NIOSH Radiation Dose Reconstruction Program

Ten Year Review – Phase I Report

Dose Reconstruction

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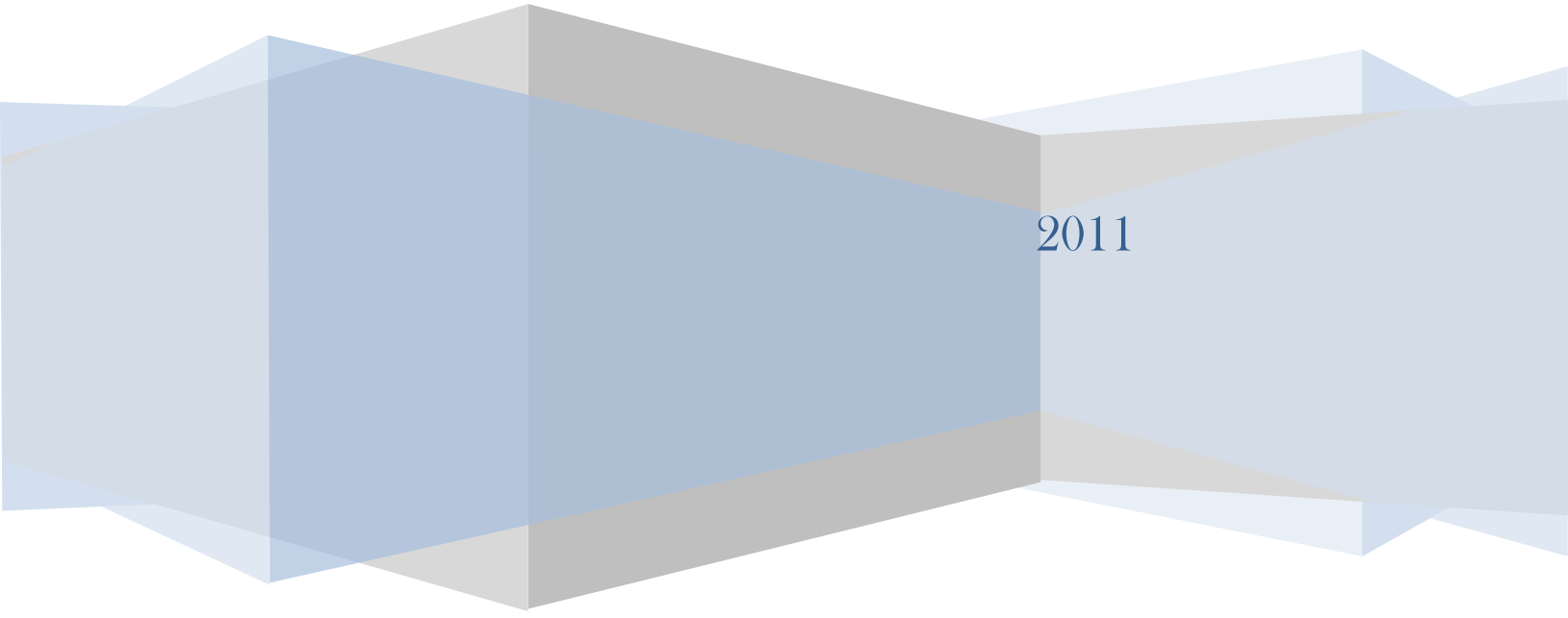

2011

Radiation Dose Reconstruction

Submitted By

Dr. Lewis Wade and Nancy Adams

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

Dose Reconstruction

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.

Dose Reconstruction

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

Dose Reconstruction

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%	

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."

Dose Reconstruction

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

Dose Reconstruction

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.

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 Based On Calendar Year Received	Calendar Year Received	Number of Claims Based On Calendar year Submitted	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

Dose Reconstruction

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.

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Dose Reconstruction

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

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Dose Reconstruction

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 use of the best available science.

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 use of the best available science 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

Dose Reconstruction

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.

