

**REPORT OF THE WORKING GROUP ON SPECIAL EXPOSURE COHORT
PETITION REVIEW (1/16/06 Draft)**

Introduction

The ABRWH Working Group on Special Exposure Cohort Petition Evaluation met in Cincinnati on November 17, 2005. Members attending the meeting included Jim Melius, Chair; Roy DeHart, Mark Griffon, and Paul Ziemer. Representing NIOSH were Lew Wade, Larry Elliot, Jim Neton, Stu Hinnifeld, and several other staff members.

The discussions at the meeting focused on methods to improve the evaluation of Special Exposure Cohort Petitions by NIOSH and the ABRWH. Although not all members of the working group were satisfied with the criteria outlined in the current regulations and reserved their right to re-examine the regulations at a later date, the Working Group decided to work on developing guidelines within the context of these regulations. The key criterion as spelled out in the regulations is “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...”

At the present time, the guidelines for implementing this regulation are quite broad. Both NIOSH and the Board have struggled to provide a fair and timely assessment of the initial SEC petitions. Both the Board and NIOSH recognize the need to develop more specific guidelines and procedures for this process. Based on the recent and ongoing SEC petition evaluations, the working group identified key criteria that needed to be considered in the review of the data being used for SEC evaluation. This report summarizes the Working Group's discussions on general criteria that should be utilized in the review of these data. The Working Group also evaluated the SEC evaluation review process and has made recommendations to facilitate and improve that process.

Key Considerations for Board Review

There are several key principles that should guide Board review of SEC evaluations:

1. **Timeliness** – NIOSH must be able to conduct the SEC evaluations, and the Board must be able to review the NIOSH evaluation and make its own recommendation in a timely fashion. This requires that the process be efficient and that both NIOSH and the Board have clear expectations for the scope and level of detail to be included in the evaluation report. Multiple meetings to consider a petition should not be required although, in some circumstances this cannot be avoided (e.g., when new information is uncovered as part of the evaluation) .

2. **Fairness** – The NIOSH evaluation and the Board’s review should try to ensure that each petitioner is treated fairly with appropriate access to all meetings regarding the evaluation and especially to the meeting where the Board is making a recommendation on their SEC petition. The evaluation also needs to be fair in the treatment of subgroups within the potential cohort and should ensure that all such groups receive a fair and complete evaluation.
3. **Understandable** – The method by which the petition is evaluated and the criteria by which NIOSH and the Board evaluate the petition must be clearly understandable by all of the involved parties. Given that the regulations provide only broad criteria and that situations involving individual DOE/AWE facilities are often quite complex and may not always be foreseen, the evaluation guidelines and procedures must be clearly stated and their application clearly based on the on the relevant circumstances involved at that site (i.e., evidence based application).
4. **Consistency** – In evaluating SEC petitions, NIOSH and the Board must try to be consistent in applying relevant criteria to each petition. Both NIOSH and the Board must be mindful of precedents established in earlier reviews.

Scope of the Review

The scope of the review will vary depending on the nature of the group covered by the petition, the complexity of radiation exposures at the site, and the quantity and type of data available. Thus, it is not possible to specify the type or level of assessment needed

to determine whether radiation doses can be determined with sufficient accuracy for any petition. However, the Working Group recommends that key criteria for assessing the different types of exposure data which are likely be used in SEC petition evaluations be established. These criteria focus on assessing the credibility and validity of the data and the representativeness of the data.

Credibility and Validity of Data Set

For each petition evaluation, NIOSH will typically review the available exposure data for that site and then focus on a few key sets of exposure data (including exposure sources) to determine if those data at that site are adequate for completing individual dose reconstructions for all members of the class. The Working group recommends that NIOSH assess the credibility and validity of these critical exposure data sets with special attention to the following criteria:

1. **Pedigree of the Data** – NIOSH should determine the history of the data set including the documented intent of the original exposure evaluation and the relation of the exposure monitoring to documented activities at the site during that time period. When using secondary sources of data, NIOSH should ensure that these data are consistent with the original data set (e.g., some data sets throw out high monitoring values because they appear to be anomalies leading to a potential loss of pedigree).

2. **Methodology** – While recognizing that radiation monitoring and analytical methods have varied significantly from site to site and over time, NIOSH should evaluate the documented methodology for the data set including whether reliable corrective estimation procedures have been applied and are appropriate.
3. **Relation to Other Sources of Information** – Often the documentation available on a set of exposure monitoring data is sparse. If the data are to be used for dose reconstruction, NIOSH should demonstrate through evidence that the data are appropriate for determining individual doses and specifically for estimating the maximum plausible dose for any member of the class. Evidence to support NIOSH’s proposed approach can include but is not limited to: 1) sources of information presented by the petitioner including addressing concerns about the data raised by the petitioner; 2) worker interviews; 3) other sampling data which may not be used in the dose reconstructions but can be used to validate the proposed approach (e.g., do does estimates from air sampling data support that derived from internal monitoring); 4) process or production information; and 5) source term information.
4. **Internal Consistency** - NIOSH should also evaluate the internal consistency of the data set.

