NIOSH Dose Reconstruction Program

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Draft

Ten Year Review - Phase I Report

Dose Reconstruction

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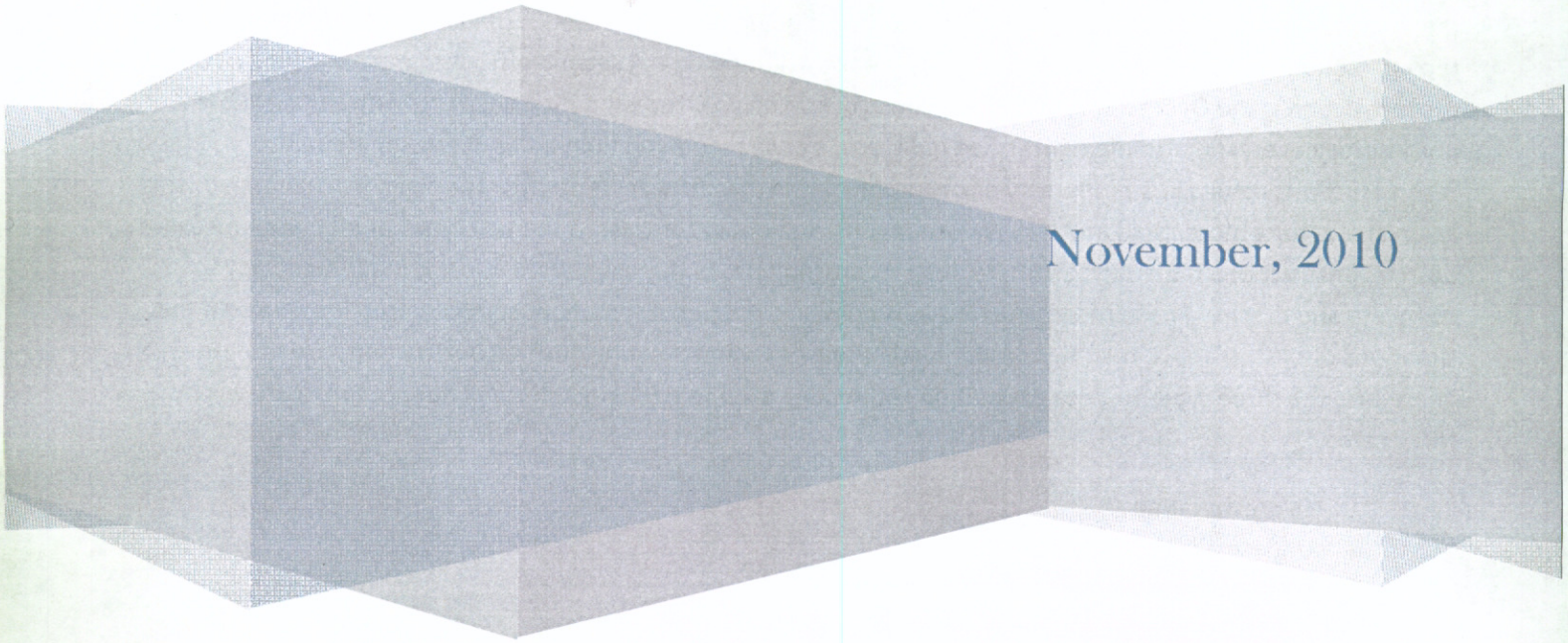


November, 2010

Ten Year Review of the NIOSH Radiation Dose Evaluation 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 an Underestimating dose reconstruction NIOSH will make assumptions that will knowing 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. 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

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.

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.

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

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%	

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."

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 and 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

Authors 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 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.

3. Statistics concerning the number and time to complete individual dose reconstructions

a. Initial Submissions

As of this writing 25,833 claims (initial versions) have been received from and submitted to DOL. Table 1 lists the number of such initial receipts based upon the year the claim was received by NIOSH as well as the year the Claim was submitted to DOL.

Table 1: Number of Initial Claims by Calendar Year Received and Submitted

Number of Claims	Calendar Year Received	Number of Claims	Calendar Year Submitted
1160	2001	0	2001
8967	2002	22	2002
4949	2003	1225	2003
3165	2004	4812	2004
2514	2005	5412	2005
2191	2006	5224	2006
3162	2007	3077	2007
2466	2008	2901	2008
2308	2009	2523	2009
806	2010	857	2010

Table 2 lists the average number of days that an initial claim was with NIOSH before being submitted to DOL based on the calendar year in which the claim was received and the calendar year in which the claim was submitted to DOL.

Table 2: Average Time in Days an Initial Claim is with NIOSH based on Year Received and Submitted

Average Time in Days	Calendar Year Received	Average Time in Days	Calendar Year Submitted
1120	2001	0	2001
1011	2002	253	2002
843	2003	440	2003
589	2004	593	2004
475	2005	897	2005
288	2006	761	2006
388	2007	720	2007
272	2008	537	2008
189	2009	569	2009
61	2010	652	2010

Author's Observations and Conclusions:

1. The number of initial claims received per year is declining from a high of 8967 received in 2002 to 2308 received in 2009.

2. The average time that an initial claim is with NIOSH is also declining from 1011 days for a claim received in 2002 to 189 days for a claim received in 2009.

3. It is reasonable to assume that the number of claims received in future years will likely be more like the number received in 2008 and 2009 as opposed to 2002. This should free up resources that can be applied to completing claims in a shorter time. NIOSH should set aggressive targets for the average time that an initial claim is with NIOSH. Any such target needs to take into account allowing for a reasonable amount of time to secure the appropriate records from DOE and others. As for NIOSH's part of completing the dose reconstruction once the information is in hand, a target of 90 days or less should be considered.

b. Returns from DOL

As of this writing 9905 claims have been returned to NIOSH by DOL. These returns may be the result of DOL adding information to the claim such as an additional cancer or modifying years of employment, or the return may be the result of a NIOSH request necessitated by the need to reevaluate the claim based upon a change in the underlying science. Of the 9905 claims returned, 5531 were returned at the request of NIOSH, 2547 were returns initiated by DOL. The remaining 1827 could not be placed in either category as information necessary to support such a judgment is not available. Table 3 lists the number of returns for the year the return was received for DOL initiated returns and NIOSH initiated returns.

Table 3: Returns by Year Returned-DOL and NIOSH Initiated

Year Return Received	DOL Initiated	NIOSH Initiated
2004	8	-
2005	7	-
2006	100	9
2007	717	3414
2008	797	1714
2009	741	382
2010	177	12
Total	2547	5531
Percent of Total -Initial Claims (25833)	9.8%	21.4%

Of the total of 9905 returns, 959 or 9.7% resulted in the probability of causation increasing from below 50% to greater than or equal to 50%. The majority of returns (90.3%) did not result in an increase of probability of causation.

