Advisory Board on Radiation and Worker Health

Findings for Dose Reconstruction Cases Sets 6-13 (Cases No. 101-334) and Comparisons to the First 100 Dose Reconstruction Cases

(Report prepared by the Subcommittee on Dose Reconstruction Reviews)
November 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.

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.

Cases Sent to NIOSH for Reconstruction

DOL reports 42,714 cases returned to DOL by November 1, 2015 with 2,075 currently at NIOSH, for a total of 44,789 cases sent to NIOSH. Get up-to-date data on the different types of dose reconstructions used for these cases, as well as SEC determinations.

Number and Types of Dose Reconstruction Cases Reviewed

Of the 234 dose reconstruction cases reviewed for this report (Cases No. 101-334) 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 1)

Table 1. 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%)

This reflects the maturation in the process of dose reconstructions during the past six years since our first Report to the Secretary. During the initial review period (2001-2009), with a limited number of site exposure profiles completed and various analytical issues related to individual dose assessments still outstanding, dose reconstructions focused on those cases that seemed relatively easy to assess due either to apparent over- or under-exposure. Thus over- and under-estimation techniques (based on maximizing and minimizing dose estimates, respectively) were overwhelmingly applied to these first 100 cases.

Since 2009 with further site profile development and resolution of various assessment issues by the Board's 37 site-specific work groups and its Procedures Review Subcommittee, 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 more precise best-estimate reviews of more than four-fifths of the next 232 completed dose reconstructions.

Case Findings

In examining the 234 cases from Sets 6-13, the Dose Reconstruction Reviews Subcommittee reviewed a total of 670 findings (approximately 3 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, that is they had only a marginal impact on the dose assessment; 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.]

The finding resolution process can be complex and nuanced. Generally, a finding is found to have a low impact if it involved a minor QA concern, a minor clarification, or involved a change (increase or decrease) in dose 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.

The above results of about 3 deficiencies per case are less than the 4 per case reported in the First Secretary's Report in 2009, where 398 deficiencies were found for the first 100 cases audited. Again the lower rate of deficiencies in this Report reflects the growing maturity of this program as many of the initial issues with dose reconstruction have since been resolved. The distribution

of impacts in the 2009 report (86%L, 12%M and 3%H, respectively) are quite similar to those above in this report.

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 also began in Set 6 (?) to assess and categorize findings by type of issue or issues involved in these deficiencies, including improper location of employee at the worksite, incorrect radiation exposure types, errors in internal and/or external exposure scenarios and quality concerns. In some cases, there were multiple categories of deficiency. The distribution of categories for Cases 101 to 334 is given in Table 2.

Case Observations

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; thus none of these 206 observations named above resulted in a change of dose assessment.

Table 2. 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.

Number of Dose Reconstruction Cases Reviewed

The Dose Reconstruction Reviews Subcommittee has reviewed 334 cases since its inception of the 44,202 claims filed as of October 2015. Thus the Subcommittee has completed reviews of 0.76% of all claims filed as of this date, slightly less than its current goal of 1% of all claims reviewed. 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 having 93% of reviews that were over- and under-estimates. But since 2009 the DRSC has increased the percentage of best-estimate reviews from 7% to 82% (Table 1). Since best-estimate reviews are more precise but more time-consuming, the review process has necessarily slowed down and our goal for claims reviewed has been reduced to 1%. The Board and the DRSC fully expects to reach this goal during the next operational period.

