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

November 30, 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

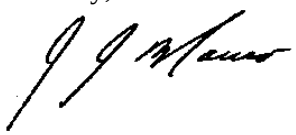
Re: Contract 200-2004-03805, Task 5, Subtask 2: *Board Procedures for Review of Special Exposure Cohort Petitions and Petition Evaluation Reports*

Dear Mr. Staudt:

SC&A, Inc., is pleased to submit our draft procedures entitled, *Board Procedures for Review of Special Exposure Cohort Petitions and Petition Evaluation Reports*. This report was prepared pursuant to Subtask 2 of Task Order No. 5 of the subject contract.

Unlike previous reports prepared by SC&A for the Board, this report is not written as an SC&A report, but as a set of draft procedures for use by the Board and its contractors in the evaluation of qualified SEC petitions and petition evaluation reports prepared by NIOSH.

Sincerely,



John Mauro, PhD, CHP
Project Manager

cc: P. Ziemer, PhD, Board Chairperson
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Project File (ANIOS/005/02)

Draft

ADVISORY BOARD ON RADIATION AND WORKER HEALTH

National Institute of Occupational Safety and Health

BOARD PROCEDURES FOR REVIEW OF SPECIAL EXPOSURE COHORT PETITIONS AND PETITION EVALUATION REPORTS

Contract No. 200-2004-03805
Task 5: Subtask 2
SCA-TR-TASK5-0002

Prepared by

S. Cohen & Associates
6858 Old Dominion Drive, Suite 301
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November 30, 2005

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 & Worker Health Review of NIOSH Dose Reconstruction Program*	Document No. SCA-TR-TASK5-0002 Effective Date: Draft - November 30, 2005 Revision No. 0 (Draft)
BOARD PROCEDURES FOR REVIEW OF SPECIAL EXPOSURE COHORT PETITIONS AND PETITION EVALUATION REPORTS	Page 2 of 32
Task Manager: _____ Date:_____ Arjun Makhijani	Supersedes: N/A
Project Manager:_____ Date:_____ John Mauro	

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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
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
NIOSH	National Institute for Occupational Safety and Health
SC&A	S. Cohen and Associates
SEC	Special Exposure Cohort

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 SEC and the ways in which the National Institute of Occupational Safety and Health (NIOSH) and its contractors would evaluate the petitions. 42 CFR 83 also specifies the role that the Advisory Board on Radiation and Worker Health (Board) plays in the process of SEC petition evaluation, advising the Secretary of HHS whether to add a class to the SEC, and providing the reasons for the Board recommendation.

This document presents the procedures that the Board will use to enable timely consideration of NIOSH SEC petition evaluations. It also contains procedures that its contractor may use if the Board asks its contractor to review NIOSH SEC petition evaluations, in whole or in part, or requests its contractor to address specific issues that arise in the SEC petition evaluation process.

In preparing this draft procedure, the authors were mindful of the process employed by the Board in deliberations related to recent SEC petition reviews, notably the Mallinckrodt 1949–1957 class (SC&A 2005; SC&A 2005a; SC&A 2005b) and the IAAP SEC Petition. The authors also integrated protocols that are emerging from the Y-12 SEC petition review (ABRWH 2005b).

1.1 PHASES OF THE BOARD'S REVIEW PROCEDURE

The regulation governing additions to the SEC, 42 CFR 83, requires that NIOSH, the Board, and the Secretary of HHS give a "full evaluation" to SEC petitions (42 CFR 83.10). 42 CFR 83.12(c) requires NIOSH to provide the Board with an evaluation plan containing details about how NIOSH plans to assess "radiation exposure potential," as well the "adequacy of existing records and information," though it does not specify when this plan should be submitted. To date, NIOSH has not yet presented a detailed evaluation plan to the Board for any SEC petitions, even though a number of petitions have qualified and several of these SEC petition evaluations have been completed. 42 CFR 83 is not specific about the role of the Board after NIOSH submission of the evaluation plan and prior to NIOSH's completion of its evaluation of the petition.

The Board has established an ad hoc working group to consider the process by which it will evaluate petitions, as well as petition evaluation reports produced by NIOSH. The members of the working group met with NIOSH staff on November 17, 2005. The meeting was transcribed, but the transcript was not available at the time of this writing (ABRWH 2005b). It is understood that these procedures may needed to be modified to reflect the findings of that working group meeting.

Under 42 CFR 83, the substantial involvement of the Board in considering SEC petitions can begin at any time after NIOSH has determined that a petition is qualified for evaluation. The

Board procedures presented here begin at that point in time in order to enable the Board to give petitions a "full evaluation" and to balance those evaluations with the requirement of timeliness of considerations relating to compensation required by EEOICPA.

These procedures consist of three phases, which begin at the time that a petition is qualified by NIOSH. The three phases are as follows:

(1) *Phase 1 – Preliminary Steps*: These steps are designed to expedite Board decisions about its course of action in the time period immediately following a NIOSH announcement that a petition has qualified for evaluation. The steps begin with the presentation of an evaluation plan to the Board by NIOSH, followed by the development by the Board of a course of evaluation for the review of the petition and its associated documentation.

(2) *Phase 2 – Intermediate Steps*: These steps relate to Board consideration of specific issues of concern, and their communication to NIOSH **while NIOSH is evaluating the SEC petition**. This phase is implemented primarily by a working group, convened specifically for a given SEC petition evaluation, to help ensure that NIOSH gives due consideration to the issues of concern to the Board. This phase provides for the development of the issues that will be evaluated by the working group and the Board.

(3) *Phase 3 – Evaluation Review Steps*: These steps consist of the Board's review of NIOSH's SEC Petition Evaluation Report **after NIOSH has submitted it**. This phase includes (a) the possible approval of the NIOSH recommendations without further review, (b) the continued review of issues raised during Phase 2, or (c) the review of new or revised issues that may emerge during this phase.

1.2 FRAMING THE ISSUES

The following process will be used to help frame the issues for consideration:

- Demonstration of the feasibility of dose reconstruction with sufficient accuracy under 42 CFR 83. The development of the issues will take place in large measure through consideration of completed and partial dose reconstructions, and, if available, through selection of issues from Site Profile Reviews, when they are available.

- Selection of dose reconstructions that center on their ability to cover the various job types and time periods applicable to members of the proposed SEC class. In other words, the dose reconstructions chosen to support SEC petition decision-making should be representative of class members.