A review of Table 3 shows that the majority of NIOSH initiated returns were in 2007 and after. To better understand the science issues that have resulted in NIOSH initiated returns, Table 4 was prepared. Table 4 lists the PER's (Program Evaluation Reports) that were prepared to account for changes in the underlying science. Table 4 also listed the date that the PER was initiated and the number of claims affected. Note the total number of claims affected as listed in Table 4 is 12,241. This number is different than the number of NIOSH initiated returns listed in Table 3 because an individual claim can be impacted by more than one PER.

Table 4: PER's by Title, Date Initiated and Claims Affected

PER Number	PER Title	Initiated Date	Claims Affected
1	OCAS-PER-01 SRS Dosimetry Records	9/8/2003	0
2	OCAS-PER-02 Error X-ray Surrogate Organ Assignment	12/15/2003	3
3	OCAS-PER-03 Add Ingestion Betheleum Steel	1/28/2005	6
4	OCAS-PER-04 Photoflurography Pinellas	2/15/2005	11
5	OCAS-PER-05 Dose Factor for Hanford	6/9/2006	30
6	OCAS-PER-06 Prostrate Target Organ	9/15/2006	0
7	OCAS-PER-07 Revision to Bethlehem Steel TBD	11/9/2006	20
8	OCAS-PER-08 IREP Lung Model	4/12/2007	95
9	OCAS-PER-009 Lymphoma	11/1/2007	500
10	OCAS-PER-010 RFP NDRP	4/13/2007	88
11	OCAS-PER-011 K-25	9/11/2007	433
12	OCAS-PER-012 Super S	11/2/2007	5689
13	OCAS-PER-013 Paducah TBD	1/14/2008	734
14	OCAS-PER-014 Construction	11/13/2007	948
15	OCAS-PER-015 Mallinckrodt	8/1/2007	15
16	OCAS-PER-016 45% to 50% POC	9/25/2007	85
17	OCAS-PER-017 ANL/INEEL data	1/14/2008	68
18	OCAS-PER-018 LANL	8/29/2007	249
19	OCAS-PER-019 SRS Neutrons	5/18/2007	4
20	OCAS-PER-020 Blockson	8/29/2007	91
21	OCAS-PER-021 RFP	9/11/2007	590
22	OCAS-PER-022 Chapman Valve	9/11/2007	31
23	OCAS-PER-023 ANL-W	9/13/2007	22
24	OCAS-PER-024 GSI	9/24/2007	4
25	OCAS-PER-025 Huntington PP	9/27/2007	1
26	OCAS-PER-026 Pantex	9/27/2007	47
27	OCAS-PER-027 Clarksville	10/23/2007	65
28	OCAS-PER-028 Pinellas	10/23/2007	24
29	OCAS-PER-029 Hanford	12/12/2007	1172
30	OCAS-PER-030 SRS TBD	12/14/2007	53
31	OCAS-PER-031 Y-12 TBD	12/15/2007	689
32	OCAS-PER-032 NTS TBD	12/15/2007	474
Total			12,241

Author's Observations and Conclusions:

1. Certainly the Dose Reconstruction Rule anticipated that there might be changes to the scientific elements underlying individual dose reconstruction techniques (Sections 82.30-82.32).[4]
2. The fact that 21.4% of initial dose reconstructions were reevaluated as the result of such changes in science is a direct result of a rigorous review of the science by the Advisory Board as well as by NIOSH. Such a rigorous review creates a tension between the program values of timeliness and the need to get the science "right".
3. The fact that 9.7% of the dose reconstructions that were redone resulted in the increase of the probability of causation from below 50% to greater than or equal to 50% (therefore likely resulting in a decision to compensate) underscores the importance of such a rigorous review.
4. Such reworks and reevaluations do add to the confusion that surrounds the program in the eyes of many claimants.
5. NIOSH Leadership needs to focus on this tension and take steps to minimize the confusion that surrounds such changes while maintaining the need to get the science "right" and ensuring that individuals that warrant compensation consistent with that "right" science receive compensation.

[4] **Subpart E—Updating the Scientific Elements Underlying Dose Reconstructions**

§ 82.30 How will NIOSH inform the public of any plans to change scientific elements underlying the dose reconstruction process to maintain methods reasonably current with scientific progress?

Periodically, NIOSH will publish a notice in the **Federal Register** notifying the public of plans to change scientific elements underlying the dose reconstruction process under EEOICPA to reflect scientific progress. Notice will include a summary of the planned changes and the expected completion date for such changes.

§ 82.31 How can the public recommend changes to scientific elements underlying the dose reconstruction process?

(a) At any time, the public can submit written recommendations to NIOSH for changes to scientific elements underlying the dose reconstruction process, based on relevant new research findings and technological advances. NIOSH will provide these recommendations to the Advisory Board on Radiation and Worker Health to be addressed at a public meeting of the Advisory Board, with notification provided to the source of the recommendations. Recommendations should be addressed to: Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS–R45, Cincinnati, Ohio 45226.

(b) The public can also submit recommendations by e-mail. Instructions will be provided on the NIOSH Internet homepage at www.cdc.gov/niosh/ocas.

§ 82.32 How will NIOSH make changes in scientific elements underlying the dose reconstruction process, based on scientific progress?

NIOSH will present proposed changes to the Advisory Board on Radiation and Worker Health prior to implementation. These proposed changes will be summarized in a notice published in the **Federal Register**. The public will have the opportunity to comment on proposed changes at the meeting of the Advisory Board and/or in written comments submitted for this purpose. NIOSH will fully consider the comments of the Advisory Board and of the public before deciding upon any changes.

c. The Timing of Initial Submissions vs. Returns

Table 5 contains data on the time that NIOSH has in its possession an initially submitted claim as well as a returned claim based upon the calendar year the claim was received.

Table 5: Time to Complete Claims, Initial and Return by Calendar Year Submitted

Calendar Year Received	Average Time in Days To Complete Initially Submitted Claim	Average Time in Days To Complete Returned Claim
2001	1120	-
2002	1011	-
2003	843	166
2004	589	205
2005	475	164
2006	288	135
2007	388	222
2008	272	293
2009	189	132
2010	61	45

Author's Observations and Conclusions:

1. It is reasonable that the time that NIOSH holds a returned claim should be less than the time NIOSH holds an initially submitted claim. Two reasons for this are, first a returned claim may well be the result of an additional cancer meaning that the claimant is experiencing deteriorating health and second the claimant of a returned claim has already been in the system for some time and therefore is understandably anxious to have their case completed.