Representativeness

The Working Group also recommends that NIOSH evaluate and demonstrate the representativeness of each key set of exposure data:

1. **Areas of the Facility Represented** – NIOSH should determine if the exposure data covers all areas of the facility relevant to the petition under consideration.
2. **Temporal** – NIOSH should assess whether the exposure data provides necessary information on all time periods relevant to the petition under consideration in order to ensure statistical representativeness.
3. **Types of Workers and Processes Covered** – NIOSH should assess whether the exposure data in combination with other information is adequate to assess the exposure of all of the different types of workers covered by the petition. This assessment should take into account the job tasks of the different types of workers, their use of protective equipment, the various processes involved, source terms, and other factors.
4. **Consideration of Data and Data Subsets** – NIOSH must demonstrate that there are sufficient data (e.g., is the sample size adequate) and that the data are representative of the highest exposed individuals within the class. This may involve looking at subsets of larger exposure data sets. Often these subsets are less comprehensive for a given time period (usually earlier years). NIOSH should assess how “robust” these data or data subsets are for the purposes of dose reconstruction. In answering this question NIOSH should consider whether they can determine the representativeness of the data. Some

questions which should be considered in evaluating representativeness include: 1) Are the data from the site in question, from a surrogate site(s), or both;. 2) If from a surrogate site, have these data been appropriately evaluated and have the uncertainties due to extrapolation from another site been accounted for; 3) Do they represent the highest exposed individuals? 4) Do they represent the entire exposed cohort; 5) Do they represent all workers ever on the site; 6) Are the data from “cohort” type sampling? And 7) Can the data be interpreted in a way to ensure that the maximum plausible dose can be determined?

Demonstration of Feasibility and Sufficient Accuracy

The Working Group recommends that NIOSH include in their SEC evaluations some steps to try to demonstrate that that it is feasible to reconstruct individual doses for that cohort (e.g., with a best estimate). This demonstration should help to focus the NIOSH evaluation and the Board’s review of that evaluation on the critical exposure information and should help to avoid a situation where it is later learned that it was not feasible to reconstruct individual doses for a denied petition. The key aspects of this demonstration include:

1. **Feasibility** – The method being proposed for individual dose reconstruction must be feasible to conduct within the constraints of this program. For example, the method must not be based on the need for further validation of

an older method if that validation will take an extended amount of time to complete. The data that are being proposed for use must be readily available.

2. **Timeliness of Dose Reconstructions** – In the event that NIOSH determines that they are able to reconstruct doses for a particular petitioning class, NIOSH must be able to demonstrate that they can complete dose reconstructions for all members of the class in a timely fashion. If a petition is denied based on the grounds that it is feasible to estimate doses with sufficient accuracy, individual claimants should not have to wait for an extensive time period for NIOSH to be ready to reconstruct their doses. Congress has placed time constraints on the evaluation of SEC petitions. Decisions must be made with the data in hand at the time of the evaluation, not based on what might become available in the future. This general need for timely response to SEC petitions and individual dose reconstructions should be respected.
3. **Avoid Disparate Treatment of Claimants** – The methods being proposed must ensure fair treatment of all claimants. Dose reconstruction procedures and assumptions (including claimant favorability) should not unduly favor or discriminate against particular subgroups. For example, dose reconstructions for claimants from a particular facility from one year should not be vastly different from those doing similar work the following year unless such a change is clearly justified on the basis of substantial changes in processes, materials and nuclides, or monitoring methods. Similarly, claimants and petitioners from different facilities should be evaluated in a similar fashion.

4. **Sample Dose Reconstructions** – NIOSH should present sample dose reconstructions that realistically demonstrate the range of dose reconstruction methods being utilized for this cohort including for each type of worker, process, and time period covered in the proposed SEC (i.e., including evidence of representativeness for each potential subgroup). These sample cases do not necessarily need to be completed dose reconstructions or completed “best estimates” but should be used to demonstrate that the method proposed in the evaluation report will be feasible for dose reconstructions within the range of data available at that time and that the approach can “bound” the radiation dose for all cancers and all members of the class.

Procedural Changes

The Working group also made some procedural recommendations:

1. **Petition Evaluation** – Currently, NIOSH prepares a petition evaluation plan for each SEC petition accepted by NIOSH. These plans provide very little detail often because they are developed before NIOSH has had an opportunity to become familiar with the available data. The plans should be expanded to reflect some of the evaluation criteria outlined above. To the extent that it is feasible for NIOSH to delineate the planned scope of their evaluation including the actual steps they plan during the SEC evaluation, this will help to facilitate

the planning and preparation for the necessary scheduling of meetings, conference calls, etc. and help the Board prepare for their review of the NIOSH evaluation and recommendation.

2. **Site Profile Review** – Wherever possible, the Board’s review of the site profile for the site where an SEC petition is being considered should precede the SEC evaluation review. This will ensure that the Board and Board’s contractor is familiar with the site and with the exposure and monitoring data available for that site. If a site profile review is not available, the Board should consider requesting that their contractor review the parts of the site profile relevant to the SEC petition evaluation review in conjunction with the SEC evaluation review.