the feasibility of estimating radiation doses for the class of employees identified in the petition.* (§6.3.3)

However, it is not clear how the relationship of the dose reconstructions that are consulted to all members of the class or a clearly defined subgroup of the class is to be established. OCAS-PR-004 has a number of gaps that could affect the accuracy of NIOSH conclusions regarding feasibility of reconstructing doses for all or parts of the petitioning class. Specifically, while OCAS-PR-004 makes provisions for relating NIOSH conclusions about feasibility of dose reconstruction for all or parts of the SEC petition class to the completed and/or initiated dose reconstructions, there are no specific guidelines for assessing "sufficient accuracy" as required by EEOICPA and 42 CFR 83. For example, the latter asks in §83.13(c)(1): "Is it feasible to estimate the level of radiation doses of individual members of the class with sufficient accuracy?" In particular, the NIOSH SEC procedures do not contain guidelines that would allow a test of whether the dose reconstructions that are examined are actually relevant to estimating maximum doses with plausible assumptions. These guidelines should be selected so that the

completed and partial dose reconstructions that are used to evaluate petitions are representative of all members of the proposed class for all periods covered by the petition. SC&A suggests that the term "representative" in this context be defined to ensure that the methods used in the selected cases yield dose estimates that would cover or bound the values for all members of the class.

In addition, the procedures should specify that the data and other information used for petition evaluation be checked for accuracy. Such validation should include verification against a sample of raw data, as necessary.

5.6 Issue 6: Incidents

The regulations discuss the case where claimant radiation exposure is asserted to have arisen from an "incident." The regulation does not include "incident" in its definition section, but discusses exposure during incidents:

> *For classes of employees that may have been exposed to radiation during discrete incidents likely to have involved exceptionally high level exposures … resulting from the failure of radiation protection controls, NIOSH will assume for the purposes of this section that any duration of unprotected exposure could cause a specified cancer, and hence may have endangered the health of members of the class.* [42 CFR 83.13(c)(3)(i)]

OCAS-PR-004 echoes the regulation by stating the following:

> *For classes of employees for which dose reconstruction is not feasible, evaluate health endangerment by examining whether the class of employees was exposed during a discrete incident likely to have involved exceptionally high level radiation exposures, comparable to the levels of exposure in nuclear criticality incidents.* (§6.3.11)

The procedures go on to say that "exceptionally high" levels of exposure during incidents "typically cause acute, radiation-related effects" (§6.3.11.3). However, they do not quantify the radiation level experienced in an incident. Acute health effects do not necessarily occur with an acute intake due to short-term breakdown of radiological controls or prolonged (days or more) breakdown. However, such an acute intake may well cause radiation doses to be more than enough to endanger health or even to cause POC > 50%. An example could be air concentration of uranium in the tens of thousands of times MAC for short periods (less than a day), as has occurred at the Fernald and Mallinckrodt plants.

The discussion of the term "incident" in OCAS-PR-004 is not encompassing enough to cover significant cancer risk in periods of less than 250 days due to failure of radiation controls, accidents, or other similar causes. The quantitative aspects of that might be difficult to define, but NIOSH should at least develop guidelines for health endangerment over periods less than 250 days that reflect the kinds of cancer risks that could be incurred. For instance, a dose threshold corresponding POC threshold of 50% or less for the most sensitive cancer(s) under

plausible circumstances for members of the class who meet the 250-day employment criterion could be developed in order to assess health endangerment over shorter periods of time due to incidents or failure(s) of radiological controls. Viewed in this way, the existing guidance could well exclude some members of the proposed class whose health may have been endangered, but who do not meet the 250-day employment test. In so far as the guidelines relating to health endangerment are concerned, the current procedures appear to be inadequate to ensure uniform and fair consideration for members of the proposed class who worked for less than 250 days in the period covered by the petition.

5.7 Issue 7: Survivor Petitioners

NIOSH guidelines do not suggest how the problems of data, such as job types, incidents, and working conditions, are to be addressed in cases where the class is heavily composed of survivor claimants, who most likely are unable to provide any of the solicited details, or in the case of survivor petitioners. SC&A suggests that this could be a significant issue in some SEC petition evaluations.

At some facilities, for instance at some AWEs, individual worker records do not exist. In these cases, it would be difficult to identify individual claimants with members of the class if that membership depends on job type. This problem could be especially acute in case of survivors who want to be petitioners and employee petitioners who cannot remember job types due to health problems or loss of memory. It would be desirable for the guidelines to be specific about how the lack of job-type data is to be addressed when defining an SEC class.