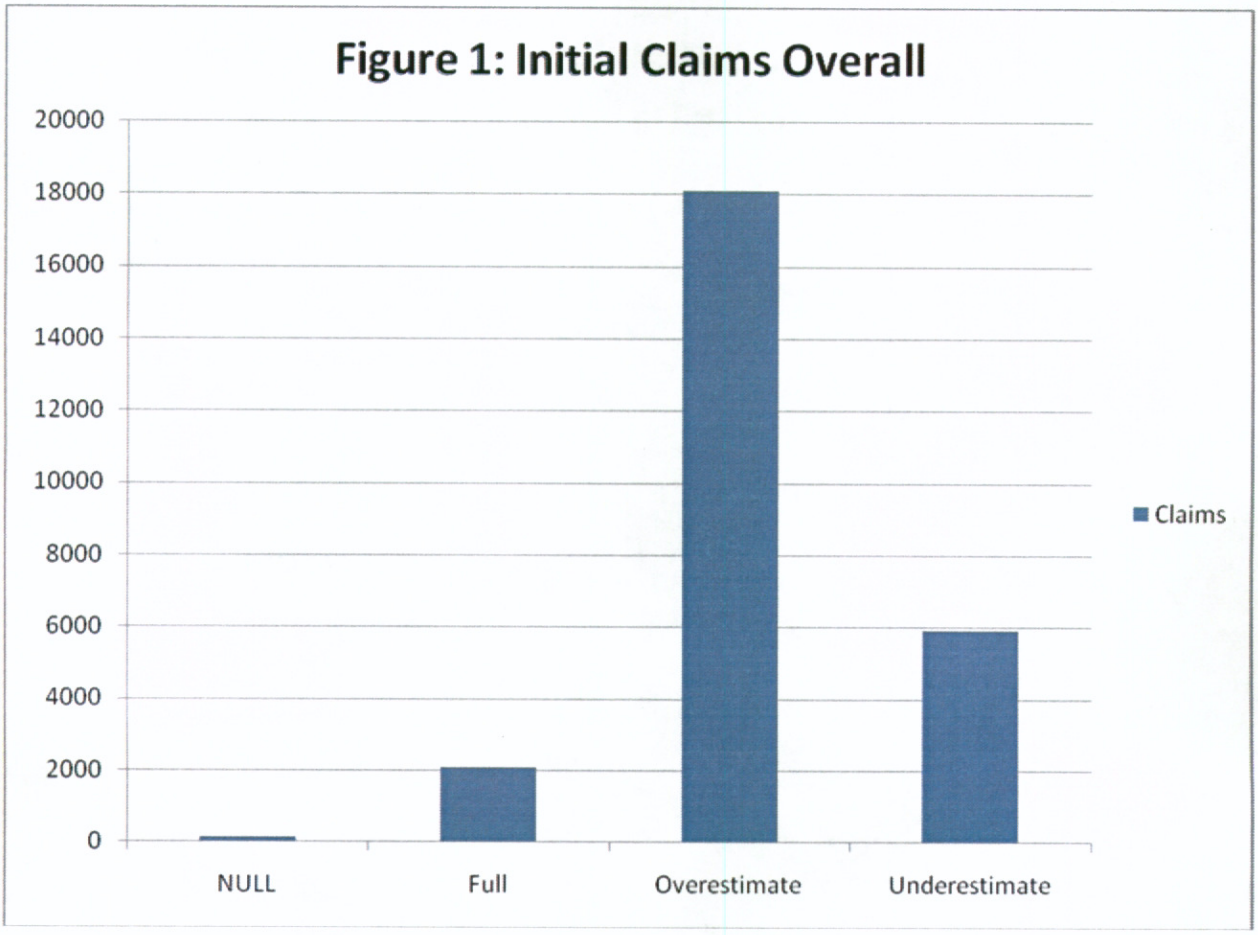
2. In all years but 2008 the average time to complete an initial claim is longer than the average time to complete a returned claim.

3. In settings its goals for the timely completion of claims NIOSH should give a higher priority to returned claims.

4. Statistics concerning the number and time to complete individual dose reconstructions by dose estimation type.

a. Number of Claims

Figure 1 [5]shows the number of initial claims that have been completed using Full Best Estimate Techniques, the term Full Best Estimate means that the dose reconstruction involved a Best Estimate determination for both internal and external dose, Overestimating Techniques and Underestimating Techniques. Initial claims were chosen for display as they better reflect NIOSH's choice of dose estimation technique when a claim is first encountered.