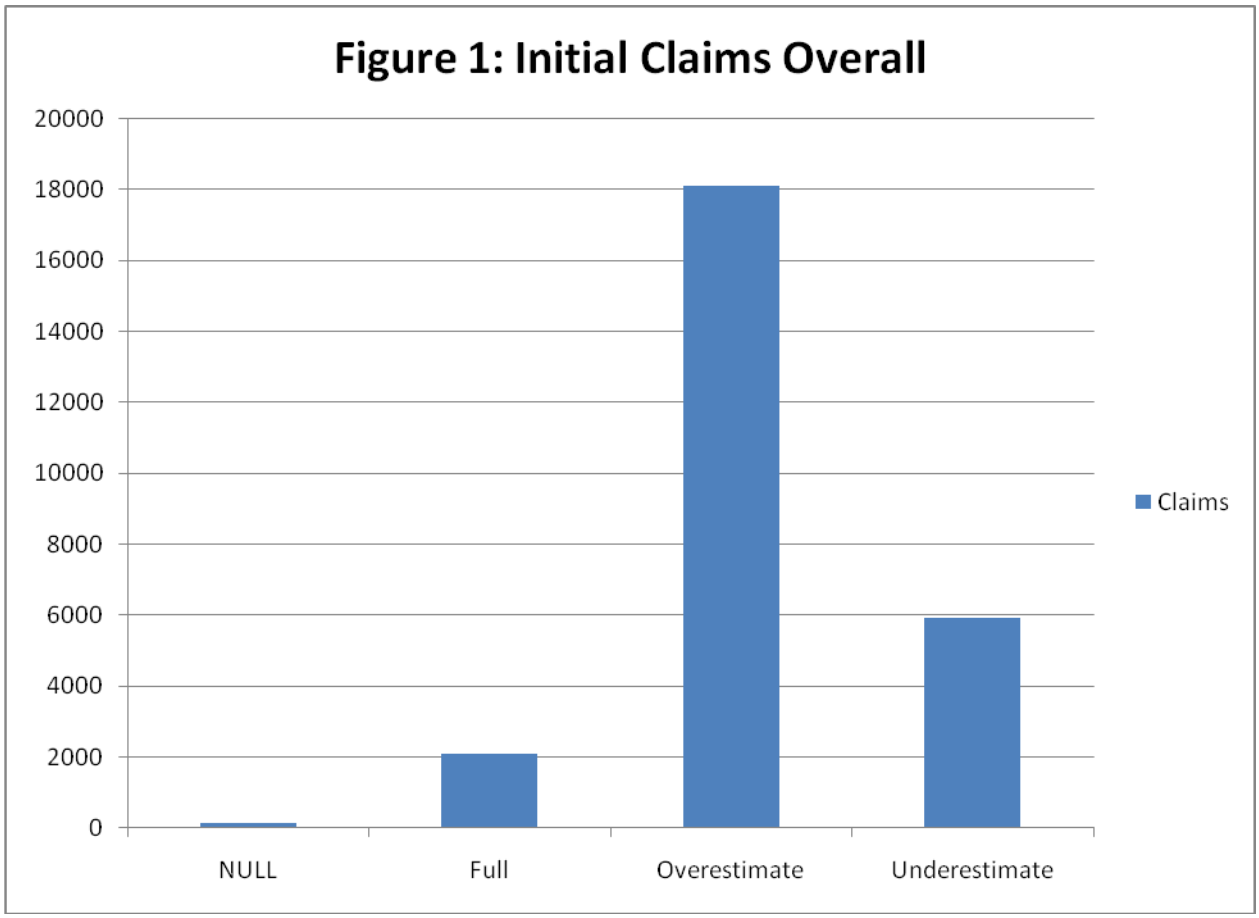
2. In all years but 2008 the average time to complete an initial claim is longer than the average time to complete a returned claim.

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

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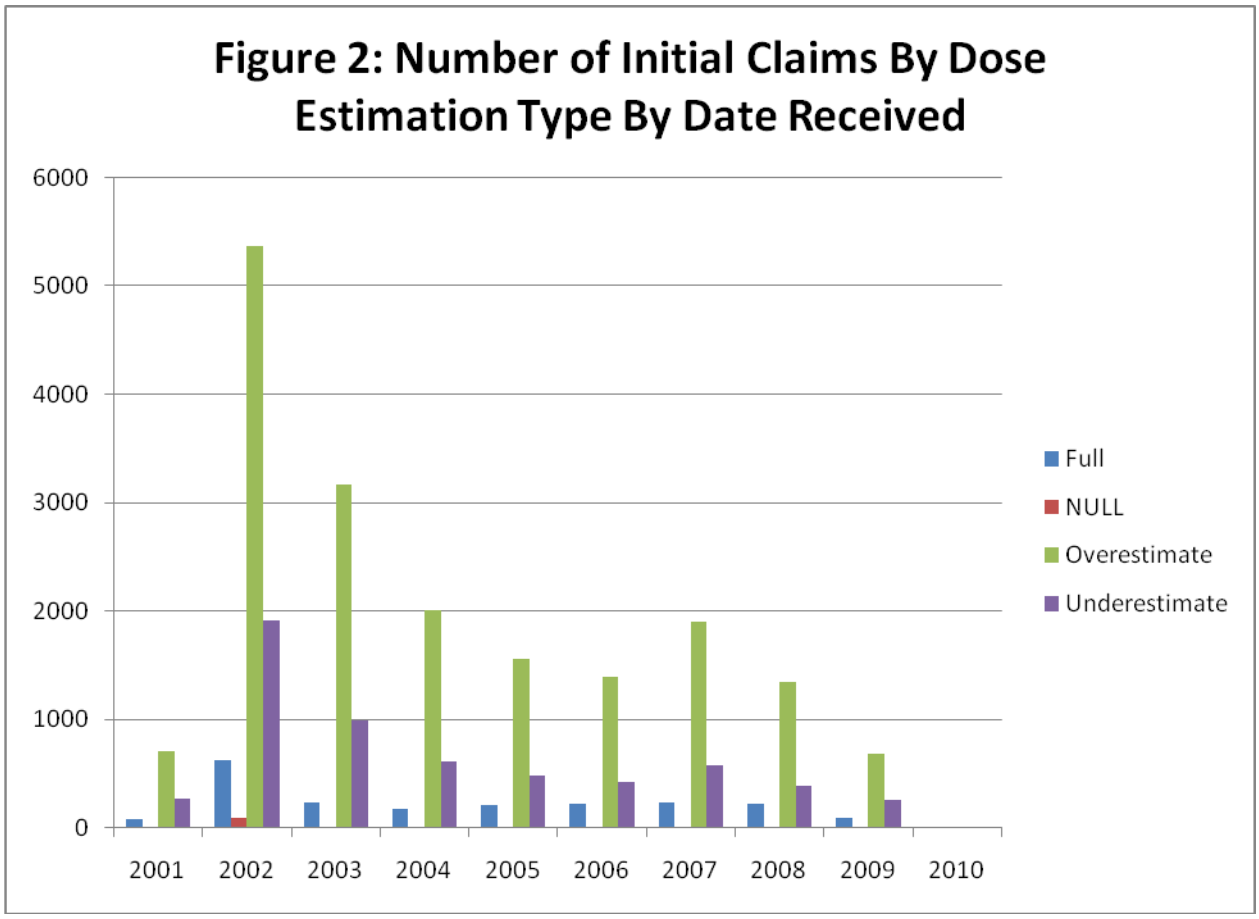
Dose Reconstruction