5.8 Issue 8: Interviews with Petitioners

OCAS-PR-004 makes provision for interviews with petitioners or their experts who may have helped to prepare the petition, but does not require that at least one thorough interview be conducted and documented on the substantive issues raised in the petition. This should be a requirement of the petition evaluation process if it appears that NIOSH believes that dose reconstruction with sufficient accuracy is possible. This is desirable both as a measure to ensure that petitioner input is taken into account and to improve petitioner confidence in the resulting NIOSH recommendation.

5.9 Issue 9: Data from Other Sites

42 CFR 83 allows NIOSH to use data from other sites to demonstrate the feasibility of reconstructing doses with sufficient accuracy, provided that some data from the facility in question is included:

> *NIOSH must also determine that it has information regarding monitoring, source, source term, or process from the site where the employees worked to serve as the basis for a dose reconstruction. This basis requirement does not limit NIOSH to using only or primarily information from the site where the employee worked, but a dose reconstruction must, as a starting point, be based on some information from the site where the employee worked.* [42 CFR 83.13(c)(1)(i)]

OCAS-PR-004 does not provide significant guidance as to how the parallels between the facility for which the petition has been filed and that from which data is being used as a surrogate set are to be compared. There are no explicit constraints on time periods, processes, measurement methods, materials processed, or general conditions of work that are set forth to guide the process of selecting a surrogate site, facility, or process for use. This has been a significant issue in site profile development and review, and in other contexts. For instance, SC&A concluded that the use of October 1948 air concentration data from Simonds Saw and Steel for dose reconstruction at Bethlehem Steel was reasonable, but that the times spent at various workstations could not be so transferred (SC&A 2005e; ABRWH 2004, pp. 143-148). Similarly, the use of the neutron-to-photon ratio from the Pantex Plant might be suitable for use at the IAAP, but not for workers involved in reactor operations.

While being too prescriptive on this account is likely to be counterproductive and unnecessarily restrictive, some guidance as to what constitutes an acceptable set of surrogate data and what constraints might rule out the use of data from other facilities would be useful.

Related to this issue is the requirement in Part 83 that "a dose reconstruction must, as a starting point, be based on some information from the site where the employee worked." NIOSH should provide guidance on what constitutes a minimum acceptable level of site-specific information required to meet this criterion.

5.10 Issue 10: Use of OCAS-IG-001 and OCAS-IG-002 in 42 CFR 83

The NIOSH SEC procedures refer the evaluator to the "implementation guidelines," i.e., OCAS-IG-001 and OCAS-IG-002, to find an elaboration of "the technical issues involved in evaluating the availability and adequacy of records and information relevant to feasibility determinations ... for internal and external dose reconstructions" (§6.3.1(2)). The section later instructs the evaluator that "feasibility should be determined by evaluating the availability and adequacy of records and information in the order established by the hierarchy of dose reconstruction information specified under 42 CFR 82.2, addressing the informational sources, types, and the adequacy of information as specified under 42 CFR Part 82 and 83 and under the OCAS implementation guidelines for dose reconstruction" (§6.3.1.(3)).

These references to procedures that were designed as guidelines for individual dose reconstruction under 42 CFR 82 are helpful and necessary, but they do not provide guidance regarding dose reconstruction that is essential in the context of SEC petition evaluation. OCAS-IG-001 and OCAS-IG-002 contain some gaps that need to be filled in for the specific purpose of assessing whether maximum dose reconstruction estimates in plausible circumstances can be made for all members of the class and for all cancers in the SEC list.

OCAS-IG-001 has already been reviewed by SC&A, and the Board's procedure for resolving the issues raised by SC&A's review has been completed. The following examples illustrate some of the specific issues that can arise in the context of estimating maximum doses in plausible circumstances for a class or portion of a class of workers that are not covered in OCAS-IG-001 and OCAS-IG-002.

SC&A also notes that OCAS-IG-001 and OCAS-IG-002 do not discuss how the data gaps arising from problems of data integrity are to be addressed (as distinguished from missed doses related to limits of detection (LOD) values). The issue of data validation is also an important gap, as noted above.

5.10.1 External Dose Guidelines OCAS-IG-001

NIOSH guidance for evaluating SEC Petitions is provided in OCAS-PR-004, *Internal Procedures for the Evaluation of Special Exposure Cohort Petitions*; Rev. 0, September 23, 2004.

