NIOSH Radiation Dose Reconstruction Program

Ten Year Review – Phase I Report

Dose Reconstruction

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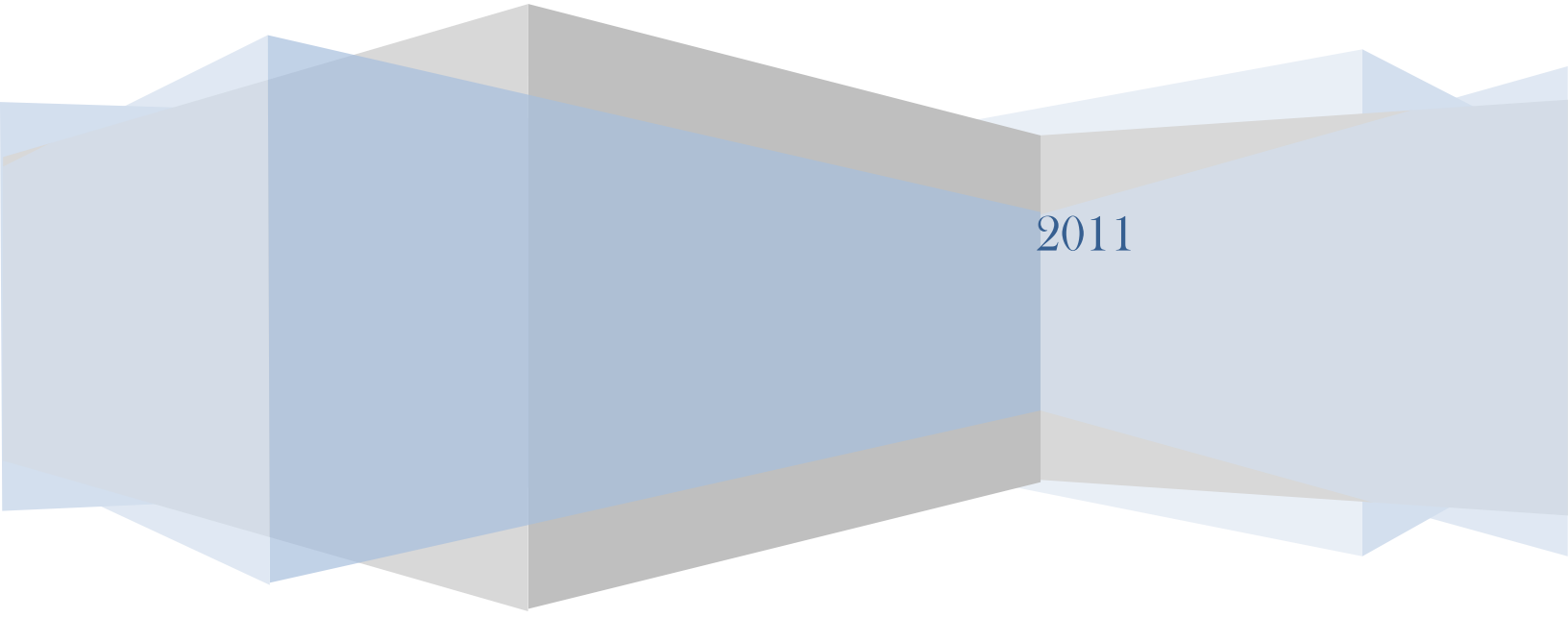

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Radiation Dose Reconstruction

Submitted By

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Dose Reconstruction

Ten Year Review of the NIOSH Radiation Dose Reconstruction Program- Phase I Report

Dose Reconstruction

I. Background:

This section of the Phase I Report focuses on the appropriateness and the consistency of decisions on individual dose reconstructions.

To date (April 15, 2010) NIOSH has completed and returned to the Department of Labor (DOL) 25,833 completed dose reconstructions. Note the data referred to in this report is constantly changing. The data in this report will be current as of April 15, 2010 unless otherwise noted.