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

Dose Reconstruction

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:

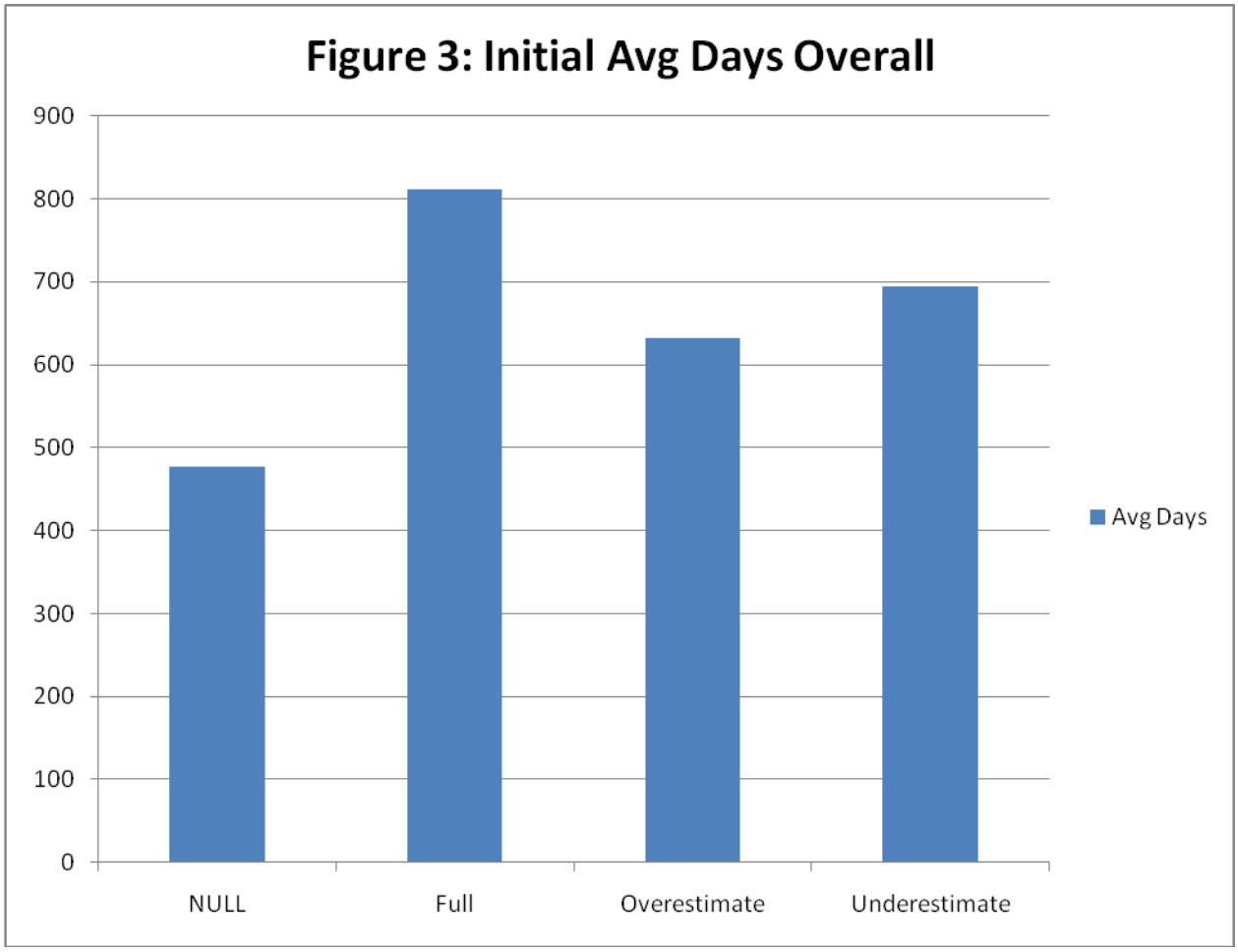
1. The author was struck by the heavy use of Overestimating Techniques; however there is no evidence to suggest that Overestimating Techniques were used inappropriately.