Section 6.3 of OCAS-PR-004 provides steps and procedures for OCAS to conduct its evaluation of regulatory criteria defined under §83.13. Specifically, Section 6.3.1 provides the following:

> ***Procedures for determining feasibility****: (1) The principal guidelines for evaluating feasibility for petitions qualifying for evaluation under 6.3 are established under §83.13(c)(1). (2) The technical issues involved in evaluating the availability and adequacy of records and information relevant to feasibility determinations are addressed in the* ***implementation guidelines for internal and external dose reconstructions. These dose reconstruction guidelines generally explain the types of information that can be used in dose reconstructions, and approaches to examine the availability and adequacy of information, as well as describing how such information should be used****. These guidelines also provide general guidance concerning how maximum doses can be estimated when necessary, and the information essential to such estimates, under section* ***5.3*** *of the internal dose reconstruction guidelines and Sections* ***3.1.3, 3.1.4, 3.2.3, 3.3.3,*** *and* ***3.3.4*** *of the external dose reconstruction guidelines.* (Emphases added.)

SC&A evaluation of the cited sections for use in the context of 42 CFR 83 indicates that each of these sections must be used with caution because it has gaps when applied to determining the feasibility of dose reconstruction for an entire class of workers over the history of nuclear weapons production and testing activities.

Section 3.1.3 provides guidance for external photon dose reconstruction when personnel monitoring data, co-worker monitoring data, and area monitoring survey data are **not** available. When such data are not available, the guide recommends the use of source term information. As applied to a class of workers, as opposed to an individual claimant, this strategy for determining feasibility of dose reconstruction is questionable, because the complexity of the source term may preclude the performance of a scientifically valid maximum dose that can be applied to all members of a class.

Section 3.1.4 provides guidance for photon dose reconstruction that is based on "control limits." This guidance is questionable as applied to an SEC petition for a class of workers. For instance, the monitoring threshold of 100 mrem per year is a current value for members of the general public and not a regulatory threshold for required monitoring of facility workers. As another example, the OCAS-IG-001 guidance restricts the use of the "annual dose limit" to **periods less**

than 1 year, which conflicts with the SEC employment requirement of at least 250 work days, as defined in 42 CFR 83.13 c(3)(ii).

Section 3.2.3, dealing with neutron dose reconstruction, recommends using NCRP 38 (1971) methodologies, which is a point source equation and which NIOSH acknowledges has an order of magnitude uncertainty. It is unclear how such uncertainties may be magnified in the context of devising methods for an entire class of workers and whether the resultant dose estimates might still qualify as having the "sufficient accuracy" required under 42 CFR 83. Further, the shielding data in NRCP 38 appear to have limited value and/or applicability to the highly restricted condition of a single point source.

Section 3.3.4 of OCAS-IG-001 briefly summarizes **current** DOE practices for controlling radiological contamination, and recommends the use of these limits for dose reconstruction. However, the use of current practices has limited validity for historical dose reconstruction. Further, the reference to the "three levels of radiological contamination postings/contamination control checkpoints" has a limited relationship to external dose rates.

SC&A's evaluation of the cited sections of OCAS-IG-001 indicates that it is unlikely that guidance currently provided will, by itself, yield dose estimates with sufficient accuracy, as mandated under §83.13. The use of external dose guidelines must be complemented by the use of completed or partial dose reconstructions that have been selected for relevance to the evaluation of the SEC petition, as discussed above.

5.10.2 Internal Dose Guidelines OCAS-IG-002

Guidelines for internal dose reconstruction in OCAS-PR-004 are limited to a reference to Section 5.3 of OCAS-IG-002 (Source Term Evaluation), which provides only a few brief statements, including the following:

> *… without bioassay or air sample data, the **last** resort is to attempt a determination of the airborne concentrations … in the individual's breathing zone … using source term evaluations.* [Emphasis added.]

Determination of internal doses that may result from the inhalation of airborne contaminant(s) requires the need to define critical parameters, including area ventilation rate/resuspension factors, chemical form/solubility of airborne contaminants, particle size, breathing rates, duration of exposure, etc. In brief, Section 5.3 addresses none of these issues and provides little guidance for deriving internal doses with "sufficient accuracy" from source term data that would satisfy the regulatory requirements of 42 CFR 83.13 for any member of the proposed class.

Some issues relating to internal dose are particular to consideration of SEC petitions; for instance, when they involve defining plausible circumstances for maximum dose estimation. For instance, doses from large hot particles to the gastrointestinal tract may be important in some evaluations. This is not discussed in OCAS-IG-002 or in OCAS-PR-004.

