

Advisory Board on Radiation and Worker Health

Findings for Dose Reconstruction Review Cases Sets 6-13 (Cases No. 101-334) and Comparisons to the First 100 Dose Reconstruction Review Cases (Report prepared by the Subcommittee on Dose Reconstruction Reviews) September 2015

FINDINGS

(Part A) This is a summary report to the Secretary of Health and Human Services with respect to the Advisory Board's independent review process of radiation dose reconstructions completed by the National Institute for Occupational Safety and Health (NIOSH) as required by the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). The purpose of the Board's review is to advise the Secretary on the "scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program". The Board feels that interim reports, such as this one, may be useful in affecting change in the methods, procedures, or policies of the NIOSH dose reconstruction program while the overall review continues.

Cases Sent to NIOSH for Reconstruction

As of November 1, 2015 DOL reported a total of 44,789 total case claims sent to NIOSH, of which 42,714 cases (95.4%) had already been returned to DOL with a compensation recommendation, with the remaining 2,075 (4.6%), both new and returned, at NIOSH . The 42,714 cases returned included both dose reconstructions and Special Exposure Cohort (SEC) cases compensated due to inability to estimate the radiation dose with sufficient accuracy and reasonable likelihood of health endangerment. (Administratively some of the latter cases were processed by NIOSH while and until the SEC classification was determined, and others directly by DOL if and after the SEC class was approved.)

Types of Dose Reconstruction

The cases reconstructed since the Board's inception fall into three basic types: 1) 'best estimate' dose reconstructions; 2) 'over-estimated' dose reconstructions; and 3) 'under-estimated' dose

reconstructions. NIOSH’s overestimating approach is an efficient way to process claims which are non-compensable. This time saving method is only intended for non-compensable claims. Under-estimation is also a time saving approach used for claims that are compensable. Since the claims are compensable a more precise estimate of dose is not necessary. The best estimate approach is used for cases that are not clearly compensable or non-compensable, and gives the most precise estimate of dose in order to make a decision on compensation. [Note that dose reconstructions are not undertaken for claims in facilities approved for SECs.

for which the cancers declared are not among the 22 covered for SECs under EEOICPA, a partial dose reconstruction may be undertaken.]

Dose Reconstruction Cases

At the conclusion of the dose reconstruction reviews for Sets 6-13, which is the focus of this part of the report, NIOSH’s Division of Compensation Analysis and Support (DCAS) reported a total of 31,534 claims with completed dose reconstructions sent to the Department of Labor. The remaining recommendations were primarily Special Exposure Cohort (SEC) cases, but also included some cases returned to DOL for administrative reasons. The distribution of types of dose reconstructions (DRs) for these claims, made since the inception of DCAS in 2001, is as follows (Table 1):

Table 1. Types of Dose Reconstruction for the First 31,534 DRs*

Best Estimate	Over-Estimate	Under-Estimate	Partial
2,452 (7.8%)	18,960 (60.1%)	8,104 (25.7%)	2,018 (6.4%)

* Completed as of Nov. 1, 2015.

Thus a majority of the claims submitted involved over-estimated dose reconstructions, and an overwhelming majority (85.8 percent) either over- or under-estimates. Only 7.8 percent required the more precise and more time-consuming best-estimate DRs. Partial dose reconstructions comprised the remaining 6.4 percent. Also 13.4 percent of the claims were made by female employees. No data were collected on race or ethnicity of the claimants except for those filing for skin cancers, for whom differences in incidence rates by race were taken into account.

Dose Reconstruction Cases Reviewed

Of the dose reconstruction cases reviewed for this report (Cases No. 101-334), the Dose Reconstruction Reviews Subcommittee, with technical assistance from NIOSH/DCAS, its subcontractor ORAU (Oak Ridge Associated Universities) and the Board's contractor (Sanford Cohen and Associates – SC&A), has been able to undertake more reviews of best-estimate dose reconstructions.

Although best-estimate dose reconstructions are relatively infrequent under the NIOSH program, they are particularly important in that errors could potentially result in DOL making incorrect compensation decisions. Also best estimates require much more sophisticated machinery, more complete records and more difficult professional decisions to bridge information gaps both reasonably, claimant favorably, and plausibly. Hence best estimates test the dose reconstruction process more effectively and intensively.