The following paragraphs are intended to provide background to the reader not completely familiar with all aspects of the NIOSH dose reconstruction program.

a. Types of Dose Reconstructions

NIOSH uses three different types of dose estimation techniques to perform individual dose reconstructions. Two of the three types are categorized as efficiency measures. If NIOSH receives a request to perform an individual dose reconstruction from the Department of Labor that NIOSH determines as extremely likely to be compensated, NIOSH will do an Underestimating dose reconstruction, in order to accelerate the completion of that dose reconstruction. In an Underestimating dose reconstruction NIOSH will make assumptions that will intentionally underestimate an individual's dose but still result in a dose that would yield a probability of causation greater than or equal to fifty percent (compensable). NIOSH makes use of the Underestimating dose reconstruction to allow for a more rapid and timely accomplishment of the individual dose reconstruction (remember NIOSH is doing tens of thousands of individual dose reconstructions so such efficiency measures can make a difference). A second efficiency measure type of dose reconstruction is the Overestimating dose reconstruction. In an Overestimating dose reconstruction NIOSH purposefully overestimates elements of an individual's dose reconstruction, in order to accelerate the completion of that dose reconstruction. . If the overestimated dose reconstructions results in a probability of causation of less than fifty percent, then the claim will be denied. This again allows for a more rapid and timely dose reconstruction. In contrast to the two types of efficiency measure dose reconstructions is the Best Estimate dose reconstruction. In this case every effort is made to do as complete and precise a dose reconstruction as is possible. The Best Estimate dose reconstruction is used if the situations discussed above relative to Underestimating or Overestimating dose reconstructions are not present. Therefore, the three types of dose estimation techniques used to perform individual dose reconstructions by NIOSH are:

1. Overestimating
2. Underestimating
3. Best Estimate

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b. Procedures , Site Profiles and Technical Basis Documents Used to Accomplish Dose Reconstructions

To facilitate the timely and uniform accomplishment of individual dose reconstructions NIOSH has developed Procedures to assist the individual doing the dose reconstruction. More than one hundred such Procedures have been developed and are in use.

In addition to generic Procedures used to facilitate individual dose reconstructions NIOSH has develop site specific documents called Site Profiles and Technical Basis Documents that contain information about the site in questions. These documents allow a dose reconstructor to have ready access to needed information about the site without having to start from scratch. Approximately seventy-five Site Profiles and Technical Basis Documents have been developed and are in use.

c. Dose reconstruction reworks

Once a "completed" dose reconstruction has been sent by NIOSH to DOL, that dose reconstruction could be returned to NIOSH to be reworked. Such reworks can be returned for a variety of reasons, including:

i. New information about the claim such as: additional employment, a new cancer, etc.
ii. NIOSH requested that the dose reconstruction be returned so that the dose reconstruction can be reworked to reflect a change in the science that the dose is based upon.
iii. DOL believes that an error was made in the dose reconstruction.

When NIOSH determines that a change in the science has taken place that will necessitate the reworking of individual dose reconstructions NIOSH will issue a Program Evaluation Report (PER) that identifies the dose reconstructions to be reworked. To date 22 PERs have been developed.

d. Partial dose reconstructions

In a case where a group of employees have been added to the Special Exposure Cohort, it is possible that there may be an individual(s) who are part of that group but who suffer from a cancer that is not included on the congressionally determined list of 22 cancers and therefore cannot be included in the SEC. In such cases NIOSH will attempt to do a partial dose reconstruction for that individual(s) by assigning all of the dose to that individual that can reasonably be assigned. For example if SEC status is granted to a group of employees because NIOSH has no internal dose information (but does have external and environmental dose information) NIOSH will attempt a partial dose reconstruction for an individual with a non-covered cancer using available external and environmental dose.

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II. Outline of this Section

Phase I reports are to be data driven assessments of NIOSH's performance. Following the data driven assessment the author will present observations and conclusions drawn from the materials presented.

