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?

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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?

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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)?

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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.

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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.

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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

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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.