Of the recently reviewed Cases 101-234, 193 (82%) were best estimates, 32 (14%) were over-estimated and 7 (3%) were under-estimated. [Two cases in Sets 6-13 have not yet been reviewed pending updates of their site profiles by other working groups.] Thus a total of 17% were either over- or under-estimated. These results stand in sharp contrast to the results from our Report on the first 100 cases reconstructed, where only 7 percent were best estimates and 93 percent either over- or under-estimates. (Table 2)

Table 2. Types of Dose Reconstruction

Report	Best Estimate	Over-Estimate	Under-Estimate	Not Completed
First 100 Cases (2009)	7 (7%)	76 (76%)	17 (17%)	0
Cases 101-334 (2015)	193 (82%)	32 (14%)	7 (3%)	2 (1%)

The reconstruction of the first 100 cases largely through over- and under-estimates reflected the imperative to rapidly process the large initial batch of claims under EEOICPA and eliminate the resulting case backlog. As the program has matured,

- The backlog of individual claims has now been reduced so that about as many individual cases as are sent to NIOSH quarterly are processed during that quarter.

- Many site exposure profiles for covered facilities have been completed based on site visits by staff and Board members and the establishment of 37 different site-specific Board Work Groups,
- Many more analytical procedures have been written down based staff input and the activities of the Board's Procedures Review Subcommittee so that dose reconstruction decisions are now better regularized and more nearly uniform.

Thus since 2009 the Dose Reconstruction Reviews Subcommittee (DRSC), with the aid of staff from NIOSH, subcontractor ORAU (Oak Ridge Associated Universities) and independent consultants SC&A (Sanford Cohen and Associates), has been able to undertake under Board guidance best-estimate dose reconstruction reviews for more than four-fifths of the next 232 completed dose reconstructions.

Findings among Reviewed Cases

In examining the 234 cases from Sets 6-13, the Dose Reconstruction Reviews Subcommittee reviewed a total of 670 findings (2.86 per case) in which there were initial differences between the dose assessments for individual cases made by the NIOSH and ORAU staffs and those made by the SC&A consultants. These were then discussed first by the staffs of the respective groups and later reviewed by the full Dose Reconstruction Review Subcommittee. Of the 670 findings, 550 (82%) were found to be of low impact, 98 (15%) had a medium impact, and 22 (3%) had a high impact. [The four findings from the 2 cases not completed were assigned their original finding rank.]

A finding is found to have a low impact if it has only a marginal impact on the compensation decision, involving for example a minor QA concern, a minor clarification, or a change in dose (increase or decrease) of only a few millirems (mrem). A finding is found to be medium impact if it was related to some change in procedures, a more involved discussion or clarification of the DR methods, or involved a change in dose of mrem to rem quantities. A finding is found to be high impact if it prompted a major change in procedures that would affect several cases, or if it involved a change in assigned dose of several rems. As a result of discussion and review of these findings the probability of causation was changed in only ____ cases, resulting in the

compensation of a claimant who was initially denied such compensation. [NOTE: An important number, perhaps as few as 3 cases, but the precise criteria for which have not yet decided by the DRSC. Further discussion of this issue is on the agenda for the Feb 10 DRSC meeting.]

As might be expected, the above result of 2.86 deficiencies per case is 28 percent than the 3.98 per case reported in 2009. However the distribution of impacts in this report (82%L, 15%M and 3%H) is quite similar to those in the 2009 report (86%L, 12%M and 3%H) . While this result might at first appear anomalous, it may reflect the facts that the dominant over- and under-estimations in the first report were broad assessments, not likely to present major errors, whereas for this report, dominated by best estimates, the chances for errors are far greater, but due to improved assessment procedures and protocols the percentage of high-impact findings has been kept low – that is, these two effects have had counteracted each other to keep the percentage of high-impact findings low.

In addition to assessing the degrees of impact for deficiencies for each case reviewed, the DRSC guided by input from NIOSH, ORAU and SC&A and approved by the Board began in Set 6 to assess and categorize findings by type of issue or issues involved in these deficiencies. The types of issues and their distribution among findings for Cases 101-334 are presented in Table 3.