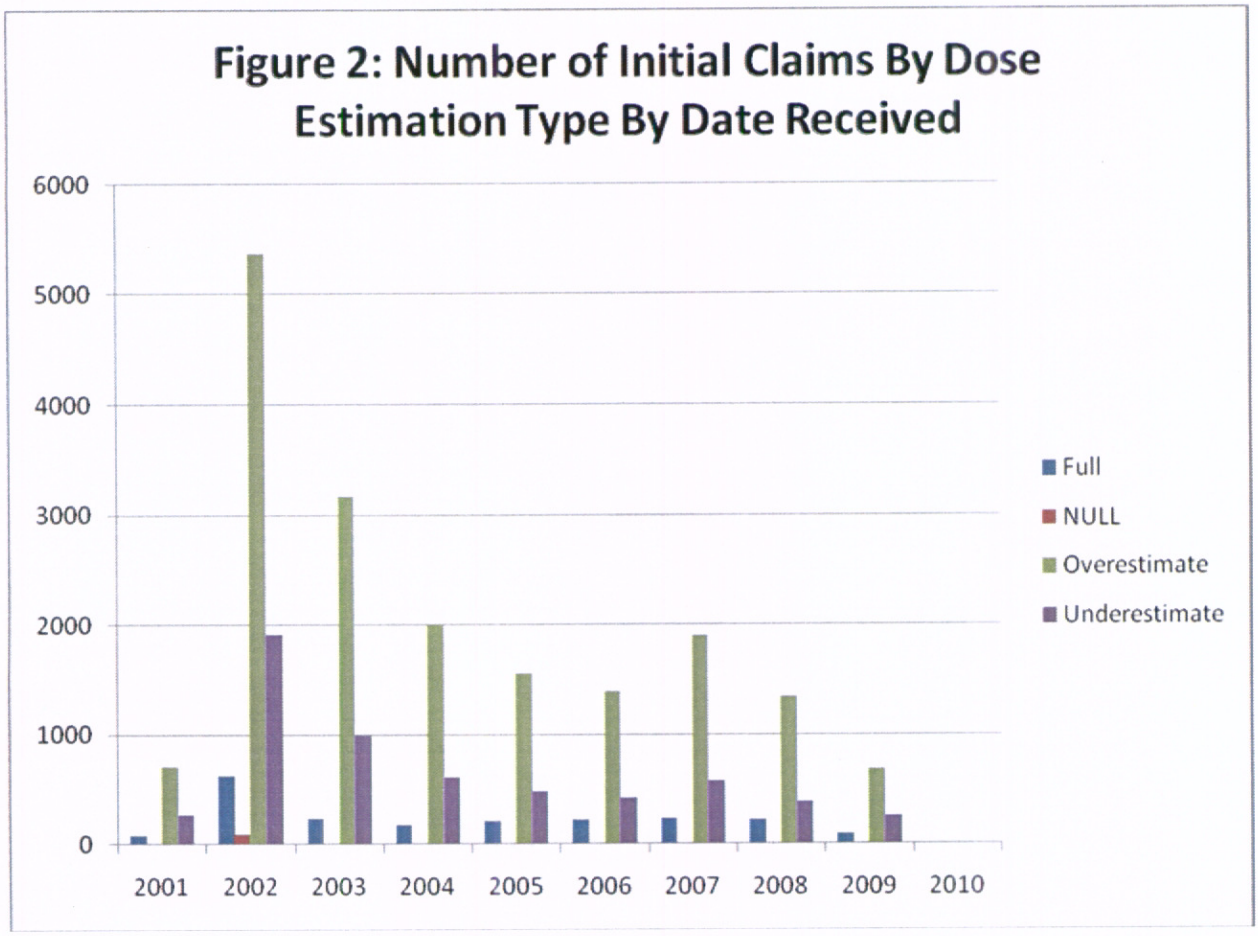


In total 8.0% of claims have been worked by Full Best Estimate Techniques, 22.5% by Underestimating Techniques, and the majority, 69.0% by Overestimating Techniques.

[5] The null bar captures claims that were worked before records were kept of such designations

Figure 2[6] shows the number of initial claims worked by the different dose reconstruction techniques each year from 2001 until 2009. For this Figure, the year represents the year in which the claim was received from DOL and not the year in which NIOSH sent the completed dose reconstruction back to DOL.

The year received was selected for display as the author feels this is more informative than using the year submitted to explore trends in NIOSH's use of dose reconstruction techniques, as a claim received in 2004 might not be submitted in 2004 or later for a number of reasons not related to the choice of Dose Estimate Technique.



[6] The null bar captures claims that were worked before records were kept of such designations

Table 6 shows the number of claims worked using the various Dose Estimate Techniques based upon the year in which the individual dose reconstruction was received from DOL.

Table 6: Number of Claims By Dose Estimation Type By Date Received

	Full	NULL[7]	Overestimate	Underestimate
2001	76	14	705	272
2002	621	96	5365	1913
2003	235	11	3162	988
2004	176	0	2008	606
2005	210	0	1554	486
2006	225	0	1391	423
2007	236	0	1897	581
2008	222	0	1347	385
2009	95	0	678	262
2010	0	0	11	3

Contrasting 2002, a year in which the dose reconstruction program was fully operational to 2008, the last year for which there are complete data indicates that the use of the Full Best Estimate Technique has increased from 7.8% in 2003 to 11.3% in 2008, note the percentage of Full Best Estimate Technique dose reconstruction in 2003 was 5.3% of the total for that year.

Author's Observations and Conclusions:

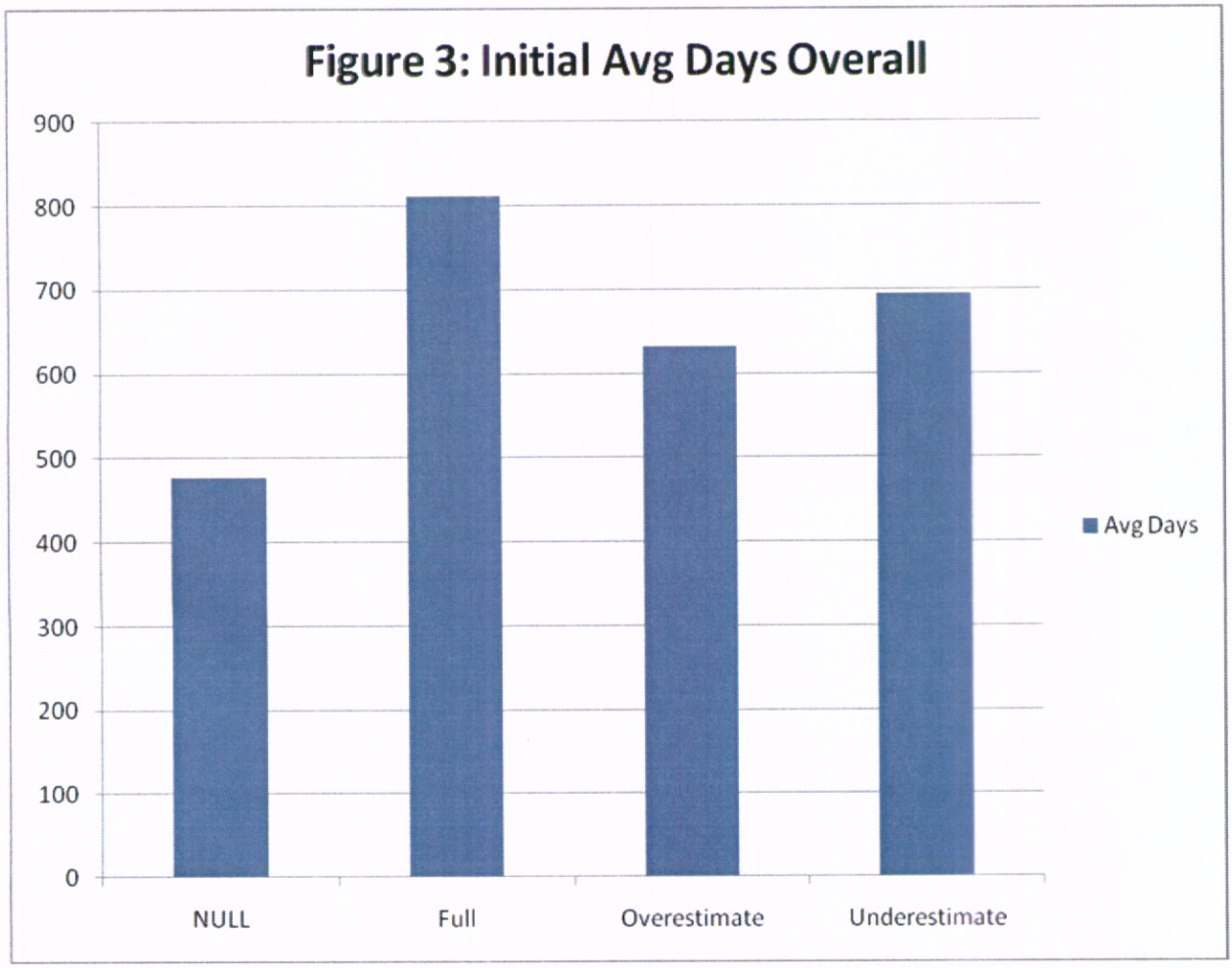
1. The author was struck by the heavy use of Overestimating Techniques; however there is no evidence to suggest that Overestimating Techniques were used inappropriately.