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

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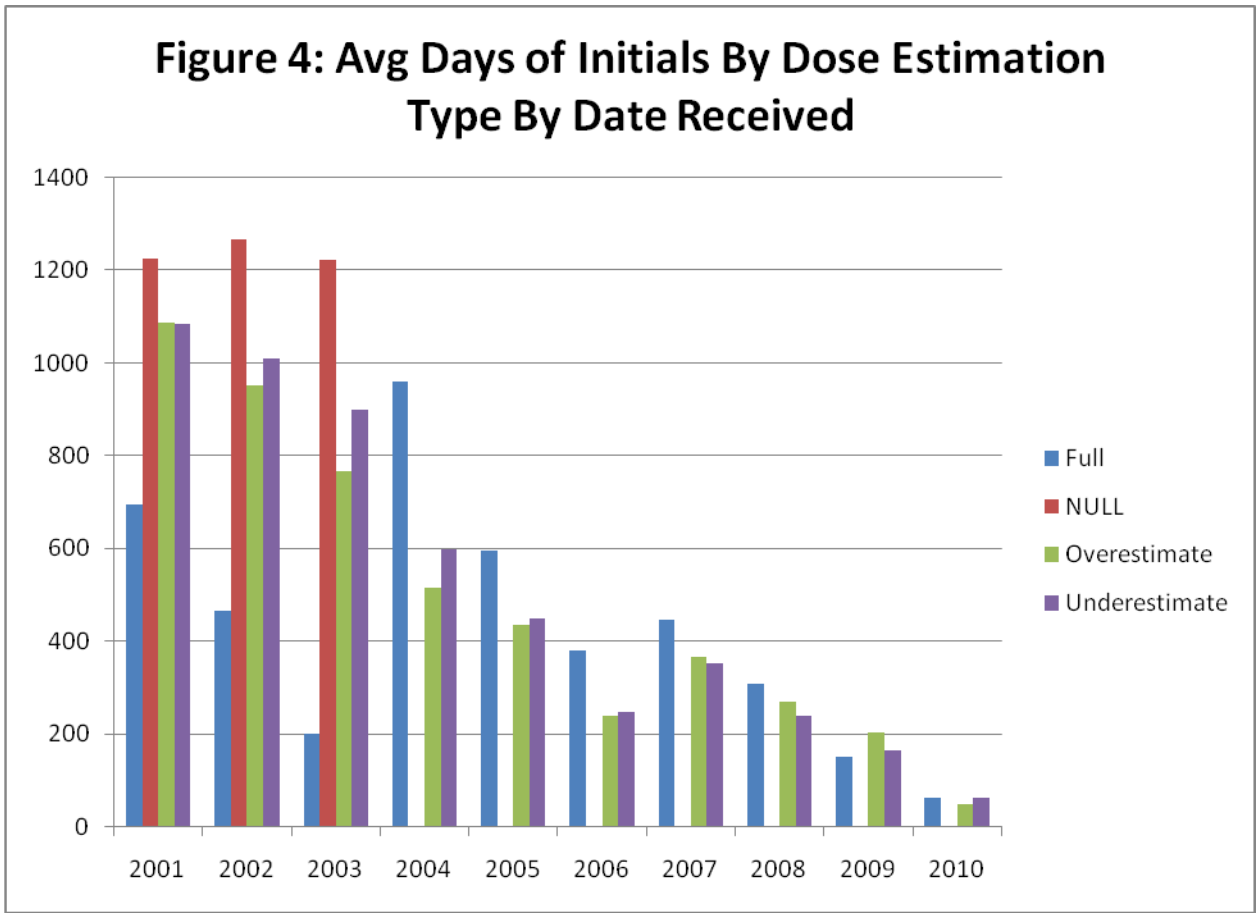
Dose Reconstruction

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

Dose Reconstruction

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 **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, i.e. with a more precise definition of the doses that cannot be reconstructed in an SEC definition it would be possible to include more components of dose in a partial dose reconstruction.
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, NIOSH, the Advisory Board, and the Department of Labor 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.

Dose Reconstruction

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.

Dose Reconstruction

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-9 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 (160,161,163-165)	34.9	65.1	436	2.9

One question that comes to mind when reviewing the data in Table 9, is whether or not this rank by compensation rate "makes sense"?

Dose Reconstruction

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*

Dose Reconstruction

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.

Dose Reconstruction

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 are contained in their entirety on the NIOSH Website for the Ten Year Review -Phase I Report Docket Number 194, http://www.cdc.gov/niosh/docket/archive/docket194.html.

In this section on 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 Simonds 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?

Dose Reconstruction

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?

Dose Reconstruction

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)?

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

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.

Dose Reconstruction

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 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.

Dose Reconstruction

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.

Expert #13

Overestimates

I was surprise by the length of time for completing overestimate claims. It appears to parallel the time required for the underestimate claims. This needs to be evaluated.

Backlog

The backlog data should be more detailed. Of the 242 active claims at NIOSH for more than 12 months, what is their distribution by year (how many have been waiting 3 years or more, etc.). Of the backlog of old claims cleared in the last year (4049 claims), how were they addressed? How many became 83-14's, etc. This information should be helpful to prevent future backlogs.

Excerpt #14

Overall comments:

The purpose of Reports was to provide a data-driven evaluation of the NIOSH Dose Reconstruction program. My understanding of the intention of the Director in soliciting this Review was to obtain a high-level assessment of the Dose Reconstruction Program with a perspective on strengths and limitations that could help to identify managerial or process changes that could lead to improvements in quality of work, efficiency, and customer service.

Reports 1 and 2 give substantial attention to concerns regarding the timeliness of the program. The reports offer substantial evidence of improvements in NIOSH's handling of claimants' cases, from the perspective of timeliness. There is no documentation about how these improvements in timeliness were achieved. It would be useful to explain the processes or changes in the dose reconstruction procedures that led to improvements in timeliness both as evidence of managerial approach, as well as to document that an improvement in timeliness has not come at the expense of quality of dose reconstruction (or, for example, inflation of costs in administering the program).