- Examination of the validity of the data used in the dose reconstructions.

- Examination of documents associated with dose reconstruction issues, including an assessment of the quality and quantity of data, data integrity, data validity, and data sufficiency. Examples include (a) radionuclide lists and individual or area monitoring

data for those radionuclides, (b) the periods covered by internal and external dose monitoring, (c) availability of job descriptions in a detail sufficient to sustain co-worker dose reconstruction in those cases where it is proposed to be used, (d) missed doses due to incomplete (rather than limits of detection (LOD)) data records, and (e) neutron source terms, including neutron energy spectra, for those periods where neutron dosimetry is either unavailable or dosimeters were inadequate to cover the entire spectrum to which members of the class were exposed.

- Examination of gaps in NIOSH procedures for dose reconstruction as they apply to consideration of dose reconstruction for an entire class of workers (SC&A 2005f).

Site profile and workbook reviews can play a significant role in ensuring consideration of all the issues that may be part of the "full evaluation" of each petition required by 42 CFR 83. While they are helpful, such reviews are not essential to the process of review of SEC petitions and their evaluation reports (see Section 4).

1.3 CONTRACTOR PROCEDURES

The contractor procedures address (a) the development of specific issues prior to or subsequent to NIOSH's submission of its SEC Petition Evaluation Report to the Board, or (b) full review of Petition Evaluation Reports after they are submitted to the Board, if requested by the Board. Steps in the review of NIOSH Petition Evaluation Reports will include the following:

(1) Review of the claims in the petition and associated documents

(2) Review NIOSH petition evaluation and associated documentation and dose reconstruction examples

(3) Review of completed and partial dose reconstructions used by NIOSH in its petition evaluation report

(4) An interview with at least one petitioner

(5) Determination of whether additional completed and partial dose reconstructions are needed

(6) Assess whether there may have been sufficient failures of radiological controls over periods of less than 250 days to endanger the health of workers who would otherwise be members of the class, if NIOSH has not already done so

Some of these steps would apply to specific issues. More details and steps of the contractor's general procedures are provided in Section 4.

In order to refine and resolve the issues, petitions will be placed into one of the following three categories (as selected by the Board):

(1) Petitions where NIOSH has published a Site Profile and a Site Profile Review has been completed

(2) Petitions where there is a Site Profile, but no Site Profile review has been done

(3) Petitions where NIOSH has not published a Site Profile

In cases where a Site Profile Review has been completed or is in the process of being completed, a list of issues pertinent to the estimation of doses for the proposed class will be extracted from the prior work. Workbooks are considered part of the site profile. In cases of ongoing site profile and workbook reviews, priority will be given to drafting those elements that are relevant to the consideration of the SEC petition in question.

In cases where there is a site profile but no review, a highly targeted review of the site profile and associated documents will be performed. This review will address issues, such as the following:

- Radionuclide lists relevant to the proposed class
- Neutron spectra and the limitations, if any, of neutron measurement devices
- Documentation that would shed light on data integrity issues, should any appear to exist or if such problems have been alleged
- Conditions under which significant failure of radiological controls may have occurred
- Job types involved in the proposed class and the kinds of dose reconstructions that would need to be considered to ensure representativeness of the examples that are chosen

For review of NIOSH SEC Petition Evaluation Reports in which there is no Site Profile Review, the completed review will include findings relating to the following:

- Completeness of radionuclide lists and areas where such radionuclides might be present
- External dose records completeness and accuracy (including neutron dose records)
- Geometry issues related to external dose, with reference to whether plausible assumptions about geometry can be made under the circumstances
- Availability and completeness of bioassay and other data relating to internal dose
- Methods of estimating missed dose

- Usability of air concentration data and area external dose measurements as substitutes for personal dosimetry data when these are not available

- Availability of job category data

- Environmental dose estimation procedure

- Availability of data on incidents, and the methods for the incorporation of this information into dose reconstruction

- Evidence of a significant failure of radiological controls for members of the proposed class

For reviews of NIOSH SEC petition evaluation reports for sites without a Site Profile, the completed review will also include a set of findings relating to the above items as they apply to estimation of doses with sufficient accuracy.

In all cases, the review of a NIOSH SEC Petition Evaluation Report will focus on the feasibility of dose reconstruction for any member of the proposed class. Hence, the use of dose reconstructions selected to be representative will be crucial to the review process.

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. 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 SEC and the ways in which the National Institute of Occupational Safety and Health (NIOSH) and its contractors would evaluate the petitions. 42 CFR 83 also specifies the role that the Advisory Board on Radiation and Worker Health (Board) plays in the process of SEC petition evaluations. The Board's role includes making a decision whether to advise the Secretary of HHS to add a class to the SEC, and if so, the reasons for that recommendation. This procedure is to be used by the Board and its contractors, as requested by the Board, to facilitate timely consideration of NIOSH SEC Petition Evaluations and the petitions themselves.

Addition to the SEC depends primarily on the inability of NIOSH to perform dose reconstructions under 42 CFR 82. EEOICPA states that a class of employees may be considered part of the SEC if the following determination is made:

> *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.*

2.1 STATEMENT OF PURPOSE AND SCOPE OF THE PROCEDURE

The purpose of this procedure is to establish a systematic protocol for use by the Board and its contractors for reviewing NIOSH reviews of SEC petitions and the SEC petitions themselves, in accordance with EEOICPA and 42 CFR Part 83. In preparing this procedure, a review was performed of the following:

- 42 CFR Parts 82 and 83
- NIOSH SEC review procedures
- A draft critique of NIOSH SEC review procedures
- Experience gained in the review of dose reconstructions, site profiles, and supporting technical information bulletins
- The experience of the Board in its consideration of the Iowa Army Ammunition Plant (IAAP) SEC Petition Evaluation and the Mallinckrodt 1949–1957 SEC Petition Evaluation

2.2 STRUCTURE AND ORGANIZATION OF THESE PROCEDURES

These procedures are organized into the following four sections:

- Section 1: Executive Summary
- Section 2: Introduction
- Section 3: Procedures by which the Board will consider SEC Petitions and their evaluations as performed by NIOSH
- Section 4: Procedures that the Board's contractors will employ in providing technical assistance to the Board in the SEC petition evaluation process