2. It is not surprising that use of the Full Best Estimate Technique is increasing as the "easier" to complete Dose reconstructions are completed leaving the "more" difficult dose reconstructions that would require the Full Estimation Technique. One might expect that the percentage increase would have been larger than it actually is.

[7] The null captures claims that were worked before records were kept of such designations

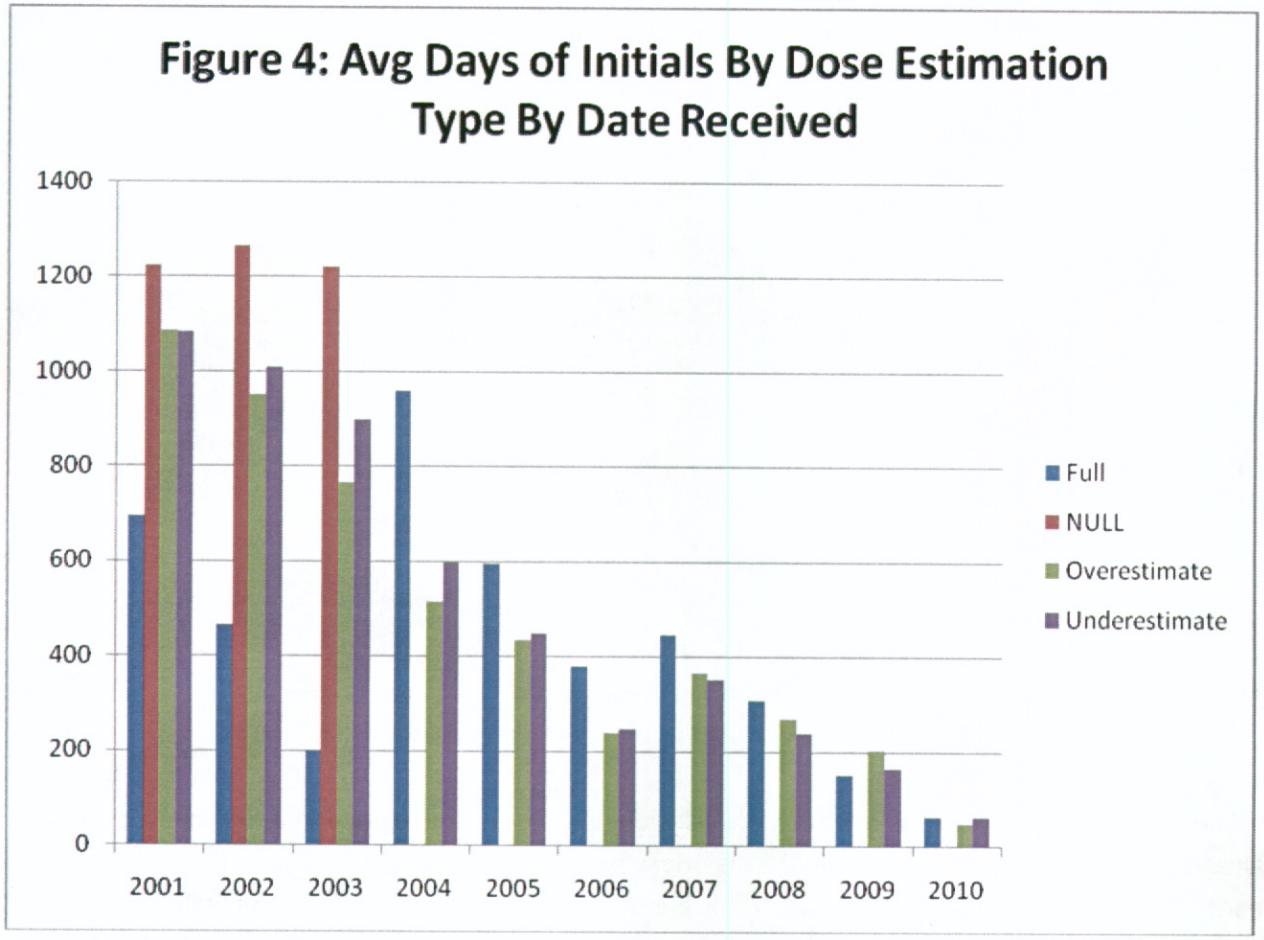
b. Time to Complete Claims

Figure 3[8] shows the average number of days to complete an initial dose reconstruction based on the Dose Estimate Technique.



[8] The null bar captures claims that were worked before records were kept of such designations

Figure 4[9] shows the average number of days to complete an initial dose reconstruction by Dose Estimate Technique by year based upon the year the dose reconstruction was received.



[9] The null bar captures claims that were worked before records were kept of such designations

Table 7 shows the average number of days to complete an initial individual dose reconstruction based on the Dose Estimate Technique by year based upon the year in which the claim was received from DOL.

Table 7: Average Days By Dose Estimation Type By Date Received

	Full	NULL[10]	Overestimate	Underestimate
2001	696	1224	1086	1083
2002	465	1267	950	1008
2003	200	1223	766	900
2004	960	0	515	598
2005	596	0	436	449
2006	379	0	240	247
2007	447	0	365	352
2008	308	0	271	239
2009	152	0	203	166
2010	63	0	49	63

Author's Observations and Conclusions:

1. Both Figure 4 and Table 7 point out the significant improvements that have been made in the time to complete individual dose reconstructions.

2. While Full Best Estimate dose reconstructions take longer, as measured by calendar time passed, than Overestimates and Underestimates (in the majority of years evaluated) that difference is not that great particularly in recent years, 2006 through 2008. For that reason NIOSH needs to explore whether or not it should continue to use Overestimating and Underestimating techniques given the confusion that their use causes with claimants (see Author's Comment 3 in section 1 above). Note: At this writing the author did not have data to determine the man hours consumed by the various types of Dose Estimate Techniques, such data would need to be considered in making any decisions on the continued use of Overestimating and Underestimating Techniques.

[10] The null captures claims that were worked before records were kept of such designations

5. **Statistics concerning the number of partial dose reconstructions and the POC's of partial dose reconstructions.**

As discussed in the **Section I. Background** partial dose reconstructions are performed after the granting of an SEC for individual cases that are covered, at least in part, by that SEC. These cases would be for cancers not included in the congressionally determined list of 22 cancers. All DR's that were completed after the establishment of an SEC, which had employment in that SEC period, were queried. There were 5,011 such cases. 1,300 cases or 27% had a POC greater than or equal to 50% and 3,561 cases or 73% had a POC less than 50%. One needs to be mindful of the fact that multiple cancer sites were involved in some of these cases and that employment in some of these cases straddles SEC and non SEC periods.

