Miller, Diane M. (CDC/NIOSH/EID)

From: Katz, Ted (CDC/NIOSH/OD)
Sent: Tuesday, August 31, 2010 10:36 AM
To: NIOSH Docket Office (CDC)
Cc: 'David Richardson'
Subject: FW: Comments on the NIOSH Dose Reconstruction Program Draft Ten Year Review-Phase I Report
Attachments: Comments by David Richardson on Ten Year Review Reports.doc

To: NIOSH Docket Office; Docket # 194

The attached are comments to the NIOSH Docket # 194 (10-year review of NIOSH Radiation Dose Reconstruction Program) from Dr. David Richardson, who is a member of the Advisory Board on Radiation and Worker Health.

--Ted

Ted Katz, M.P.A.
NIOSH, Office of the Director
404-498-2533

-----Original Message-----
From: David Richardson [mailto:david_richardson@unc.edu]
Sent: Thursday, August 26, 2010 10:31 PM
To: Katz, Ted (CDC/NIOSH/OD)
Cc: David Richardson
Subject: Comments on the NIOSH Dose Reconstruction Program Draft Ten Year Review-Phase I Report

Ted,

Attached as a MSWORD document are some comments on the NIOSH Dose Reconstruction Program Draft Ten Year Review-Phase I Report.

The attached comments are fairly detailed and so I would like to transmit them to NIOSH via the appropriate channel, as we discussed.

I would be grateful if you could help me by passing these along to the correct point of contact at NIOSH.

Thank you,

David Richardson

Comments on the NIOSH Dose Reconstruction Program Draft Ten Year Review-Phase I Report.

David B. Richardson

The following comments relate to 3 documents that were circulated at the August meeting of the Advisory Board on Radiation and Worker Health.

- I will refer to the document titled "Timeliness of Program Task Accomplishments" by Nancy Adams (August, 2010 draft) as Report 1.

- I will refer to the document titled "Dose Reconstruction" by Dr. Lewis Wade (August, 2010 draft) as Report 2.

- I will refer to the document titled "Special Exposure Cohort Evaluation Report" by Randy Rabinowitz (August, 2010 draft) as Report 3.

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 staff 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 1:

Page 1, line 2 – 'bottom line prospective' should read 'perspective'

Page 1, para 2 "NIOSH completed and returned to the DOL 25,883 completed dose reconstructions" Strike second 'completed' in this sentence.

Pages 1-3 starting with the section headed 'Special Exposure Cohort" offers a very useful description of the SEC process. However, it is unclear why this appears at the start of report on Timeliness of the Dose Reconstruction Program. I would suggest that this material might appear more logically at the start of Section 3 'Timing of Task Accomplishments – SEC Petitions'.

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 3 – Add to column 3 the min, med, and max time in days to complete a returned claim.

Figure 1 – Strike this figure. This figure takes ¾ 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 4.

Table 4 – it would be very 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 – Strike this figure. This figure takes ¾ 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 5.

Table 5 – 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.

The author's observation on Page 14 (point 2) is very useful . The author notes that the average number of days for a full best estimate and overestimate are similar in recent years, raising a question regarding the rationale for continuing to conduct overestimates of doses.

Section 3 – Steps in dose reconstruction (starting on page 15)

Strike Figures 1- 9. The information in figures 1-9 would be more usefully presented in tabular form which would allow the reader to integrate the number of days for each step (and examine how these have changed year-by-year). Consider a table with rows for the steps covered by figures 1-9, with a column for each year. In one column of the table you would report the average days for: initial DOE request, initial CATI scheduled, CATI summary,... At the bottom of the column you would have the total time for an initial claim received in that calendar year. Looking across a row of the table you would see how the average days for a step in the process has changed (e.g., the drop in the average number of days for initial CATI summary from 491- 25 days between 2001 and 2010).

Table 1 (page 19) could be struck if the figures replace this. Figures 5 and Figure 9 appear redundant and suggest that one could be dropped.

Figure 17 is useful and might be printed landscape for better viewing.

Table 2 (page 28) should be struck – it simply repeats the information in Figure 17.

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 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 ¾ 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 ¾ 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.

Detailed comments on Report 3:

Page 3 – the author reports that 'we compared the total number of DOL claims at sites with either pending SEC petitions or SEC petitions that had been approved. We sued the number of DOL claims as a proxy for site size." The author could clarify the question/hypothesis under investigation. I believe that it is that 'large' sites or classes are less likely to be recommended as a SEC than 'small' sites or classes. The consideration of NIOSH or the Board could be: 1) the number of claims pending at time of deliberation (i.e., the number of DOL claims pending at the time of SEC consideration); or, 2) the potential number of claims (which is an unknown number, but presumably related to the size of the work force covered by the class definition). The author lays out a number of other factors that are empirically evaluated as potential predictors of SEC class approval; this would suggest a simple logistic or binomial model to evaluate the significance of explanatory variables as predictors of SEC approval.