Table 3. Findings by Type of Deficiency for Cases 101-334*

Category	Type of Deficiency	Nr. Of Findings
A	Was the proper judgment made regarding placing a person physically at a work location?	16
B	Were all exposure scenarios considered (i.e., neutron, thorium)?	33
C	Were the correct external dose model and assumptions used?	270
D	Were the correct internal dose model and assumptions used?	143
E	Is it a quality concern?	98
F	It does not meet either of the above criteria.	114
	Total	674*

*NOTE: Some cases had more than one type of deficiency.

As is clear from this Table, the greatest source of findings (40 percent) is disputed modeling or assumptions about external doses, followed by the same (21 percent) for internal doses. The

former often reflects different information between NIOSH and SC&A about radioactive materials present at a site. If a discrepancy is found in a reviewed case on the part of NIOSH, all cases, present and former, are re-run by NIOSH and non-compensation decisions reversed when appropriate. Dose reconstructions related to internal doses are quite complex and thus the reasons for discrepancies between NIOSH and SC&A are quite varied, but again if after review and subcommittee discussion if a discrepancy is found on the part of NIOSH all affected cases in that and other similar facilities are re-run and appropriately compensated.

Observations among Reviewed Cases

In addition to the findings under review, SC&A consultants also made 206 observations (slightly less than one per case reviewed). Observations, which began being noted and recorded in Set 8, are instances where SC&A had questions about NIOSH/ORAU dose assessments which were discussed by the parties and reviewed by the DRSC to confirm that proper procedures were followed and applied correctly. If not confirmed, the instances initially assessed as observations were changed to findings and re-examined as appropriate. Thus none of the 206 observations recorded resulted in a change of dose assessment.

Number of Dose Reconstruction Cases Reviewed

The Dose Reconstruction Reviews Subcommittee has reviewed 334 cases since its inception among the 31,534 claims filed as of Nov. 1, 2015 which required dose reconstructions. Thus this Subcommittee has completed reviews of 1.06 percent of all such claims filed as of this date, achieving its current goal of 1% of all claims reviewed involving DRs. Initially the DRSC and the Board had set a goal of 2.5% of all claims reviewed, as reported to the Secretary in 2009, reflecting our experience of conducting reviews 93 percent of which were over- and under-estimates. But since 2009 the DRSC has greatly increased the percentage of best-estimate reviews to 82 percent from 7 percent (Table 2). Such best-estimate reviews, while more extensive but also more time-consuming, have necessarily slowed down the Program's pace of reviews. At that time the Board approved reducing our goal to 1 percent of DR cases to be reviewed and this goal has been met. The Board and the DRSC fully expects to continue meeting this goal during the next operational period. **[Note to Board members: At earlier Board meetings and in the first draft of this report, I announced that we had achieved only 0.86% reviewed.]**

Grady recently sent me the total nr of DRs conducted since our inception, and this is much less than the total the program has processed, which I had used in the past (which unwittingly included SECs). When I used Grady's nr in the denominator, the percentage shot up to 1.06%.]

Distribution of Dose Reconstruction Sites across Employment Sites

In addition the DRSC has worked assiduously since 2009 to assure that cases selected for review represented an appropriate cross-section of all the plants and facilities for which compensation claims have been made. The breakdown of employment sites covering cases 101 through 334 is presented in Figure 1. (Copy Figure 1 from revised Summary Statistics, Rose Gogliatti, SC&A, January 7, 2016.) As indicated in this Figure many small sites were covered by 64 of the cases reviewed – 38 from sites with one reviewed case and 26 from sites with two cases reviewed.

These reviewed cases reasonably well cover the array of claims filed under EEOICPA. In Figure 2 (Copy Figure 3 from revised Summary Statistics, Rose Gogliatti, SC&A, January 7, 2016.) the blue bar next to each of the 26 large and medium sites represents the number of cases needed to be reviewed in order to achieve our goal of 1% of all claims reviewed for that site. The second bar next to each site is the sum of cases which have been reviewed, combining those for Cases 1-100 (in brown) and those for Cases 101-334 (in green). Thus if the height of the brown-green bar for the reviewed exceeds that of the blue bar, then the Board has accomplished its goal of 1% of claims reviewed for that site.