Regarding quality of the dose reconstruction program: the report offers scant information regarding quality assurance efforts or empirical assessment of validity, reproducibility, or consistency of dose

reconstructions (between staff or over time). Report 2 describes that the development of procedures to assist the person doing the dose reconstruction facilitate uniformity in dose reconstruction. This is a strength of the program, but does not address concerns regarding consistency in application of the procedures. The reported material on quality assurance draws heavily upon information assembled by the ABRWH and current text of draft Report 2 provides no insight into the existence of, or details regarding, an internal process of evaluation of the quality of the work being done by the reconstruction staff or the reproducibility of findings. The report would be strengthened if it were to offer some insight into how staffs are evaluated to assure quality work in the dose reconstruction process. Again, this cannot rely solely upon the limited sample of records evaluated by the ABRWH, as the Board's 2% sample of cases provides no basis for assessing the relatively quality of work of NIOSH staff on an individual level. It would be useful for Report 2 (Dose Reconstruction) to provide information on how the work of an individual dose reconstructor is evaluated to assure high quality, and how consistency between staff is assessed and maintained over time.

These reports provide no documentation regarding internal process of quality improvement; again, the report draws solely upon evidence of responses on a case-by-case basis to errors identified in dose reconstructions on illustrative claimant cases examined by the ABRWH. The review suggests a surprising need, ten year into the program, for an internal program of quality assurance and ongoing quality improvement in the dose reconstruction process that would identify gaps, weaknesses, inefficiencies, or sources of delay in the process of dose reconstruction and implement improvements.

Claimant's perspectives regarding the Dose Reconstruction Program are not captured in these reports. Would it be possible to evaluate claimants' concerns regarding NIOSH's work and perhaps assess how those have changed over time in response to changes in how the program operates?

Lastly, Reports 1 and 2 are single authored documents. It is surprising that large sections of the text and tables in Report 2 appear verbatim in Report 1. This raises a concern regarding authorship and responsibility for the opinions and conclusions reported in these documents. It is unclear how the opinions in these reports can be assessed when it appears that sections of the text are not independent products.

Detailed Comments on Report 2
Page 6 -the author notes that NIOSH "must undertake a rigorous review of its internal quality control quality assurance procedures." This report would seem to be the place for such a review to be presented. At minimum this report should document the existing internal quality control quality assurance procedures used by the NIOSH Dose Reconstruction Program; ideally this report would provide data regarding the internal QCQA program and its findings over time.

Page 8 -the author notes that "The number of findings reinforces the need for NIOSH to focus on its internal quality control/quality assurance efforts." At minimum this report should document the existing internal quality control quality assurance procedures used by the NIOSH Dose

Dose Reconstruction

Reconstruction Program; ideally this report would provide data regarding the internal QCQA program and its findings over time.

Page 9 Table 1 and Table 2. This text is identical to that in Report 1 page 6.
This is striking since these documents each are listed as single-author documents with 'Author's observations and conclusions' attributed to different authors in each report. Table 1-Restructure the table to include 3 rather than 4 columns as follows: column 1 'Calendar Year'; column 2 'Number of Claims Received by NIOSH'; column 3 'Number of Claims Submitted to DOL.'

Table 2 -Restructure the table to include 3 rather than 4 columns as follows: column 1 'Calendar Year'; column 2 'Claims Received by NIOSH, Time in days Mean (min, med, max)'; column 3 'Claims Submitted to DOL, Time in days Mean (min, med, max):

Table 4 is not a well described presentation of information. Values of NULL are not defined and appear in multiple columns. The relevance of day and month of initiation date, and of PER number, are not obvious.

Table 5 -The information in the first 2 columns of this table simply repeats information already reported in Table 2 of the same report.

Figure 1-This Figure and text are identical to that in Report 1 page 9. Strike Figure 1.
This figure takes 3/4 of a page and reports only 4 numbers (3 of them of interest). Replace the figure with a single sentence that states "The number of initial claims completed using the full best estimate technique was XXX, using the overestimate technique was YYY, and using the underestimate technique was ZZZ. A small number of claims (AAA) could not be classified as they were completed before records were kept of such designations.

Figure 2 -Strike this figure. All of the information in the figure is repeated in Table 6 (page 16 of report 2).

Table 6 (page 16)-The Table and text on this page are identical to that in Report 1 page 11.
This is striking since these documents each are listed as single-author documents with 'Author's observations and conclusions' on page 16 of report 2 are identical to those attributed to the author of report 1 (page 11). It would be useful to add the row percent to this table (in parenthesis) so that the reader could assess whether the percentage of claims worked using a specific dose technique has changed over time.

Figure 3 (page 17, report 2)-Strike this figure. This figure takes Y. of a page and reports only 4 numbers (3 of them of interest). Replace the figure with a single sentence as suggested for Figure 1. In this sentence describing the average number of days to complete an initial dose reconstruction by dose estimation technique you should also report the min, median, and max

number of days for each. "The average number of days to complete an initial dose reconstruction using the full best estimate technique was XXX days (min=xxx1 days, median=xxx2 days, maximum=xxx3 days) using the overestimate technique was YYY days (min=yyy1 days, median=yyy2 days, maximum=yyy3 days), and using the underestimate technique was ZZZ .....