In this Phase I report focusing on Dose Reconstruction, eight subsections will be presented each consisting of a data presentation followed by observations and conclusions. The eight topical subsections are:

1. The Advisory Board's review of completed dose reconstructions.
2. The Advisory Board's review of Site Profiles and procedures used to accomplish individual dose reconstructions.
3. Statistics concerning the number and time to complete individual dose reconstructions.
    a. Initial Submissions
    b. Returns from DOL
    c. The Timing of Initial Submissions vs. Returns
4. Statistics concerning the number and time to complete individual dose reconstructions by dose estimation type.
5. Statistics concerning the number of partial dose reconstructions and the POC's of partial dose reconstructions.
6. The percent of dose reconstructions that have resulted in a POC of greater than or equal to 50%.
7. Individual dose reconstruction compensation results based upon the cancer model used.
8. Comments made to the docket.

Dose Reconstruction

1. The Advisory Board's review of completed Dose Reconstructions

The Advisory Board has set a goal of reviewing two and one-half percent of completed individual dose reconstructions. To date the Advisory Board has reviewed 215 dose reconstructions. Such reviews are conducted by the Subcommittee on Dose Reconstructions. On February 10, 2007, Dr. Paul Ziemer, then Chairman of the Advisory Board sent a letter to the Secretary of Health and Human Services reporting on the results of the first 40 cases reviewed by the Subcommittee.[1] On July 31, 2009 Dr. Zeimer again wrote to the Secretary of Health and Human Services this time reporting on the review of the first 100 cases.[2] The following excerpts are taken from the attachments to the July 31, 2009 letter:

> *"NIOSH indicated that based on approximately 20,000 cases completed approximately 8% have been best estimate cases, 63% over-estimate, and 29% underestimate. Of the cases discussed in this report 7% were best estimate, 76% were over-estimate and 17% were underestimates.*
>
> *In the seven (7) cases that were reviewed which incorporated a 'best estimate' approach for dose reconstruction, several findings related to professional judgment and consistency were made which may have impacted the overall outcome of the case. Explanations were offered, after the fact, of how and why the dose reconstructor arrived at the final dose reported. Reanalysis of the cases, based on modified procedures, was offered to the Subcommittee in response to findings. While the re-analysis appeared to demonstrate that the final decision was likely appropriate it raised concerns regarding other cases of this type completed during this time period.*
>
> *There were seventy-six (76) cases that were completed using an over-estimating approach. This approach has been adopted by NIOSH to allow for faster completion of non-compensable cases. This approach, while logical and well-intended, does have problems. First of all, in the cases reviewed, NIOSH used this over-estimating approach for eight cases that were later compensated. This is a rather serious quality assurance finding since it brings into question the fairness of the overall program. Additionally, unintended consequences have been created by this efficiency approach. One such consequence is that claimants that are diagnosed with an additional cancer after a decision has been made, and are therefore eligible to resubmit a claim, may receive a lower overall dose because NIOSH recalculated the dose using a best estimate approach rather than an over-estimating approach. While the dose reconstruction may be appropriate, this has created a credibility problem because the claimants do not understand how the doses and Probability of Causation (POC) could go down when a new cancer is diagnosed. A similar misunderstanding has occurred when NIOSH re-evaluates a case(s) based on a modified dose reconstruction method.*

[1] February 10, 2007 Board Letter to Secretary HHS
[2] July 31, 2009 Board Letter to Secretary HHS

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There were 386 deficiencies found in 100 cases audited. With respect to the impact on the dose for the individual cases, the majority of the deficiencies (341 of 398) were low-level deficiencies which likely would not significantly affect the individual dose evaluation; however, there were 46 scored as medium-level deficiencies and 11 as high-level deficiencies." The nature of the 11 high-level deficiencies was:

1. *"Use of ORAUT-OTIB-0004, Rev.02 is inappropriate for compensable cases" responsible for 8 of the 11 high-level findings.*
2. *"Failure to properly address radiological incident" 1 finding.*
3. *"CATI information inconsistent with data used to calculate internal dose" 1 finding.*
4. *"Failure to assign unmonitored neutron dose for all years of employment" 1 finding.*