3.0 BOARD PROCEDURES

3.1 LEGISLATIVE AND REGULATORY CONTEXT OF THE BOARD PROCEDURES

The section of EEOICPA dealing with the Board's advice on EEOICPA states the following:

> ***§7384q. Designation of additional members of Special Exposure Cohort***
>
> *(a) ADVICE ON ADDITIONAL MEMBERS—(1)* ***The Advisory Board*** *on Radiation and Worker Health under section 7384o of this title* ***shall advise the President whether there is a class of employees at any Department of Energy facility who likely were exposed to radiation at that facility but for whom it is not feasible to estimate with sufficient accuracy the radiation dose they received.***
> *(2) The advice of the Advisory Board on Radiation and Worker Health under paragraph (1) shall be based on* ***exposure assessments*** *by radiation health professionals, information provided by the Department of Energy, and such other information as the Advisory Board considers appropriate.*
> *(3) The President shall request advice under paragraph (1)* ***after consideration of petitions by classes of employees described in that paragraph for such advice.*** *The President shall consider such petitions pursuant to procedures established by the President.*
> *(b) DESIGNATION OF ADDITIONAL MEMBERS—Subject to the provisions of section 7384l(14)(C) of this title, the members of a class of employees at a Department of Energy facility, or at an atomic weapons employer facility, may be treated as members of the Special Exposure Cohort for purposes of the compensation program if the President,* ***upon recommendation of the Advisory Board on Radiation and Worker Health****, 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.* [Emphasis added]

Pursuant to this section, 42 CFR 83 describes the relationship between the process that NIOSH must follow in receiving and evaluating petitions, and the role of the Board in advising the Secretary of HHS regarding SEC petitions. Once NIOSH accepts the petition for evaluation, the overall responsibility of NIOSH, the Board, and HHS is spelled out in 42 CFR 83.10:

> *Satisfying the informational requirements for a petition does not mean the class will be added to the Cohort. It means the* ***petition will receive a full evaluation by NIOSH, the Board, and HHS****, as described under §83.13 through §83.16.* [Emphasis added.]

The process of "full evaluation" by the Board begins when NIOSH submits an evaluation plan to the Board, in accordance with 42 CFR 83.12(c):

> *NIOSH will present petitions selected for evaluation to the Board* ***with plans specific to evaluating each petition****. Each evaluation plan will include the following elements:*
> *(1) An* ***initial proposed definition for the class*** *being evaluated, subject to revision as warranted by the evaluation conducted under §83.13 or §83.14; and*
> *(2) A list of activities for evaluating the* ***radiation exposure potential*** *of the class and the* ***adequacy of existing records*** *and information needed to conduct dose reconstructions for all class members under 42 CFR Part 82.*
> *(d)* ***NIOSH may initiate work to evaluate a petition immediately, prior to presenting the petition and evaluation plan to the Board****.* [Emphasis added]

In view of the Board's mandate to give SEC petitions a "full evaluation," and given the past experience with SEC petitions and the emerging process in the case of the Y-12 petition, these procedures are designed to help ensure that early and significant Board involvement will begin in all but the simplest cases as soon as NIOSH has declared that a petition has qualified for evaluation.

The next explicit step for Board consideration specified in 42 CFR 83 is when NIOSH submits its Petition Evaluation Report to the Board for consideration under 42 CFR 83.13(d), which specifies the elements that the evaluation should contain, including the class definition(s), and associated details of the methods demonstrating the feasibility of dose reconstruction with sufficient accuracy for all members of the proposed class(es) in those cases where NIOSH proposes to deny the petition, as well as NIOSH's findings in regard to health endangerment. At that point, the Board considers the evaluation, and provides the petitioner with an opportunity to present their views regarding the petition and NIOSH's petition evaluation, in accordance with 42CFR83.15. At this point the Board may:

(1) Accept NIOSH's evaluation

(2) Make its own recommendations to the Secretary of HHS that may differ from NIOSH recommendations

(3) Choose to "obtain and consider additional information not addressed in the petition or the initial NIOSH evaluation report" (42 CFR82.15(c))

In the latter case, the Board may make its own evaluations on issues, ask its contractor to perform partial or full reviews of NIOSH's Petition Evaluation Report, or request NIOSH to conduct additional evaluations, which in turn would be submitted to the Board for consideration (42 CFR 83.15(d)). The rule allows for iterative Board consideration of additional information and requests for additional NIOSH evaluations, and does not set an explicit time limit for the process. However, in view of the general requirement of timeliness in consideration of petitions and claims under EEOICPA, 42 CFR 83, and 42 CFR 82, Board procedures are required to

consider the needed information with due attention to the balance between "full consideration" of the petition and the need for timely compensation decisions. These procedures address the need for that balance, even in complex cases. As noted above, the procedures provided herein are mindful of the experience of the rather extended Board consideration of the Mallinckrodt petition for the class of employees who worked there between 1949 and 1957, which raised issues of timeliness. These procedures also give careful consideration of the emerging process of consideration of the Y-12 SEC petition in which the Board has directed a working group to develop specific issues for NIOSH to address in the course of its evaluation of the petition. This process is occurring after the qualification of the petition for evaluation and before NIOSH's submission of an evaluation report to the Board.

To date, NIOSH has not presented a detailed evaluation plan to the Board prior to the submission of an evaluation of an SEC petition or for a petition that has been qualified. 42 CFR 83 is not specific about the role of the Board after NIOSH submission of the evaluation plan and prior to NIOSH's completion of its evaluation of the petition. However, the outlines of that role are emerging in the review of the Y-12 SEC petition currently under consideration.

The Board has established a working group to consider the process by which it will evaluate petitions, as well as petition evaluation reports produced by NIOSH. The members of that working group met with NIOSH staff on November 17, 2005. The meeting was transcribed, but the transcript was not available at the time of this writing. This procedure may need to be revised upon further consideration of the working group's and the Board's deliberations on these matters. In addition, as the Board gains experience in the implementation of these procedures, these procedures may need to be periodically revised.

Under 42 CFR 83, the substantial involvement of the Board in considering SEC petitions can begin at any time after NIOSH has determined that a petition is qualified for evaluation. The Board procedures presented here begin at that point in time in order to meet the requirement under 42 CFR 83 that the Board give petitions a "full evaluation" to be balanced with the requirement of timeliness of considerations relating to compensation required by EEOICPA.