Figure 4 -Strike this figure. All of the information in the figure is repeated in Table 7.

Table 7 (page 18 -it would be very useful to add columns to this table to report values other than the mean number of days. You could (for each dose estimation technique) include 4 columns that reported the mean, median, min, and max.

Table 9 reports the 10 cancers which have the highest percentage of claims compensated. It would extremely helpful to also present a table reporting the 10 cancers which have the LOWEST percentage of claims compensated. Column 4 of Table 9 could be struck (percent not compensated) as this is simply the complement of the value reported in column 3 of the table (percent compensated).

Table A is a reproduction of a table from the UNSCEAR 2006 report. As the authors note, UNSCEAR data were not used to develop individual dose models in NIOSH-IREP. Rather, cancers were grouped differently for the purposes of IREP. Therefore, it is not at all clear to this reviewer why this NIOSH report should dedicate space to reproducing a table of risk estimates which are not directly relevant to understanding and interpreting findings derived from NIOSH IREP. It should be easy enough to produce a table that summarizes the ERR/Sv estimates and associated confidence intervals for the categories of cancer of interest that accurately reflect the values used by NIOSH IREP.

Excerpt #15

Comments Part B Statistics of February 2010

The statistics below provide insight regarding the rate at which Part B individual dose reconstruction claimants have been able to challenge denied claims successfully as of February 2010. The data received from the DOL ombudsman's office indicates the following:

As of February 1, 2010, DEEOIC has identified 611 total cases from the beginning of the program that were denied for a probability of causation of less than 50% and then were eventually accepted for a PoC of greater than or equal to 50%. Of these 611 claims, 334 were based on a DEEOIC initiation of a review or rework based on the issuance of a NIOSH Program Evaluation Report or a Program Evaluation Plan. The DEEOIC database is not constructed to track statistics on the remaining 277 claims that were initially denied and subsequently were accepted. Additionally, the break down also indicates the following:

Dose Reconstruction

Of the 611 reversals: 318 were based on PEP, 16 were based on PER, 151 were based on a rework; of those 151 reversals based on a rework 62 were reversed based on an appeal initiated by the claimant

126 were based on a remand + rework; of those 126 reversals based on a remand rework 78 were reversed based on an appeal initiated by the claimant

Of the 277 reversals based on a rework or a remand + rework only 140 cases were reversed based on appeals initiated by the claimant.

Accordingly, of the 23,125 dose reconstruction reports submitted to DEEOIC only 140 claimants were able to challenge the denial successfully by an appeal that the claimant initiated; .6%.

Significantly the overall rate of reversal on dose reconstructions as of February 2010; 2.6% (based on the February 2010 statistics DCAS provided to the Advisory Board in February 2010 that as of December 31, 2009, 23,125 dose reconstruction reports were submitted to DEEOIC).

That's a disturbingly low number but not surprising considering the inability to understand a dose reconstruction report and therefore the inability of an individual claimant to challenge the information used in that report that the DEEOIC uses to eventually deny the claim.

Furthermore, the small amount of reversals based on "appeals" which is 140 as of the February 2010, those reversals seem to be based on claimants providing new info based on medical evidence or employment evidence --and not on a claimant's actual ability to decipher the incomprehensible information contained in a dose reconstruction report. The Part B program is being functionally administered by health physicists for comprehension by health physicists and not for claimants. This is not a program that is claimant friendly as it provides claimants the functional ability to appeal a denied claim in name only. This is the most fundamental reason why the Part B program denies claimants basic due process.

Excerpt #16

Program over granting SECs. DCAS's predisposition to deny SECs in favor of the individual dose reconstruction program has been wholly supported by the recent SEC review report issued by Randy Rabinowitz for the EEOICPA Ten Year Review. Specifically, Ms. Rabinowitz concludes in the report that:

"NIOSH Policy Favors Individual Dose Reconstruction over SEC Approval: The SEC regulations state that NIOSH's goal is a uniform, fair, scientific consideration of SEC petitions. But the policy NIOSH adopted favors [sic] creates a preference for completing dose reconstructions over approving additional SECs, even where little actual monitoring data from a site exists or obtaining such data requires a large expenditure of resources or a long delay"

Worker advocates urge NIOSH to investigate the conclusions reached within this report thoroughly and consider the impact of those conclusions on the pressing question of whether NIOSH and DCAS are fully supporting the purpose of EEOICPA --to administer this compensation program in a truly claimant friendly manner.

Dose Reconstruction

Excerpt # 17

Regarding the dose reconstruction review, ANWAG questions the approach of simply reviewing the work conducted by Advisory Board on Radiation and Worker Health (the Board). The Board has only sampled 100 dose reconstructions. However, to date, 25,676 dose reconstructions have been completed by NIOSH. A review of less than 1% of the completed dose reconstructions cannot possibly provide NIOSH with any semblance of a comprehensive evaluation of the conclusions reached by the Board to date. ANWAG recommends either a greater sampling size for review by the Board or that NIOSH personnel supplement the review already completed by the Board to increase the dose reconstruction sampling size that NIOSH will ultimately analyze for the Ten Year Review.