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 Summary Statistics, Rose Gogliatti, SC&A, September 16, 2015) 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 Summary Statistics, Rose Gogliatti, SC&A, September 16, 2015) 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 Summary Statistics, Rose Gogliatti, SC&A, September 16, 2015. NOTE: Drop selection goals from second line of chart.) shows the distribution of Probabilities of Causation (POC) among cases reviewed in Sets 6-13 (Cases 101-334). Cases with POC between 45-50% 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 an increased number of best-estimate cases reviewed in the post-2009 period and a 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 mis-compensation 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 complete and compare dose reconstructions and POCs for these cases and have them reviewed by the Dose Reconstruction Subcommittee. While this process is resource-intensive it is the best, most appropriate way to assure that the SC&A and DRSC reviews of the original NIOSH/ORAU dose determination are not inadvertently influenced by that determination. So far fourteen cases have been reviewed using thus process, and all are in agreement, that is in all cases the compensation decisions based on the NIOSH and SC&A POCs are the same. (Table 3)

Table 3. Blind Case Reviews

Blind Case No. (Facility)	POC by SC&A	POC by NIOSH/ORAU
A. First contract period		
016075 (Portsmouth GD)	49.35%	48.75%
016735 (X-10)	66.15%	43.63%
B. Set 17 Blinds		
037069 (Allied Chemical)	85.40%	45.90%
029613 (Fernald	38.12%	48.27%
035096 (Hanford)	43.18%	45.27%
037053 (Rocky Flats)	56.71%	47.51%
037013 (Savannah River)	51.00%	51.39%
031828 (Y-12, X-10)	50.47%	50.46%

C. Set 20 Blinds		
009125 (Nevada Test Site)	40.59%	41.17%
028943 (Hanford/WSP)	40.71%	42.49%
036747 (Hanford/PNNL)	36.43%	42.31%
038531 (Rocky Flats)	43.78%	42.91%
039235 (Brookhaven Natl. Lab.)	51.05%	52.54%
040180 (Y-12)	49.48%	49.46%

Of particular interest are those blind review cases where the one of the POCs, either the SC&A or the NIOSH/ORAU or both, are between 45 and 55. For the seven cases in Table 3 for which this is the case, the median difference between POCs = |POC(SC&A) – POC(NIOSH/ORAU)| = 0.39% and the average difference = 2.1%. This is quite good agreement given the complexity of the dose reconstruction calculation and the frequent absence of internal and external dose measurements for many individuals. (NOTE: To be modified after completed dose reconstructions for 3 cases (in red) by SC&A. This awaits resolution of a few items between NIOSH and SC&A.)

Distribution of Dose Reconstructions by Years of Employment

Figure 4 (Copy Figure 8 from Summary Statistics, Rose Gogliatti, SC&A, September 16, 2015. NOTE: Drop selection goals from second line of chart.) 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). These results are consistent with the observation that many common types of cancers caused by chemical and physical exposures take about 20 years to develop after first exposure.

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 they develop cancers and apply 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. (Good data from American Cancer Society- Facts and Figures 2015, Need a better source for Secty., e.g. SEER data) 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 by Risk Model

Figure 5 (Copy Figure 9 from Summary Statistics, Rose Gogliatti, SC&A, September 16, 2015.) 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 18 cases are Urinary excluding bladder and 18 cases Bladder. These results are similar in distribution to those reviewed for Cases 1-100. (NOTE: Figure 10 from Summary Statistics seems to me similar, but too messy.)

Distribution of Cases by Decade First Employed

Figure 6 (Copy Figure 6 from Summary Statistics, Rose Gogliatti, SC&A, September 16, 2015. NOTE: Drop selection goals from second line of chart.) presents the distribution of Cases 101-334 by decade first employed. As expected almost half the cases reviewed (49%) were from the 1950s. In addition 21% were from the 1940s and even 2% were from the 1930s. These percentages decline also as expected in more recent decades, from 18% in the 1960s to 6% in the 1970s and then to 4% in the 1980s. None were reviewed in this cohort from the 1990s or later, reflecting the very few claims from these employment periods (Check. Were there any from the 1990s?) and the longer latency periods for most cancers. Comparing these results with those from the first Secretary's Report, there is now an increase in the percentage of claims reviewed from the 1940s and 1950s to 70% compared to 49% in the earlier report. This appears to reflect both the increases in cancers with age and years of exposures and in filings of claims as the 1940s/1950s cohort reached retirement ages. (Weak. Any suggestions of stronger arguments?)