3.2 BOARD PROCEDURES

These procedures reflect the experience of the Board in reviewing previous SEC petitions, notably the Mallinckrodt 1949–1957 class (SC&A 2005; SC&A 2005a; SC&A 2005b) and the IAAP SEC Petition. In addition, lessons being learned from the current review of site profiles and other SEC petitions, such as the Y-12 SEC petition, were considered during the preparation of these procedures (see ABRWH 2005b).

These procedures consist of three phases, beginning with the qualification of a petition for evaluation, as follows:

(1) *Phase 1 – Preliminary Steps*: These steps are designed to expedite Board decisions about its course of action in the time period immediately following a NIOSH announcement that a petition has qualified for evaluation. They include NIOSH presentation of an

evaluation plan to the Board, and lead up to the point that the Board decides on the course of its evaluation.

(2) *Phase 2 – Intermediate Steps*: These steps relate to Board consideration of specific issues of concern, and their communication to NIOSH **while NIOSH is evaluating the SEC petition**. This phase is implemented primarily by a working group specifically convened for a given qualified petition, to help ensure that NIOSH gives due consideration to the issues of concern to the Board. This step provides for the development of the issues by the Board or designated working group.

(3) *Phase 3 – Evaluation Review Steps*: These steps consist of the Board's review of NIOSH's SEC Petition Evaluation Report **after NIOSH has submitted it**. The steps include possible approval or rejection of the NIOSH recommendations without further review, or additional partial or full review of the NIOSH SEC Petition Evaluation Report.

The experience of the Mallinckrodt and IAAP SEC petition evaluation processes and the emerging process of Y-12 SEC petition evaluation indicate the centrality of demonstrating feasibility of dose reconstruction for the class through partial or completed dose reconstructions. For instance, NIOSH's initial conclusion that it would be able to reconstruct doses from the 1949–1957 Mallinckrodt class was based on a partial evaluation of the significance of certain radionuclides, notably thorium-230 and the decay products of uranium-235. The importance of these radionuclides for many members of the class became clear only when internal dose reconstructions using representative examples were attempted using more complete radionuclide lists and source terms and suitable claimant-favorable assumptions (see Attachments to SC&A 2005b). The crucial importance of validation of data against original records and of choosing representative dose reconstruction has also been demonstrated in the SEC petition reviews completed to date. The data validation point also emerged as critical in the course of review of the Bethlehem Steel Site Profile (SC&A 2005g).

In view of the Board's experience to date, the following general scheme is adopted for framing the issues for consideration:

- The issues are defined in terms of the ability of NIOSH to demonstrate the feasibility of dose reconstruction with sufficient accuracy under 42 CFR 83. Therefore, the development of the issues will emerge through consideration of completed and partial dose reconstructions, and, if available, through selection of issues from Site Profile Reviews, when they are available.

- The choice of dose reconstructions and the number of dose reconstructions considered will be determined by their ability to cover the various job types and time periods applicable to the members of the proposed SEC class. In other words, the dose reconstructions chosen should be representative of class members. It should be pointed out that representative cases can be considered without performing a complete dose reconstruction; the main objective is proof of principle – prove that there is sufficient

information to calculate a maximum plausible dose for all organs for all members of the class.

- A suitable level of examination of the validity of the data used in the dose reconstructions.

- Examination of documents associated with dose reconstruction issues will include an assessment of the quality and quantity of data, including issues of data integrity, data validity, and data sufficiency. Examples include (a) radionuclide lists and individual or area monitoring data for those radionuclides, (b) the periods covered by internal and external dose monitoring, (c) availability of job descriptions in sufficient detail to sustain co-worker dose reconstruction in those cases where it is proposed to be used, (d) missed doses due to incomplete (rather than LOD) data records, and (e) neutron source terms, including neutron energy spectra, for those periods where neutron dosimetry is either unavailable or dosimeters were inadequate to cover the entire spectrum to which members of the class were exposed.

- Examination of gaps in NIOSH procedures for dose reconstruction as they apply to consideration of dose reconstruction for an entire class of workers (SC&A 2005f).

Site profile and workbook reviews can play a significant role in ensuring consideration of all the issues that should be part of the "full evaluation" of each petition required by 42 CFR 83; however, such reviews are not essential to the process of review of SEC petitions and their evaluation reports (see Section 4).

3.2.1 Preliminary Steps

- NIOSH provides the Board with a list of SEC petitions it is examining for qualification and the expected schedule for the completion of the qualification process.

- NIOSH informs the Board that a petition has qualified for evaluation.

- NIOSH provides the Board with a preliminary evaluation plan as soon as NIOSH has begun its evaluation of the petition. This plan specifies the approach that NIOSH has decided to use to assess the feasibility of dose reconstruction with sufficient accuracy for any member of the class, at least as a starting point. NIOSH ensures that documents and data that it plans to use are accessible to the Board. While NIOSH is not required under 42 CFR 83 to submit a plan simultaneously as it starts its own evaluation, an explicit preliminary plan appears essential to ensure that (a) NIOSH will consider issues of concern to the Board, and (b) timely Board consideration of the petition and the Petition Evaluation Report in a manner that does not conflict with the Board's full evaluation. The request that NIOSH provide the Board with data, records, reports, and other material that it is using in its own work is expected to minimize any impact on NIOSH's work in performing the evaluation, and is likely to shorten the review process by minimizing the number of iterations needed to support a Board decision.

- The Designated Federal Official schedules a Board meeting or conference call in consultation with the Board.

- The Board convenes a working group as needed to ensure a comprehensive and timely review of the issues.

- The Board's designated working group makes a preliminary evaluation of portions of the information provided by NIOSH in preparation for the Board call. This includes a preliminary consideration of the issues in the petition.

- Board meets (by conference call, if necessary) to review the NIOSH evaluation plan, and to decide whether it is going to consider issues prior to NIOSH's submission of its Evaluation Petition Review. The Board defines the initial scope of the evaluation of the petition by the Board, in order that the working group might consider the issues in a manner that is transparent and that enables full involvement by the petitioners.

The Board may meet to consider the scope of its evaluation at any time after the qualification of the petition for review. NIOSH will submit its evaluation plan in an expeditious manner, and the Board will meet within a few weeks of that time to determine its course of action. Such an approach to each petition is desirable in order to expedite the review process and minimize delays in Board decision-making.