As noted in Figure 2, of the 26 sites listed the DRSC has met or exceeded its one-percent goal for 11 of them and has not met its goal for 15 sites. However six of the 15 are large sites with 15 or more reviews needed. These six sites represent about 80% of the reviews needed for the 15 deficient sites and all six are within 25% of the 1% goal. The remaining nine sites represent only about 20% of the reviews needed and all are smaller sites, with less than 15 reviews needed. For these nine sites the DRSC has conducted only 43% of the reviews needed. For sites with very small numbers of claims (Figure 2, bottom line) the DRSC has far exceeded its goal, with 82 reviews completed when 53 were needed, more than 50 percent greater than its one-percent goal. The deficiencies at the 15 large and medium sized sites can readily be corrected through a focus on selecting and reviewing cases from these sites during the next review period.

Distribution of Probabilities of Causation among Cases Reviewed

The chart in Figure 3 (Copy Figure 7 from revised Summary Statistics, Rose Gogliatti, SC&A, January 7, 2016.) shows the distribution of Probabilities of Causation (POC) among cases reviewed in Sets 6-13 (Cases 101-334). Cases with POC between 45-52% have been targeted for selection in the recent past since slight errors in these have the potential to change the compensation decision from non-compensated to compensated. Thus almost one-third of the case reviews (30%) since the 2009 Secretary's Report have been in the POC range of 45 to <50 percent. This is a major increase in reviews in this POC range, compared to only 5% of reviews in this range during the first 100 case reviews reported in 2009. This reflects both the increased percentage of best-estimate cases reviewed since 2009 and our more fine-tuned focus on assuring correct compensation decisions.

Another subgroup, those cases with POC from 50-52%, have also been targeted recently along with the 45 to <50% group. For the subgroup from 50-52% the DRSC wants to assure that small over-estimation errors in this subgroup has not resulted in erroneous compensation decisions. While as a matter of agency policy when such errors are found the claimant is not asked to return his/her compensation money, finding such overestimation errors can help both the Board and associated staff avoid such compensation errors in the future. Even with this focus, however, the percentage of reviews in this report (21%) which have POC at or over 50% is less than the corresponding value of 27% in the 2009 Report. This reflects a sharp decline in over-estimation cases since 2009. Similarly the percentage of cases reviewed with POC below 45% has declined from 68% before 2009 to 49% in this report, in this instance reflecting a decline in under-estimation reviews since 2009. The bottom line in both of these instances is that the Board is now more clearly focused on reviewing cases for which small errors in radiation dose can change the compensation decision, and hence on assuring that the final compensation decision is correct, based on the data collected for each individual claimant's exposure.

Blind Reviews

To further assure the accuracy of claimants' dose reconstructions and hence POCs, the Board adopted a policy in 2012 of soliciting blind reviews in a limited number cases – that is, tasking the NIOSH/ORAU and SC&A teams independently to conduct and compare dose reconstructions and POCs for these selected cases and have them reviewed by the Dose Reconstruction Reviews Subcommittee. While this process is resource-intensive it is the best, most appropriate way to check the consistency and precision of the program's dose reconstruction assessments and their derived PoCs. During the past two years, the program has solicited six blind review cases per year, and plans to do so again in 2016. So far fourteen cases have been reviewed using this process, and 13 are in agreement with respect to their compensation decisions, **while the resolution of one case (#3) remains under discussion by the DRSC [and will be resolved at the Feb 10 DRSC meeting. discussion.** (Table 4) This is quite good agreement given the selection of cases which needed best-estimate assessments (typically resulting in PoCs in the 45-52 percent range), the complexities of these dose reconstruction