As another example, the importance of a complete radionuclide list and complete job types for the members of the class is often more critical for internal dose, since explicit monitoring is required to detect them and apply the appropriate dose conversion factors. In contrast, if the members of a class or sufficiently representative sub-groups of the class had adequate monitoring for photons, beta radiation, and neutrons, the specific radionuclide lists are not as crucial for external dose estimation. The importance of this issue was illustrated in the various approaches suggested by NIOSH for dose reconstruction for the 1949–1957 SEC class at Mallinckrodt. It is also a significant issue for some groups of workers at Y-12. While site profiles and individual dose reconstructions can be selective in the issues and radionuclides that they address at any particular time, with elaboration reserved for the future, such an option is not available for any significant length of time for SEC petition evaluations. In the absence of monitoring data for specific radionuclides, bounding approaches have to be developed. This poses considerable challenges as was demonstrated in the case of the development of methods for the 1949-1957 Mallinckrodt class (see Attachments to SC&A 2005b).

In summary, as with the external dose guidelines, the internal dose guidelines in OCAS-IG-002 must be complemented by the use of relevant completed or partial dose reconstructions in order to demonstrate the feasibility of dose estimation with sufficient accuracy for all members of the proposed SEC class.

5.11 Issue 11: SEC Petition Evaluation Plan

NIOSH is required to present its plan for evaluating an SEC petition to the Board once NIOSH has determined that a petition is qualified for evaluation (42 CFR 83.12(c)). The procedures state that the Board will be provided with such a plan, but do not contain any details of what would be provided. They also do not contain any provision for updating the information provided to the Board as NIOSH increases and/or changes the kinds of data, documents, and other information that it may bring to bear on the evaluation process.

5.12 Issue 12: Definition of the Class under 42 CFR 83.14

If NIOSH determines that it cannot do a dose reconstruction and requests a claimant to file Form A to initiate inclusion in a SEC, a corresponding class of petitioners must be defined, if that has not already been done. NIOSH proposes to use 42 CFR 83.13 to do this. However, the NIOSH SEC procedures provide no guidance or checklist to be followed in defining the class and reaching potential class members.

5.13 Issue 13: Site-Specific Data

42 CFR 83 requires that "a dose reconstruction must, as a starting point, be based on some information from the site where the employee worked" (42 CFR 83.13(c)(1)). This could be a potentially significant constraint, since it specifies that site-specific data should be the starting point, and that it should form part of the basis of the dose reconstruction methods proposed for members of the class. While the regulation allows NIOSH to use information from other sites liberally, the constraints in the rule would appear to require some elaboration in the NIOSH procedures. This is needed for some consistency across site profiles.

5.14 Miscellaneous Comments on OCAS-PR-004

(1) NIOSH states that it focuses its evaluation on the specific issues raised in the petition; this is appropriate for timeliness. But, if the petition is rejected for a technical (not procedural) reason, NIOSH is, in effect, certifying that it is able to do dose reconstruction for the entire class. Hence, an explicit process and checklist to ensure that the relevant aspects of dose reconstruction have been taken into account would be helpful. Such a checklist might be developed, at least in part, from the findings above and the suggestions for improvement provided in this review, as well as from that material already in OCAS-PR-004.

(2) The phrase “at least one petitioner cannot be verified” is confusing. NIOSH might consider changing it to "one or more petitioners cannot be verified.”

(3) Section 6.1.3.3 on page 5 refers to "processes" included in the class definition. However, "processes" are not mentioned in either 42 CFR 83.9 or the Petition Form B (though “process” is mentioned in 42 CFR 83.13(c)(1)(i)). This item would be clearer if the term “processes” were related to the term “job types.”

(4) In Section 6.1.5.1.3 on page 9, General Accounting Office should be changed to Government Accountability Office.

(5) In Section 6.1.9 on page 10, the words "who were not involved in developing the proposed finding" should appear after "HHS personnel."

(6) In Section 6.1.10 on page 10, 31 days should be changed to 30 days.

(7) In Section 6.3.11.2 on page 19, the words "was likely" should be changed to "could possibly.”

(8) In Section 6.4.4 on page 22, 6.2 should be changed to 6.3.

(9) In Appendix B on pages 33 and 34, the calibration of monitors and the functionality of monitors, in so far as these aspects might affect the feasibility of dose reconstruction with sufficient accuracy, should be mentioned (see also a similar comment for Form B).

(10) A separate line item in the summary sheet of the petition evaluation report for each class discussed in the report would be helpful. The current form is confusing when there are different actions for different classes discussed in the same evaluation report.

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