3.2.2 Intermediate Steps

(1) NIOSH adds documents, and chooses partial and completed dose reconstructions that it will use to demonstrate feasibility of dose reconstruction for any member of the class. NIOSH promptly informs the designated working group of the choices as they are made, and the work group provides feedback on whether they feel the selected cases are representative of all members of the class. These steps serve as a practical update of the evaluation plan as it evolves during NIOSH's evaluation. The data, documents, and analytical basis should include, but are not limited to, the following items as NIOSH begins to use them in its evaluation:

- Completed dose reconstructions illustrating various aspects of the feasibility of some aspect of dose reconstruction with sufficient accuracy for members of the class

- Partial dose reconstructions with the same objective

- Co-worker data and analysis

- All documents referred to in the petition

- The site profile, supporting technical information bulletins, and other documents, as applicable to the petition

- Data validation analyses

- Documents relating to radionuclide lists, source terms, air concentration data, and other similar documents that NIOSH is using in its evaluation.

(2) The working group creates and updates the list of issues and develops them sufficiently to ensure that NIOSH gives them appropriate consideration in its evaluation. This step is a precursor to the Board's discussion and review of the completed NIOSH Petition Evaluation Report. The goal of the working group consideration of the issues is to ensure that reconstruction approaches being suggested by NIOSH cover the exposure conditions of the job types in the class and the time periods covered by the petition. In other words, this step allows the working group the opportunity to consider the adequacy, validity, and representativeness of the data, and that of the partial and complete dose reconstruction examples used by NIOSH to demonstrate its ability to reconstruct doses for any member of the proposed class.

(3) NIOSH promptly informs the Board of any changes to the schedule of submission of its evaluation report to the Board.

(4) The Board, through its working group, will familiarize itself with the SEC petition and related documentation and analysis. It will also consider whether it needs additional information or analysis on specific issues, and decide on the means and the schedule for meeting its requirements. This might include one or more of the following:

- A partial, targeted Site Profile Review, if one does not already exist for the site

- Reviews of selected completed dose reconstructions that illustrate NIOSH's approach to one or more aspects of dose reconstruction for the proposed class

- Advanced dose reconstruction reviews for cases from data of claimants or non-claimants selected to illustrate one or more aspects of methods of dose reconstruction that are relevant or representative of some or all of the members of the proposed class

- Validation of selected data

- Compilation of radionuclide lists for selected critical job types

- Interviews with one or more petitioners or their experts or representatives

- Review of selected documentation

During the phase in which NIOSH is evaluating the petition, the main goals of the Board procedures are to (a) satisfy itself that NIOSH is considering a range of issues appropriate to the class of workers that the petition proposes to add to the SEC, and (b) familiarize itself with the issues that NIOSH is considering in its evaluation to a sufficient extent to be able to review and consider NIOSH's petition evaluation efficiently and expeditiously when NIOSH presents it to the Board. Transparency measures that the Board and NIOSH have adopted during the consideration of the Mallinckrodt SEC petition, as well as the Bethlehem Steel Site Profile, are part of the Board procedures, so that petitioners have a full measure of participation in the process. In the case of SEC petitions, opportunity for petitioner participation is part of 42 CFR 83.

3.2.3 Evaluation Review Steps

- NIOSH submits its SEC Petition Evaluation Report prior to a Board meeting, as required under 42 CFR 83.

- The designated working group considers whether NIOSH has adequately addressed the issues raised by the Board in the course of the evaluation report preparation process. The working group makes a recommendation on a course of action to the Board. Petitioners will be given an opportunity for full participation.

- Board hears NIOSH's explanation of its SEC Petition Evaluation Report.

- Board hears petitioner presentation of the issues.

- Based on the above, the Board may take one of three actions:

  (1) Approve the recommendations in NIOSH's SEC Petition Evaluation Report

  (2) Make a recommendation to HHS that does not agree with the position presented in NIOSH's evaluation report

  (3) Recommend further review of the evaluation report, including:
  (a) Select issues for further review by the Board's working group
  (b) Request NIOSH to review selected issues and present a supplemental evaluation report
  (c) Decide to review the entire NIOSH SEC Petition Evaluation Report

Steps 3a and 3b above are not mutually exclusive and could be pursued in a manner similar to the comment resolution process for site profiles that the Board used for the review of NIOSH's Mallinckrodt SEC petition evaluation reports for the 1949–1957 class. This approach is also similar to the process being pursued for the Y-12 SEC petition review. The process consists essentially of the working group, NIOSH, and the petitioners working to resolve outstanding

technical concerns and issues and, where agreement is not possible, to define the technical disagreements clearly and sharply. In case further review is necessary, the procedures outlined in the intermediate steps may be followed in an iterative manner.

The procedures presented here seek to expedite the Board review process by providing for a detailed consideration of relevant issues prior to NIOSH'S submission of an evaluation report to the Board.

3.3 TIMELINESS CONSIDERATIONS

As discussed above, reconciling the requirements of a "full evaluation" of SEC petitions by the Board and timeliness required by EEOICPA would seem to require a substantial Board effort during the period that NIOSH is preparing its SEC Petition Evaluation Report. This approach to SEC petition review by the Board draws on the experience of the Board's consideration of the 1949–1957 Mallinckrodt SEC class. That experience shows that, in complex cases, a careful consideration of the petition and petition evaluations by the Board could bring full consideration and timeliness into serious conflict if the Board begins its evaluation essentially at the time that NIOSH submits its evaluation of the petition to the Board. Appendix A presents a description of the timeline associated with SEC decision-making related to the Mallinckrodt SEC petition. This example is indicative of the need to begin the Board's review of issues related to SEC petitions as soon as possible. A review of the initial portion of the timeline of that process illustrates the central importance of this first part of the Board procedure.[1]

Prompt disclosure by NIOSH of its plans and procedures as it evaluates the petition does not guarantee that Board consideration of complex SEC petitions will be less arduous in the future. It is, however, the basis on which the Board can base its own process to better ensure that the full evaluation it is required to give each petition will be as timely as possible, even in difficult cases.

[1] This timeline is based on the various documents relating to the Mallinckrodt SEC petition on the SEC portion of website of the Office of Compensation, Analysis, and Support, http://www.cdc.gov/niosh/ocas/ocassec.html.