Author's Observations and Conclusions:

1. Unless partial dose reconstruction is attempted for cases that are in part covered by an SEC but are for a cancer not on the list of 22, that individual would have no hope of being considered for compensation. Therefore the process of partial dose reconstruction should be continued and if possible expanded upon.
2. The percentage of partial dose reconstructions that have resulted in a POC greater than or equal to 50% of 27% is not that different from the percentage of all dose reconstructions with a POC greater than or equal to 50% of 28.5% (see Table 8 below).
3. NIOSH should be commended for its efforts to perform partial dose reconstructions. All scientifically supportable efforts to further expand the process should be explored, such as more precise SEC class definitions that specify exactly the doses that cannot be reconstructed and therefore what doses can be used for partial dose reconstructions.
4. The Advisory Board should be commended for its efforts to recommend SEC class definitions that allow to the degree scientifically supportable, partial dose reconstructions.
5. All parties should undertake a detailed review of past SEC class definitions to determine, (1) how to better define classes in the future (that would allow for robust partial dose reconstructions) and (2) if any of those class definitions could be rewritten to allow for the consideration of addition dose in a partial dose reconstruction.
6. The Department of Labor should be consulted with in the development of SEC class definitions to better ensure that such class definitions can be effectively administered.

6. **The percent of dose reconstructions that have resulted in a POC of greater than or equal to 50%**

Table 8 shows the number of individual dose reconstructions that resulted in POC's arrayed in 10% intervals from 0% to greater than or equal to 50%.

Table 8: Number of DR's by POC Range for All NIOSH DR's (26,707 cases as of 4/30/2010)

POC Range	Number	% of Total
0-10%	6690	25.0%
11-20%	3478	13.0%
21-30%	3072	11.5%
31-40%	3451	12.9%
41-50%	2401	9.0%
Greater Than or Equal to 50%	7615	28.5%
All Ranges	26707	99.9%

Author's Observations and Conclusions:

1. Care must be taken not to read too much into the data reported in the ranges below 50% as the dose reconstructions in these ranges can be the result of efficiency measure-dose reconstructions.
2. The current percentage of DR's greater than or equal to 50% of 28.5% is larger than this author's recollection of estimates of compensation rate during the planning and start up of the dose reconstruction activities (10% or less). This seems reasonable owing to the fact that the available data upon which to base dose reconstructions is (in the opinion of the author) more complex, and based upon monitoring methods of less accuracy than those in use today and therefore more suspect and incomplete particularly in the early years (40's and 50's) of the weapons programs than was thought to be the case at the start of the program.
3. Given the fact that the percentage of DR's with a POC greater than or equal to 50% is a function of, among other factors, the availability and reliability of data from sites across the DOE complex, I am not aware of a method to more rigorously evaluate whether the current value of 28.5% is reasonable.

7. Individual dose reconstruction compensation results based on the cancer model used

Table 9 shows the Rank by Compensation Rate for the top ten ranked NIOSH-IREP Models for claims with a single primary cancer. Also shown is the percent compensated and not compensated as well as the percent of the total number of claims and the percentage of the total number of claims. The ten NIOSH-IREP Cancer Models listed were the only NIOSH-IREP Cancer models with a percent compensated above the overall program average of 28.5%. Only claims that involve a single cancer are included as multiple cancer claims would mask the actual compensation rate for individual cancers.

Table 9: Rank by Compensation Rate for Ten NIOSH-IREP Cancer Models

Rank by Compensation Rate	NIOSH-IREP Cancer Model (ICD-9 Code)	Percent Compensated (PC greater than or equal to 50%)	Percent Not Compensated (PC less than 50%)	Number of Claims with this ICD-9 Code	Percent of Claims with this ICD-(Code of the Total Number Of Claims
1	Lung (162)	70.2	29.8	3438	22.5
2	Chronic Myeloid Leukemia (205.1)	59.7	40.3	67	0.4
3	Non-melanoma Skin Basal Cell (173)	57.8	42.2	1108	7.3
4	Acute Lymphocytic Leukemia (204.0)	56.9	43.1	65	0.4
5	Liver (155.0)	48.2	51.8	112	0.7
6	Acute Myeloid Leukemia (205.0)	41.6	58.4	149	1.0
7	Malignant Melanoma (172)	38.8	61.2	405	2.7
8	Lymphoma & Multiple Myeloma (200-203)	38.1	61.9	1161	7.6
9	Leukemia, excl. CLL (204-208, excl 204.1)	35.4	64.6	99	0.6
10	Other respiratory(160,161,163-	34.9	65.1	436	2.9

	165)				

One question that comes to mind when reviewing the data in Table 9, is whether or not this rank by compensation rate "makes sense"? In an attempt to address that question NIOSH provided to the author the analysis that follows:

> *"Evaluation of Reasonableness of Program Relative Compensation Rates*
>
> *Two factors influence the relative compensability of the IREP cancer models, the relative radiation risks of the individual cancers and the typical magnitude of doses received by the target organs for each of the IREP models. While radiation risks have been studied extensively, the discussion of relative doses received by various target organs will necessarily be somewhat general.*
>
> *In 2006 the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) published a summary of radiation risks for 22 specific types of cancers as well as for all solid tumors. Data from that report are reproduces in Table A. The data includes not only the central estimate for the radiation risk, but also the range of the 90% confidence interval. The cancers in this table do not coincide exactly with the cancer models in IREP, but they can generally be related to IREP models.*

Table A. Excess Relative Risk per Sievert (ERR/Sv) for Various Cancers

Cancer risk values reported in UNSCEAR 2006 - All values based on RERF incidence data

(Values extracted from tables 19 through 44)

		90% Conf. Interval		
Cancer	**ERR/Sv**	**Low**	**High**	**Cases**
All solid cancers	0.62	0.55	0.69	7851
Salivary gland	2.55	0.87	5.72	23
Esophagus	0.51	0.14	0.99	152
Stomach	0.37	0.26	0.49	2095
Colon	0.64	0.42	0.9	671
Rectum	0.18	<0	0.46	376
Liver	0.41	0.22	0.63	645
Pancreas	0.29	<0	0.72	229
Lung	0.69	0.49	0.92	789
Bone and connective tissue (males)	3.34	0.9	9.69	4
Breast (female)	1.49	1.17	1.85	572
Uterus	0.1	<0	0.32	504
Ovaries	1.18	0.39	2.31	103
Prostate	0.12	<0	0.51	156
Urinary Bladder	0.92	0.46	1.5	222
Kidney	0.16	<0	0.78	70
Brain and CNS	0.55	0.16	1.07	137
Thyroid	1.59	1.1	2.19	265
non-Hodgkin's lymphoma	0.08	<0	0.62	76
Multiple myeloma	0.2	<0	21.7	30
Leukemia	4.84	3.59	6.44	141
Malignant melanoma	<0	<0	0.74	7
Non-melanoma skin cancer (male)	1.27	0.65	2.17	66

Since compensability is determined by the 99th percent confidence limit of the probability of compensation statistic, the upper range of the 90th percentile in the UNSCEAR data serves as a better source of comparison of relative radiation risk than the central estimate. In addition, cancers with few observations in the UNSCEAR data were not used to develop individual dose models in IREP. Rather cancers with few observations were grouped into broader models in IREP. Therefore the radiation risk values for salivary gland, bone and connective tissue, and malignant melanoma do not translate to associated cancers in IREP.