To better understand the nature of the findings associated with the Board's review of individual DR's consider the following list of technical nature of the "quality related" findings for the review of the first 178 individual DR's reviewed by the Board, this information was provided by the Board's Technical Support Contractor:

# Findings	Percent	Technical Nature of Finding
14	7%	Data Collection
35	17%	Claimant Information
78	38%	Photon Doses
14	7%	Shallow Doses
30	14%	Neutron Dose
5	2%	Hypothetical Internal Dose
33	16%	IMBA Internal Dose
208	100%	

The findings and conclusions expressed in this report are exclusively those of the author(s) and do not necessarily represent the views or position of the National Institute for Occupational Safety and Health (NIOSH), the Centers for Disease Control and Prevention (CDC), or the Department of Health and Human Services (HHS). This document is only one of many inputs that the NIOSH Director may consider in the ten-year review of NIOSH's performance under the Energy Employees Occupational Illness Compensation Program.

Dose Reconstruction

Author's Observations and Conclusions:

1. The number of findings resulting from the review of the first 100 cases and the important nature of those findings emphasizes the importance of NIOSH continuing to subject itself to a high level of external review.

2. NIOSH, guided by the nature of the findings from the first 178 DR reviews, must undertake a rigorous review of its internal quality control quality assurance procedures followed by a committed effort to improve those procedures to reduce the deficiencies found in Board reviews.

3. Not only must Overestimating approaches be used with great care, but thought should be given to the continued use of such techniques at this stage of the program's evolution given the confusion to claimants as stated by the Board, "this has created a credibility problem because the claimants do not understand how the doses and Probability of Causation (POC) could go down when a new cancer is diagnosed."

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2. The Advisory Board's review of Site Profiles and procedures used to accomplish individual Dose Reconstructions.

The Advisory Committee reviews the procedures used by NIOSH to conduct individual dose reconstructions. Such reviews are conducted by the Subcommittee on Procedures. To date one hundred five (105) such procedures have been reviewed. On January 29, 2010, Dr. Paul Zeimer sent a letter to the Secretary of Health and Human Services reporting on the results of three selected sets of procedures.[3]

The following is an excerpt from that letter:

> *"The complete group of procedures so far scrutinized totals 105, including revision of certain procedures when circumstances appeared to require that action. The number of individual findings totals 538, more than 80% of which have been deliberated upon and 49% of the total have been closed.*
>
> *Findings and observations made from the technical reviews range from minor issues with no measurable impact on compensation decisions to matters of scientific debate which may have complex-wide implications.*
>
> *In addition seventy five Site Profiles that have been prepared by NIOSH, the Advisory Board has or is involved in the review of thirty four. The status of those thirty four is as follows:*
>
> 1. *All work completed -3*
> 2. *Active review under the direction of a Work Group -20*
> 3. *Initial review report received from the Board's Support Contract, but no Work Group yet assigned -8*
> 4. *Recent assignment of task to Support Contractor to prepare an initial review but no report yet received and no Work Group yet assigned-3*
>
> *An evaluation of several such Site Profile reviews would lead to the conclusion that twenty or more findings for each review are typical. Considering the thirty four Site Profile reviews, the total number of findings is more than 700."*

[3] January 29, 2010 Board Letter to Secretary HHS

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Author's Observations and Conclusions:

1. The number of findings (538 resulting from procedures reviews and more than 700 resulting from Site Profile Reviews) reinforces the need for NIOSH to focus on its internal quality control/quality assurance efforts.

2. The significant amount of work still to be completed, i.e. 20 site profiles under active review by Work Groups, 11 Site Profiles Reviews without a Work Group assigned; only three of seventy five site profiles closed out: and more individual DR reviews to reach the 2.5% goal, underscores the need for NIOSH to develop and implement a detailed resource management plan to ensure that finite NIOSH resources are deployed in ways consistent with program priorities.

3. NIOSH needs to conduct an analysis of completed reviews to identify if there are reoccurring issues that appear in a number of reviews and if so these issues should be given a high priority to be corrected.