4.0 BOARD CONTRACTOR PROCEDURES

This section presents and discusses the procedures that will be used by the Board's contractors in supporting the Board's review of SEC petitions. The review will vary depending on the availability of site profiles and site profile reviews, as follows:

(1) Reviews in cases where NIOSH has published a Site Profile and a Site Profile Review has been completed

(2) Reviews in cases where there is a Site Profile but a Site Profile review has not been performed

(3) Reviews in a case where NIOSH has not published a Site Profile

Within this framework, procedures are provided for use prior to NIOSH's submission of its SEC Petition Evaluation Report. These procedures reflect the experience of the Mallinckrodt SEC petition evaluation review process and the emerging process for the Y-12 SEC petition review.

In all cases, the procedures focus on the feasibility of dose reconstruction for any member of the proposed class. Hence, the use of dose reconstructions selected to be representative are essential to the review procedures.

The contractor's quality assurance and privacy protection procedures, which are part of other tasks (such as dose reconstruction audits), would also apply to review of SEC Petition Evaluation Reports.

4.1 GENERAL PROCEDURES FOR CONTRACTOR REVIEW OF SEC PETITION EVALUATIONS

The contractor Task Manager will first select a team for each petition evaluation in consultation with the contractor Project Manager once the Board has asked the contractor to review a NIOSH petition evaluation. This team will be selected with due consideration to the familiarity of the team members with internal and external dose reconstruction issues, the site, NIOSH documents related to the site (such as site profiles and individual dose reconstructions that have been performed), and with interviews.

The procedures include the following:

(1) A review of the claims made in the petition using a checklist that explicitly addresses internal dose, external dose, data adequacy, data integrity, missing data, and other types of issues as appropriate.

(2) A review of documents specified in the petition.

(3) An interview with at least one petitioner, followed by the preparation of a summary of the interview, and confirmation of the summary by requesting that the interviewee(s) review the minutes of the interview(s) prior to finalizing the summary.

(4) A review of NIOSH documentation pertinent to the Petition Evaluation, including references provided in the Petition Evaluation.

(5) A review of the NIOSH Petition Evaluation, including its description of job titles, radionuclide lists, neutron source terms, adequacy of personnel monitoring data as described by NIOSH, completed and partial dose reconstructions used in the evaluation, and other data and documentation directly referred to by NIOSH in its evaluation.

(6) If necessary, interview one or more NIOSH and contractor principal personnel who prepared the SEC petition evaluation, keeping a record of the interviews, and including that record as part of the review report to the Board.

(7) Prepare a full checklist of issues relevant to the review, including those in item 1 above. Assign issues to members of the review team. A review form will be completed for each issue identified (see Exhibit 1). Completed review forms will become part of the review presented to the Board.

(8) Decide if reviews of DOE, NIOSH, Defense Nuclear Facilities Safety Board, Nuclear Regulatory Commission (NRC), DOE contractor archives, AWEs, State or Federal regulatory agencies, academic institutions, Federal records archives, or individuals relevant to the SEC petition evaluation are needed in addition to the above document review. If so, complete the necessary reviews. In addition, under the direction of the Board, review comments and testimony submitted to or presented before the Board.

(9) Consult with contractor reviewers of dose reconstructions and determine if any reviews of dose reconstructions relevant to the proposed class have been performed or are scheduled to be performed. If they are scheduled, but have not yet been performed, make an internal request for the contractor to prioritize the completion of those reviews.

(10) Consult with the designated Board working group and with NIOSH, while keeping summary records of such consultations, including e-mails and phone calls, to determine what additional completed and partial dose reconstructions, if any, are needed in the course of the petition review.

(11) Assess whether there may have been sufficient failures of radiological controls over periods of less than 250 days to endanger the health of workers who would otherwise be members of the class, if NIOSH has not already done so.

(12) Make a list of other sites or facilities from which NIOSH has used data or information to make its determination of the feasibility of dose reconstruction.

(13) Evaluate the data used by NIOSH about other sites and facilities against documents and other information from those sites, as necessary.

(14) Review any special issues specific to the proposed class, including review of classified documents, if necessary. The latter will be carried out by contractor personnel with the appropriate clearances. The procedures already established for classified Site Profile Review will be followed, including submission of interviews and other materials for declassification review to the appropriate authorities.[2]

(15) Attend Board and working group meetings where the SEC petitions and their evaluations are being reviewed or discussed.

(16) Make presentations to the Board when requested, according to a schedule determined by the Board.

4.1.1 Interview Procedures

Interviewing Principal Authors of the SEC Petition Evaluation

If necessary, the contractor will request that it be allowed to interview one or more of the principal personnel who helped prepare the NIOSH SEC Petition Evaluation. Such interviews may not be necessary, given that there are likely to be working group meetings in complex cases and that contractor personnel are likely to attend such meetings.

Interviews with NIOSH/ORAU petition reviewers will be conducted either in conference calls or in person, with the latter option reserved for instances where the complexity of the issues require a more thorough review. All conference calls or discussions held in person will be documented, and NIOSH/ORAU will be given the opportunity to review written material for accuracy and completeness. Questions submitted to NIOSH/ORAU and discussion materials will be included in the SEC Petition Evaluation Review prepared by the contractor.

Interviewing Petitioner(s) and Sources of Site Knowledge

As necessary, the contractor will conduct one-on-one or group interviews with selected sources, including the following:

- Petitioner(s) and contributors responsible for petition development
- DOE Records, AWE Records, and/or Federal Records Repository Personnel
- Potential members of the class or their survivors

[2] Much of this procedure was first established in the course of the contractor's ad hoc technical support request by the Board in the process of the Board's consideration of the IAAP SEC Petition (SC&A 2005c).

- Labor organizations who represent or represented employees at the facility during the relevant period of time

- Managers, radiation safety officials, and other witnesses present during the relevant period of time

- Researchers, epidemiologists, medical screening program personnel, and other persons involved in related activities conducted to evaluate the health and/or radiation exposures of DOE employees, DOE contractors or subcontractors, and/or AWE employees

- Other sources as necessary.

The objective of this activity is to assess whether NIOSH proposals for class definitions are well-founded, to obtain as clear an understanding as possible of the petitioner(s) basis for filing the petition, and to obtain data, documents, and information that site experts or others may know about, but are not contained in the available records.

Interviews will be conducted where convenient for those individuals or groups, including near the actual site in question. The objective of this activity is to obtain the benefit of the first-hand experience and recollection of individuals who, through their association with the site in question, have original perspectives and information regarding site practices and exposure history. By design, the interview process is an integral part of the SEC review process. Contractor personnel will also review interviews conducted by NIOSH/ORAU during their evaluation of the petition, provided that documentation of those interviews is available.