With respect to relative doses reconstructed for target organs for the various IREP models, certain general statements can be made. Many claimants were potentially exposed to airborne

actinides, most commonly uranium or plutonium that delivers large doses to lungs and respiratory tract when inhaled. What's more, bioassay methods for these radionuclides are not very sensitive, so simply missed dose calculations for one of those radionuclides results in large doses to lungs, the respiratory tract, and the pulmonary lymphatic tissue. Other target organs

concentrate internal radionuclides that become systemic, resulting in relatively large doses to those target organs. Examples of those organs are bone (and therefore bone marrow), thyroid, liver, and kidney. Internal doses to other organs are generally fairly uniform, caused by radioactive materials that are in the blood supply to those organs, but do not concentrate in those organs. A slight exception is the alimentary canal, which receives additional irradiation from internal radioactive material as it is resident there. External doses are generally delivered relatively uniformly except to the skin. Beta particles, called electron dose by IREP, deliver external dose only to the skin, mainly to exposed skin. In addition, medical x-ray doses are typically higher for skin than for other organs. Consequently for many claims external doses to skin are quite a bit larger than for other target organs.

Evaluating compensability rates starting with the most highly compensated, lungs have the highest rate because of the internal dose factor discussed previously. The high compensation rate for the various leukemia models is explained by the high relative radiation risk for leukemia. The high compensation rates for non-melanoma skin – basal cell and malignant melanoma are explained largely by the higher doses to skin for many claims. The high compensation rates for liver, other respiratory organs, oral cavity and pharynx, bone, and thyroid are due to the higher doses received by those organs from internal radionuclides.

In summary there does seem to be an intuitive reasonableness to the relative compensation rates for the IREP cancer models, but definitive analysis is not likely to be available. "

Author's Observations and Conclusions:

I have no evidence to refute NIOSH's claim, "....there seems to be an intuitive reasonableness to the relative compensation rates for the IREP cancer models....", nor am I aware of any more rigorous method to investigate the situation.

8. Comments from the Docket

A docket was held opened on the NIOSH website to receive public comments related to the Ten Year Review. Many excellent comments were received. All public comments will be contained in their entirety in the Appendix to the Phase I Report. In this section I dose reconstruction I have included all of the excerpts of comments that I think directly related to dose reconstruction. These comments are included to provide the Phase II authors with all related dose reconstruction materials in this section.

I will not offer opinion on the excerpts presented. It is possible that the Phase II authors may wish to expand or modify the Phase I report based upon their consideration of public comments.

Excerpt 1:

"In conclusion we ask that the review of the program will:

-Review all technical documents that were authored or contributed to by a person who was responsible for the dosimetry department at a site. Any site profile that was a conflict of interest with the contributors shall be deemed null and void and SEC awarded to these sites."

Excerpt 2:

"The use of Surrogate Data in Dose Reconstruction

NIOSH used surrogate data obtained from Simonds Saw and Steel in Lockport, NY as the basis for the dose reconstructions for workers at Bethlehem Steel. Even though these facilities are different in topology, ventilation, and air quality employed, and the basic steel making technologies used, NIOSH insists that it is reasonable to take data from Simons Saw and Steel and use it to compile the Bethlehem dose reconstructions."

Excerpt 3:

"Two separate NIOSH representatives gave conflicting accounts as to whether worker oral histories, offered during CATI interviews, are given consideration when reconstructing dose. The presenter in the morning session stated, "No". However the afternoon presenter stated that NIOSH does indeed consider workers' accounts of their work experience and will sometimes attempt to verify these histories by researching Department of Energy documents.

Consequently, ANWAG questions whether NIOSH accepts and subsequently investigates work histories provided by worker/claimants during the CATI interviews or whether such accounts are ignored when reconstructing dose? Moreover, is it possible that one dose reconstruction team considers these histories while other teams consider them suspect? What criteria have been established by NIOSH to determine and/or assess the credibility

of worker's statements during CATI interviews? Have the dose reconstruction teams developed any site specific metric to evaluate workers' statements to initiate subsequent data capture efforts to verify workers' Statements?"
Excerpt 4:

"I think the total cost of the "management" of the program should be compared to the claims settled, as a measure of the efficiency and effectiveness of taxpayer dollars being spent."

Excerpt 5:

"It is imperative that both DCAS and the Advisory Board scrutinize the appropriate application parameters for the use of co-worker data models to mirror the scrutiny applied to "other site" surrogate data applications."

Excerpt 6:

GENERAL COMMENTS

It is not clear how this review will be conducted since NIOSH has not created any specific review criteria. In preparing these comments we have generally applied the criteria used by the National Academy of Sciences in their review of NIOSH programs. We believe that there are certain overriding issues that NIOSH needs to consider throughout this review.

- **Alternative Options:** The review should consider alternative options which were available to NIOSH for each of these components and whether or not alternative options might have produced better results. For instance, it is not clear that the selection of ORAU as the sole program support contractor benefitted NIOSH more than would have a net-work of academic based experts performing DRs.
- **Review of Program Components:** The review should examine the extent to which each of the different components of the program have been responsible for the outcomes:
  - NIOSH's internal oversight of DCAS[1] .
  - The leadership of DCAS.
  - The rules that were created to guide the work of the program.
  - The operational structure of the program and the decision to select one large contractor with lots of potential for conflict of interest.
  - The execution of the operations.
- **Efficiency of the Operation:** How well have resources been optimized? Has there been waste?

Excerpt 7:

RECOMMENDED REVIEW CRITERIA

Our position has been that where it is possible to settle compensation claims based on the individual claimant's history, it should be done, but there should be clear criteria to guide the process, including:

- ***Accuracy***: Is the dose given to a worker an accurate reflection of his or her experience?
- ***Fairness:*** Are cases similarly situated treated alike and given a similar outcome in the dose reconstruction process?
- ***Timeliness:*** Are cases processed in a timely manner?