Additionally, ANWAG agrees with the concerns raised by Dr. William Richardson regarding the fact that whole sections of the dose reconstruction review report appear verbatim in the report on timeliness. Significantly, as Dr. Richardson noted, the similarity between the two documents raises a concern that the opinions and conclusions in both documents are not independent products; which in turn poses question regarding the overall integrity of the review process. Moreover, the author of the review appears occasionally to apologize for NIOSH's failure to reconstruct dose in a timely fashion versus offering a neutral critique of the program. We do wish to note, however, that we agree with the author's conclusion found on page 39. We appreciate and welcome the inclusion of the Table delineating how many claimants have died while waiting for their dose reconstruction to be completed.

Excerpt #18

It is NIOSH's unofficial policy to impose significant delays for any re-works or re-dosing of previously denied claims that have been appealed either administratively or through federal court litigation. Regarding the ongoing SEC evaluations of the Linde SEC petitions, NIOSH and the HHS Office of Legal Counsel have indicated that the Technical Basis Document for Linde may be revised by the end of the year, at which point the dose reconstruction should be re-visited for previously denied claims.

This inexcusable delay and uncertainty penalizes individual dose reconstruction claimants and violates the claimant's right to have their denied claims evaluated in a timely manner. The goal of timely compensation is abandoned simply because SEC petition evaluations often uncover significant deficiencies in Technical Basis Documents. This policy is antithetical to the evaluation of all individual dose reconstruction claims pursuant to a claimant friendly paradigm. When such extreme uncertainty prevents DCAS from revisiting previously denied claims because the Technical Basis Document needs re-evaluation, DCAS should be required to recommend the approval of an SEC petition under section 83.14. A recommendation for the approval of an SEC petition under section 83.14 should be predicated on the very fact that a dose reconstruction rework cannot be completed under any semblance of a reasonable time frame.

Generally, this NIOSH delay tactic stands in direct contradiction to Dr. Howard's recent directive to DCAS staff to complete old dose reconstructions by July 1, 2010. DCAS cannot be permitted to create endless uncertainty as to when and if they will revisit and re-evaluate previously denied claims. Specifically, regarding the Linde Ceramics

site, DCAS's policy of favoring the individual dose reconstruction program over SEC approval is unfairly penalizing individual claimants that deserve to have their claims re-evaluated independently of the SEC evaluation process. Again, this directly contradicts Dr. Howard's directive as it relates to revisiting previously denied Linde claims.

These claimants should not suffer inexcusable delay simply because DCAS is on a mission to recommend the denial of SEC petitions at any cost.
I respectfully request that NIOSH re-evaluate how and when previously denied claims will be revisited when an ongoing SEC evaluation process delays when and if DCAS will eventually revise a Technical Basis Document. Moreover, I urge NIOSH to recommend the approval of an SEC petition under section 83.14. The Linde workers have waited far too long to have their claims evaluated in a fair and timely manner.

Excerpt # 19

I have tried several times to submit comments to the Ten Year Review .. and perhaps I will make it this time.

My husband's claim has been in the DOL/ DOE/ EEOICPA claim process for 9 years..... 6 cancers, 4 or 5 dose reconstructions, 3 hearings, and numerous remands. He is now deceased.

From the beginning, files were lost.... resent, lost. ... and over 3 years for the first denial....Now almost 7 months since last remand.... which was to have been reworked immediately as it was the same type of cancer in different area.... which DOL accepted as a separate cancer.

Corrections have NEVER been made. We have submitted multiple papers, EE-4s, etc. radiological proof and job description for a fireman in a nuclear site..... and He is still classified as a "low exposure position".... No fireman in the nation is a "low exposure position".

In the hearing transcripts and denials, no acknowledgement or changes have been made when we tried to correct.

One NIOSH employee told me that my husband was given less POC than a outside citizen driving past the gates. This is a sad situation.

This Co-worker data is not with firemen.... NIOSH stated it could be from any site or area.... This is not an accurate assessment of exposure.

Oncologist, Cancer Surgeon, and neurologist all wrote they believed in their medical opinion his cancers were caused by radiation and/ or toxic chemicals. These are the doctors who treated the claimant.... they know more of the situation than a computer or a claims examiner and their statements are not accepted.

The claim for my husband (now my surviver claim) and others could have been paid over and over for the amount spent to deny. 18 firemen in the same Oak Ridge National Laboratory, Oak Ridge, TN. have cancers ... most below the waist.... 9 have been paid as far as I have records.... others denied. There is no reasoning behind the calculations of the Dose Reconstructions.

Dose Reconstruction

Administration of claim, 4 or 5 dose reconstructions, several remands, and 3 hearings..... where is the reasoning in denials? These costs alone could pay the claim.

I have found that several times the record has been remanded and it has ended up in Storage ... and once in an office for closed files.

This is incomprehensible to claimants, how many mistakes can be made over and over. The continued delays are not acceptable to claimants.

There is no possible way the dose reconstructions can calculate the amount of exposure for a First Responder, a Fireman, EMS, etc. They are first on the scene... sometimes first to find a problem. My husband found himself standing in liquid nuclear material early on in his employment and was told to not write it up..... He also went to the nuclear waste burial grounds every day he worked... as all firemen did on a continual check for fires. A couple of years ago 70 mason jars were found with nuclear waste... still active. The men ran ... and the equipment was left as contaminated. This is a definite high level exposure area.... to go into without Protective Equipment.... which is the norm.