The information gathered from these interviews will be used to complement other data and analyses performed as part of the SEC petition review process. Any discrepancies or issues surfaced in this manner will be pursued through the review of other available information sources, as well as additional interviews for corroboration, if needed.

All interviews will be documented, and individuals interviewed will be given the opportunity to review the interview summary for accuracy and completeness. This is an important safeguard against missing key issues or misinterpreting some vital piece of information. References to specific individuals in the contractor petition review report will be omitted at the request of the interviewee. Summary of interviews will be included in the SEC Petition Evaluation Review prepared by the contractor.

4.1.2 Evaluation Review Form for Single Issues

A member of the contractor review team will complete a review form for each issue identified as relevant to the review. Exhibit 1 shows a draft of the review form. This form may be expanded to add items, as necessitated by the specifics of a particular evaluation review.

Exhibit 1. SEC Petition Evaluation Review Form for Review of Single Issues

Page____of_____

Review Number:	**Date:**	**Petition Number:**
Reviewer(s):		
Summary of Issue:		
Review record summary (Describe below what records examined)**:**		
List of person(s) interviewed (Attach a copy of the interview documentation to this report)**:**		
Review conclusions: Summary of main findings in matrix form regarding the issues being reviewed	Review recommendations: Suggestions for how issues raised may be addressed (if applicable)	Comments regarding dose reconstruction examples relevance for issue, if any
Provide a summary discussion of the findings (Attach all calculations, notes, reports, etc., used in your conclusions)**:**		
General comments:		
Signature(s) of reviewer(s):		
Area of review:		
Date:		

4.2 REVIEW OF SEC PETITION EVALUATIONS WITH A SITE PROFILE AND SITE PROFILE REVIEW – ADDITIONAL TASKS

In addition to the procedures for all reviews of SEC petition evaluations, the procedures for reviews in those cases where there is a Site Profile and a Site Profile Review will consist of the following:

(1) Make a list of issues based on the Site Profile Review and associated Board discussion and other documentation that the contractor deems relevant.

(2) Compare this list to the list of issues described in Section 4.1.

(3) Compare the job titles, radionuclide lists, neutron source terms, and other items relevant to determining dose reconstruction feasibility with the descriptions and analysis in the NIOSH Petition Evaluation.

4.3 REVIEW OF SEC PETITION EVALUATIONS WITH A SITE PROFILE, BUT NO SITE PROFILE REVIEW – ADDITIONAL TASKS

The contractor will perform a partial review of the Site Profile and associated documentation with a view to determining job titles, adequacy of data, radionuclide lists, and other information relevant to dose reconstruction with sufficient accuracy for members of the proposed class. This review will omit many issues, such as limits of detection for monitoring equipment, review of area monitoring if NIOSH does not propose to use it in determining dose reconstruction feasibility. This review will be a supplement to the review of the documents, to the interviews, and other tasks defined in Section 4.1 above. It will be oriented towards preparing a list of issues based on the Site Profile, and comparing the list with that in Section 4.1, as described in Section 4.2 above.

4.4 REVIEW OF SEC PETITION EVALUATIONS WITH NO SITE PROFILE

For SEC petition evaluation reviews for which there is no Site Profile, the completed review will also include findings relating to the following:

- Completeness of radionuclide lists and areas where such radionuclides might be present
- External dose records completeness and accuracy (including neutron dose records)
- Availability and completeness of bioassay and other data relating to internal dose
- Methods of estimating missed dose
- Usability of air concentration data and area external dose measurements as substitutes for personal dosimetry data when these are not available
- Availability of job category data

- Environmental dose estimation procedure

- Availability of data on incidents, and the methods for the incorporation of this information into dose reconstruction

- Evidence of significant failure of radiological controls

Unlike site profile reviews, which are concerned primarily with the scientific validity and claimant-favorability of the data and methods employed in the site profile and its supporting documentation, SEC petition reviews and NIOSH's reviews of SEC petitions will emphasize whether it is (1) feasible to estimate with sufficient accuracy the radiation dose that the class received; and (2) whether there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class. This is an important distinction, because SEC petition reviews are less concerned with the optimum method for performing dose reconstructions for individuals and more concerned with whether dose reconstructions can, in fact, be performed with sufficient accuracy for classes of individuals.

For SEC petition reviews for sites without a site profile, the completed review will also include a set of findings relating to the above items as they apply to estimation of doses with sufficient accuracy. SEC petition reviews will not be site profile reviews, but a set of findings that will support conclusions regarding NIOSH's ability to perform dose reconstruction with sufficient accuracy, as defined in 42 CFR Part 83.

4.5 STRUCTURE OF THE CONTRACTOR REVIEW REPORT

Each completed review will consist of the following:

- A review of the petition and the documentation associated with the petition

- Summaries of interviews with petitioners, site experts, and technical experts

- A review of NIOSH's petition evaluation, including sections consisting of findings in the various areas of dose reconstruction, along with supporting documentation and calculations

- A list of issues identified for review based on the above

- A completed review form for each issue

- A list of documents reviewed

- Attachments describing correspondence with NIOSH relating to the review, such as questions sent to NIOSH, responses received, and transcripts of meetings (if available)

4.6 REVIEW OF SPECIFIC ISSUES

The specific issues to be reviewed will be assigned to the contractor by the Board or its working group. The identification of the issues will depend on whether NIOSH has published a Site Profile and whether it has been reviewed. The issues will also depend on whether the workbooks now being used by NIOSH for dose reconstruction have been reviewed, especially as they apply to "best case" dose reconstruction examples.

Drawing on the experience of Mallinckrodt, IAAP, and Y-12 SEC petition evaluation processes (the latter is ongoing), the contractor's procedures for the identification and evaluation of issues could include one or more of the following elements:

- A targeted review of elements of the site profile and workbooks where such a review does not exist, with a view toward identifying radionuclide lists, elements of dose reconstruction that address the need for representativeness of selected dose reconstructions for the class, issues associated with neutron spectra, and individual dose records.

- Preparation of an issues list based on completed site profile and workbook reviews.

- One or more interviews with petitioners and/or site experts, if needed.