For each of these criteria, there should be a separate analysis for:

- Claims submitted by ***workers*** and claims submitted by ***survivors***
- The overall program and each DOE/AWE site covered by the program
- The different occupational groups covered by the program
- The different time-periods covered by the program, beginning in 1943, and separately for at least each decade

To perform its review, NIOSH should consider the following issues

1. **Accuracy**: *Is the DR outcome a true reflection of exposure?*
    - **Dose Reconstructions**
        - **Initial Review**
            - Are the methods used consistent with the law?
            - Can DRs be verified (i.e., if you review a DR using the case documentation do you get the same POC as the official DR?)
            - Can DRs be independently replicated (i.e., if you take a case and perform a blind DR using DCAS procedures, do you get the same POC as the official DR?)
            - Are reports sent to claimants being prepared in such a way that they can be understood by a high school graduate, as is specified in both the 2002 and 2009 ORAU contracts?
        - **Reworks** (NOTE: This is a big issue. Half of all DRs have been reworked, some more than once.)
            - What is the basis for rework (number of cases by cause, site, type of cancer, time period of exposure, etc.)?
            - Can DRs be verified?
            - Can DRs be independently replicated?

Excerpt 8:

2. **Fairness:** *Are cases similarly situated treated alike and do they have similar outcomes in terms of POC or referral to SEC?*
    - **Dose Reconstruction**
        - **Initial review**
            - Are the applied methods consistent between cases regardless of site?
            - What is the statistical sensitivity/predictive value of the DR (i.e., how often does a DR result in a POC<50% when it should not, by DOE sites, type of cancer, occupation, time period of exposure, etc)?
            - Is the rationale for referring cases to the SECs applied consistently (i.e., by DOE and AWE sites, type of cancer, occupation, time period of exposure, etc)?
            - Is there a clear and rationale approach for using surrogate/co-worker data when data are missing for a worker?
            - Has NIOSH exceeded its authority in using surrogate data?
            - Does the statute authorize the use of other facility data in the first place with respect to the definition of "such facility" within the statute?
        - **Reworks**
            - Are all cases eligible for rework identified and included?
            - What is the statistical specificity/predictive value of the reworked DR (i.e., how often does a DR result in a POC<50% when it should not, by DOE sites, type of cancer, occupation, time period of exposure, etc)?

Excerpt 9:

4. **The appropriateness and the consistency of decisions on individual dose reconstructions.**

   The term "appropriateness" is meaningless until NIOSH defines it. We have heard repeatedly from our members that "Joe" worked right next to "Jim" doing exactly the same work in the same location, yet they received very different dose reconstruction outcomes. That complaint needs to be investigated.

   We also urge NIOSH to review whether or not the case files for all the claimants affected by a policy or procedure update, or other requirements for reworking, have been identified and properly updated, and whether or not the claimants and DOL have been informed of such updates.

Excerpt 10:

Recommendation

While DCAS really cannot control anything the ABRWH does, nor should we as the Advisory Board must be independent to provide advice to the Secretary, what NIOSH/DCAS can do is get back to conducting solid peer reviewed science. Thus my sole recommendation to the ten year program review committee is that DCAS institute a formal scientific review process using outside independent peer reviewers (not the ABRWH, and not SC&A). One of the reviewers must be from the scientific community to represent the non-biased science; one reviewer must be from a labor organization to provide valuable worker insight, and a third must be from site management to obtain a balanced perspective. This tripartite review should be conducted on all NIOSH methods and documents to help; 1) re-establish NIOSH/DCAS scientific credibility, 2) build trust among labor organizations, and 3) promote more cooperation and trust from DOE sites to support future occupational epidemiological studies conducted by either NIOSH staff or our various partners at academic institutions.

Excerpt 11:

1. **The appropriateness and the consistency of decisions on individual dose reconstructions.**

For example, has NIOSH uniformly used scientific techniques available at the time that account for whether exposures may have been under-estimated or over-estimated? Has NIOSH been consistent in its assumptions for developing "best-estimate" dose reconstructions where data for making estimates were incomplete or missing? When NIOSH revisits completed dose reconstructions (as it does for the benefit of claimants, when new information becomes available in cases where the completed dose reconstruction suggested low probability that a cancer was work-related), does it do so in a consistent fashion?

Answers to all three questions are forceful "NOs."

Answer to question #1. NIOSH must already realize that here is no way for outsiders to know enough to answer this question as there is no means for us to see the aggregated data on how many DRs from their sites were under- or over-estimated or were best estimates. The results of the DR subcommittee reviews on individual DR reports are opaque to outsiders. NIOSH provides no site-specific public data on the number and percentages of completed DRs that were under- and overestimates and best estimates. Publishing such statistics would be immensely useful in two regards: (a) The data would inform claimants and SEC petitioners, (b) this would provide a useful metric for assessing consistency across AWE and DOE sites on the mix of methods that NIOSH actually used in its dose reconstruction program.

Answer to question #2. There is no way for outsiders to know enough to answer this question as there is no means for us to see the aggregated data on how many DRs from their sites were best estimates. My perception is best-estimates are underutilized by NIOSH and ORAU dose reconstructors. Publication of aggregate data by site would inform the public about the mix of DR methods NIOSH has employed to date.

Answer to question #3. NIOSH often refuses to use new evidence, often declines to accept valuable new evidence as such, and obscures the process and criteria whereby new evidence can be accepted. I have been told that DOL and NIOSH bases decisions on "weight of evidence," and my experience is that hard copy reports usually are given undue weight. Worker comment NIOSH 10 Year EEOICPA program review eyewitness affidavits are often either not accepted or are not acted upon. Many times the new evidence would require as an appropriate response revising a key technical document that NIOSH does not want to do for reasons that are not apparent to me, whereas some other technical documents are frequently revised. There is no consistent pattern to how NIOSH uses new evidence at particular sites, whether or not CATI information is routinely used to revise TBDs and TIBs and individual DRs, and whether new evidence presented by workers, site experts, and SEC petitioners is even read or used at all. This is profoundly disturbing and discouraging when one has spent enormous time and evidence assembling this new site information. My perception is that at some sites NIOSH stakes its scientific reputation on the fact that it can reconstruct dose. I and many advocates believe SEC evaluation reports should be based only on currently available methods. They liberally use surrogate and

coworker data. I would cite the Rocky Flats, Blockson, GSI and TCC SECs as excellent examples of NIOSH using key methods developed long after NIOSH submitted its evaluation report to the Board.

Excerpt 12:

Self review of any governmental program is heavily biased to cast previous agency actions in a positive framework. The internal review should have be complemented by a truly independent review by persons that have no agency ties.