Table 4. Blind Case Reviews

Blind Case No. (Facility)	POC by SC&A	POC by NIOSH/ORAU
A. First contract period		
1. Portsmouth Gas Diffusion	49.35%	48.75%
2. X-10	48.00%	43.63%
B. Set 17 Blinds		
3. Allied Chemical	85.40%	45.90%
4. Fernald	38.12%	48.27%
5. Hanford	43.18%	45.27%
6. Rocky Flats	42.65%	47.51%
7. Savannah River	51.00%	51.39%
8. Y-12 and X-10	50.47%	50.46%
C. Set 20 Blinds		
9. Nevada Test Site	40.59%	41.17%
10. Hanford/Weldon Springs Plant	40.71%	42.49%
11. Hanford/Pacific NW Natl. Lab.	36.43%	42.31%
12. Rocky Flats	43.78%	42.91%
13. Brookhaven Natl. Lab.	51.05%	52.54%
14. Y-12	49.48%	49.46%

calculations and the absence of extensive internal and external dose measurements for many individuals.

For the 14 cases in Table 4 the median of the absolute value of the difference between POCs = $|\text{POC}(\text{SC\&A}) - \text{POC}(\text{NIOSH/ORAU})| = 1.6\%$. The average value of these absolute differences = 5.2%. Even excluding the one outlier case (#3) the median is essentially unchanged at 1.8% as expected and the average value is halved to 2.5%. While these figures give pause for cases in which PoCs are near 50%, it should be noted that these case were chosen from among those which needed best-estimate DRs, that is with PoCs expected to be in the 45-52% dose range – and 10 of these 14 were -- and that in all cases but one both blind assessments were either above or below the 50% and hence agreed on compensability. (NOTE: To be modified after completed dose reconstructions for the remaining case (in red) by SC&A.)

Distribution of Dose Reconstruction Reviews by Years of Employment

Figure 4 (Copy Figure 8 from revised Summary Statistics, Rose Gogliatti, SC&A, January 7, 2016.) shows the distribution of dose reconstructions by years of employment. As noted two-thirds (67%) of those for whom doses were reconstructed and reviewed by the DRSC worked in EEOICPA-covered facilities for 20 years or more, 13% for 10 to 20 years and 20% for less than 10 years (median 30.9 years).

The present results (Cases 101-334) reflect a slight average increase in years of employment compared to those reported in the first Secretary's Report at 53% for 20 years or more, 21% for 10 to 20 years and 26% for less than 10 years, respectively (median 21.2 years). This is not surprising since the current report has been developed six years after the first, allowing more years of employment by claimants before developing cancers and/or applying for claims. Also in the ensuing years since the first Secretary's Report the trends 5-year relative survival rates of cancer victims has continued to rise, allowing claimants more years of employment before they file their claims if they so choose. Consistent with these observations the estimated median values of these two sets of dose reconstruction data developed through 2009 and 2015 differ by about 10 years – 21.2 years versus 30.9 years.

Distribution of Cases Reviewed by Risk Model

Figure 5 (Copy Figure 9 from revised Summary Statistics, Rose Gogliatti, SC&A, January 7, 2016.) presents the breakdown by type for 28 cancers in Cases 101-334. The types with the largest numbers of cases evaluated are Non-melanoma Skin (BCC and SCC) (63 cases), All Male Genitalia (47 cases), Lung (45 cases), and Urinary Tract (36 cases), of which half are cancers of the bladder and the other half urinary tract excluding the bladder. These results are similar in distribution to those reviewed for Cases 1-100.

Distribution of Cases Reviewed by Decade First Employed

Figure 6 (Copy Figure 6 from revised Summary Statistics, Rose Gogliatti, SC&A, January 7, 2016.) presents the distribution of Cases 101-334 by decade first employed. Fully 72 percent of the cases reviewed were first employed before 1960: 49 percent were from the 1950s, 21 percent from the 1940s and even 2% from the 1930s. As expected given the decades-long latency periods of most cancers, these percentages decline in more recent decades from 18% in the 1960s to 6% in the 1970s and 4% in the 1980s. None were reviewed in this cohort from the 1990s or later. Comparing these results with those from the 2009 Secretary's Report, there is now a large increase in the percentage of claims reviewed from before 1960 (72%) compared to 51% in the earlier report. This appears to reflect both the increases in cancer incidence rates with age and years of exposures and in filing of claims as the 1940s/1950s cohort reached retirement ages.