- Development of issues, such as the connection of radionuclide lists to job types, data validation, evaluation of representativeness of dose reconstructions used by NIOSH in its demonstration of dose reconstruction feasibility, and data integrity issues (should any appear to exist or if any are alleged).

- Participation in working group/NIOSH/Petitioner meetings, and preparation of targeted written materials directed at specific issues at the direction of the Board. Examples include the specific issues identified and evaluated as part of the review of the Mallinckrodt 1949–1957 class SEC petition and its supporting site profile (SC&A 2005a; SC&A 2005b).

REFERENCES

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; Final Rule*, Department of Health and Human Services, Federal Register, Vol. 69, No. 104, May 28, 2004.

ABRWH 2005. Transcript of the Twenty-eighth meeting of the Advisory Board on Radiation and Worker Health held at the Adam's Mark Hotel, St. Louis, Missouri, on February 8 and 9, 2005, Excerpt relating to Mallinckrodt.

ABRWH 2005a. Letter from Paul Zeimer, Chair of the ABRWH to Michael Leavitt, Secretary of the U.S. Department of Health and Human Services, September 15, 2005.

ABRWH 2005b. Transcript of the meeting of the Working Groups of the Advisory Board on Radiation and Worker Health (Site Profile Working Group and the SEC Working Group) held at the offices of NIOSH in Cincinnati, Ohio, 16 and 17 November 2005.

NIOSH 2005. *SEC Petition Evaluation Report, SEC 0012-2*, Report Review Draft #2 (no date, submitted to the Board in February 2005).

NIOSH 2005a. *SEC Petition Evaluation Report, SEC 0012-1 and 0012-2*, Report Review Supplement, 3-30-2005.

SC&A 2005. *Supplemental Review of the NIOSH Site Profile for Mallinckrodt Chemical Company, St. Louis, Downtown Site, St. Louis MO*, SCA-TR-TASK1-0002, April 18, 2005.

SC&A 2005a. *Second Supplemental Review of the NIOSH Site Profile for Mallinckrodt Chemical Company, St. Louis, Downtown Site, St. Louis, MO*, SCA-TR-TASK1-0002, July 1, 2005.

SC&A 2005b. *Third Supplemental Review of the NIOSH Site Profile for Mallinckrodt Chemical Company, St. Louis, Downtown Site, St. Louis, MO*, SCA-TR-TASK1-0002, August 16, 2005.

SC&A 2005c *Review of NIOSH Site Profile for the Atomic Energy Operations at the Iowa Army Ammunition Plant (IAAP) Final Integrated Version*, SCA-TR-TASK1-0009c, June 2005.

SC&A 2005d. *The Review of NIOSH/ORAUT Procedures and Methods Used for Dose Reconstruction*, Report, SCA-TR-Task3-0001, S. Cohen and Associates, McLean, Virginia.

SC&A 2005e *Review of the NIOSH Site Profile for Mallinckrodt Chemical Company, St. Louis, Downtown Site, St. Louis, MO*, SCA-TR-TASK1-0002, January 2005.

SC&A 2005f Review of NIOSH/ORAU Special Exposure Cohort Evaluation Procedures, SCA-TR-TASK5-0001, November 23, 2005.

SC&A 2005g. *Review of NIOSH Site Profile for Bethlehem Steel Plant, Lackawanna, NY*, SCA-TR-TASK1-0001, S. Cohen & Associates, McLean, Virginia. October 2004.

APPENDIX A: TIMELINE OF THE BOARD REVIEW OF THE MALLINCKRODT SEC PETITION

(1) July 21, 2004: Petitioner submits a petition asking for a class defined by the employees who worked in Mallinckrodt's Uranium Division at Destrehan Street between 1942 and 1957 to be added to the Special Exposure Cohort. Petition alleges lost or destroyed data, and also alleges that data may have been altered.

(2) December 20, 2004: NIOSH publishes a notice in the *Federal Register* that the petition has qualified for evaluation.

(3) January 18, 2005: NIOSH tells the Working Group that it has discovered six additional boxes of documents relating to Mallinckrodt, and that records that were alleged to be lost have been found (ABRWH 2005, p. 68, p. 224).

(4) February 3, 2005: NIOSH publishes a notice in the *Federal Register* that the Board consider NIOSH's Mallinckrodt SEC petition evaluation at its February 7 to 9, 2005 meeting in St. Louis.

(5) February 7–9, 2005: NIOSH splits the class into workers who worked in three periods: 1942–1945, 1946–1948, and 1949–1957. In its evaluation reports, NIOSH recommended an addition to the SEC for the first two classes, stating that it could perform dose reconstructions for the 1949–1957 class, and requesting Board advice on how to address the data integrity issues raised in the petition (NIOSH 2005; NIOSH 2005a). Board contractor presents a Site Profile Review that raises numerous questions, including questions regarding the adequacy of the data in the Site Profile and associated documents for dose reconstruction (SC&A 2005e).

(6) February 8–9, 2005: Board identifies five issues for NIOSH to evaluate further in relation to the 1949–1957 class, including evaluation of the documents in the six boxes, and how internal doses would be estimated, given that bioassay records were available for uranium only in light of the fact that several other radionuclides were present.

In February and March 2005, the Board was able to begin to fully evaluate the documentary basis and part of the analytical basis of NIOSH's claim that it could estimate doses for the 1949–1957 period (apart from the data integrity issue). Even though the data integrity question was resolved and it appeared that there had been no large-scale tampering with the data that would prevent dose reconstruction, the adequacy of the monitoring records in relation to the radionuclide list and internal doses became the dominant issue. The Board considered the issue for over 6 months after its February meeting, a period which involved three supplemental reviews of the Site Profile and the emergence of new analytical methods and data validation exercises in response to Board requests for further evaluations.

By its August 2005 meeting, the issue of timeliness had come to the forefront, along with some remaining technical issues. This is evident in the Board's letter recommending to the Secretary

of HHS that 1949–1957 Mallinckrodt Uranium Division employees be added to the SEC (ABRWH 2005a, pg. 2). The Board's concerns arose from the fact that it sent its letter to the Secretary of HHS on September 13, 2005, after considering the Petition for well over 6 months.

The Mallinckrodt SEC petition was the first one to be considered by the Board. The unprecedented nature of the problem, as well as its complexity, gave rise to the iterative evaluations that the Board needed to make to ensure that it had evaluated the problem fully before voting.