DOL claims no exposures for his claim (all zeros) ... but an International Certified Health Physicist as found proof in the DOE system that the zeros mean "not adequately monitored". This HP has worked in Hanford, ORNL, Savannah River, etc. and has full working knowledge of the system. This has been presented, but not acknowledged. With dosimeter cards having notations of "failed abundance", and numbers written out from the zeros in pencil... this is difficult to reconcile.

My husband's records are missing... for 32 years of work at Y-12 and X-I0 there are a scant 8 years of records. (last years at ORNL X-I0).... and for his "zeroed out dosimeter cards"..... they are all there from 1974 to 2000..... EXCECPT THE YEAR 1987.... The year he had two emergency call ins on his normal days off..... "come ASAP --your dosimeter reading is off the charts"..... 4 plus hours later.... each time.... that year is missing. Very suspicious....as we reported from the initial claim. NIOSH wrote that he did not work a monitored job in 1987... but we sent numerous documents to show he did..... then told error in reading.... Two times..... not likely.

When NIOSH will not accept 7 radiological badges, letter from the Fire Chief, co-workers, plus a job description for a fireman ---stating working with hazardous materials, listing Radiation and toxic material ls .... THIS IS A MAJOR PROBLEM.....

NIOSH has stated that the badges were for years 1998 to 2001..... and that did not prove he worked a radiological job for 27 years..... letters from Chief were not accepted.... We have tired to explain that the badges are renewable..... always the practice and continues.

How can 18 cluster cancers be ignored.? Paying some and not others in the same job position is unjust. Firemen in the early claims (when my husband's file was lost for 2 years) ... and we continued to resubmit --numerous times ---were paid. The firemen since the DRs came into play, have been denied...The Dose Reconstruction Module is a gross injustice.

And when rems have gone from 30.263 rems on bladder cancer to less than 2 rems --and the operator who answers the telephone at NIOSH tells you "you know when you refile for another cancer, your percentage will go

down." Well, they did -every time. Sad state of this program. The denials always have the words that when refiling your probability will go down. Where is the common sense in this?

The Government brought the contamination to these sites and should accept responsibility for the illnesses and death.

Many claimants are struggling to keep their homes.... when medical bills are draining their 401Ks. We did our part to help with the Cold War and the actual wars..... are we no less important to America than the people killed on 9/ 11? The firemen went in when others were running out... and time has shown the numerous health problems with the firemen. The same situation is with firemen and others working in the nuclear sites.

When the hospital where the firemen took the ambulance and exposed workers is named an SEC (which could include anyone working in the hospital --even in OB/GYN -)-and are paid and the firemen working in the site are not... something is definitely wrong.

The Veterans and Sick Workers have gotten a slap in our faces for doing our job to keep America safe.

We have had a major problem with the interviewers.....not knowing one thing about the sites, the job positions... and not able to answer questions. One man answered just like a robot....yes, no, yes, no ... I don't know. I don't know....

How can a claimant get help? Even the resource centers have given us multiple answers...

The Claims Examiners are the same... Lack of knowledge... not cross referencing jobs from one site to another. I was told no firemen in DOL SEMS jobs data base for ORNL... but they were there for Y-12 and K-25..... She said she could not approve. Then after questioning this I was told she should have cross referenced..... Since that time in 2008, I have gotten 3 classifications for firemen at ORNL put into the SEMS...

The SEMS and other data bases are wrong by omissions for job categories, building information, functions of the buildings.. and even denying the 19 buildings (*as no buildings) in the 6000 area of ORNL.

We have had 17 plus claims examiners... Each making more mistakes and no one ever corrects. This program is definitely not claimant friendly as touted by the administration.

My husband asked me on his death bed... "don't give up.... get my justice". Many times when he was denied... he would say "they are slapping me in the face for doing *my* job".

As with him and myself, we worked out jobs... and only in the late 80s and early 90s was any safety information given.... and I was allowed to go into labs, Radiation areas, etc. ... where the men working in labs had on protective clothing... but me going in to collect time cards was o.k. I would ring the buzzers.. and they would let me in ..... .

Even now the 400 plus buildings on the Demolish and Destroy list for Y-12 and X-IO have workers in the buildings. The fire department building 2500 being on that list from the beginning..... When a fire truck is contaminated... and clothes are taken.. and the fireman is kept in a "clean up room".... something definitely happened..... but the rule is and has been confirmed by many firemen even at our hearing.... if it is not written

down... it did not happen. This is an injustice to the workers from early years and the practice still continues.

Please acknowledge the inconsistencies.... accept data from the workers, the data from doctors that treat the claimants.... not from a computer module that has changed several times over the years.

America --governmental agencies.... help the sick workers and their families --do away with the DRs.... give money to claimants with cancers and other illnesses.

Excerpt # 20

1. Post documents used during Advisory Board meetings on website so people participating by phone can have access to the same materials that people physically attending the meeting have.
2. There has been much discussion about the super-s classification of high-fired plutonium. What about other high-fired radionuclides? Do they share the same super-s category?
3. It does not seem scientific for NIOSH to ignore the lesser used radionuclides in dose reconstructions, particularly during a SEC period. Example: a worker with Hodgkin's disease who worked during an SEC period proved exposure to an additional 50 radionuclides. NIOSH evaluated the worker for just the few radionuclides that were common at the site for which the worker had some monitoring data and ignored the additional non-common 50 radionuclides. Claimant was told the dose reconstruction was adequate and that it covered the additional radionuclides because of the overestimate.