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### ADVISORY BOARD ON RADIATION AND WORKER HEALTH

1150 Tusculum Ave Cincinnati, Ohio 45226 (513) 533-6825

January 8, 2020

The Honorable Alex M. Azar II Secretary Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Mr. Secretary:

Enclosed for your information is a report prepared for you by the Advisory Board on Radiation and Worker Health (the Board). The Board conducts independent reviews of selected radiation dose reconstructions completed by the National Institute for Occupational Safety and Health (NIOSH) in accordance with the requirements of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000. The purpose of the Board's review process, as mandated by the EEOICPA, is to advise you on the "scientific validity and quality of radiation dose estimation and reconstruction efforts being performed for purposes of the compensation program."

This report was prepared by the Board's Subcommittee for Dose Reconstruction Reviews, with input from the full Board. It was approved by the full Board on December 11, 2019. This report covers the Board's review of 166 individual dose reconstructions conducted since the Board's last Reports to the Secretary in 2009 and 2016. The three reviews represent over one percent of the total number of radiation dose reconstructions performed by NIOSH since the start of its program in 2002.

These reviews are generally representative of the overall worker population and work locations covered by the EEOICPA program. The reviews were prioritized to focus on radiation dose reconstructions that involved more comprehensive dose reconstruction procedures, and on those dose reconstructions for which errors in dose reconstruction could have a greater impact on claimant compensation decisions.

The Board's review of the 166 dose reconstructions identified 243 findings, approximately half the rate of findings since the 2016 report, representing a marked improvement which has now been a continuing trend over these reviews. The current report also summarizes 32 "blind" case reviews in which the Board oversaw independently conducted dose reconstructions which it compared to the final dose reconstructions conducted by NIOSH. The comparison allows the Board to ascertain whether independently performed dose reconstructions would produce similar results for claimants and to further examine the scientific quality and validity of the methods being applied. The findings from these comparisons further verify that NIOSH dose reconstructions are being performed consistently with appropriate quality and validity.

Our review of these 166 dose reconstructions, as well as the 32 blind case reviews and our ongoing review of the NIOSH procedures used for dose reconstruction, provide the Board with a high level of confidence that the radiation dose reconstruction process is scientifically sound.

Finally, the Board has made several recommendations to continue and improve its review process.

We hope that you will find this information useful and informative.

Sincerely,

[Signature on File]

David Kotelchuck. Ph.D., MPH.
Chair, Subcommittee on Dose Reconstruction Reviews on behalf of the
Advisory Board on Radiation and Worker Health

Enclosure

Report to the Secretary, HHS, on Dose Reconstruction Case Reviews Completed by the Advisory Board on Radiation and Worker Health

Findings for 166 Dose Reconstruction Cases Reviewed (Sets 14-21) and Comparisons to Dose Reconstruction Cases Previously Reviewed December 11,2019

# Dedicated to the memory of James Malcolm Melius, M.D., Dr.PH.

Member (2001-2018) and Chair (2009-2018), Advisory Board on Radiation and Worker Health

# Chair, Steering Committee, World Trade Center Medical Monitoring and Treatment Program (2011-2018)

"For us on the Advisory Board on Radiation and Worker Health, Jim Melius was a consummate bridge builder between all three perspectives represented on this Board: scientific, medical and worker.

"In this pursuit, he was patient, humorous, attentive and insightful in doing his part to bring us as closely into consensus as possible for a given decision. Throughout our activities, he was caring of his fellow Board Members, of the program and the Board staff as well as the claimants, their families and advocates."

-- Dr. Paul Ziemer on behalf of the Advisory Board on Radiation and Worker Health, April 11, 2018

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#### **INTRODUCTION**

Under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), the Advisory Board on Radiation and Worker Health (the Board) is required to "verify a reasonable sample of the doses" calculated by the National Institute for Occupational Safety and Health (NIOSH) through its radiation dose reconstructions for claimants with cancer who apply for compensation. In the early years of the program, the Board established methods and procedures for conducting these verifications. The Board also established the Subcommittee for Dose Reconstruction Reviews (the Subcommittee) to select cases for review and oversee the reviews, which were conducted with the assistance of its technical support contractor, SC&A Inc. It set as a goal the review of one percent of all dose reconstruction cases.

In July 2009, the Board reported to the Secretary of the Department of Health and Human Services (the Secretary) its findings from the first 100 individual dose reconstruction cases it reviewed (Case Review Sets 1-5). Then in December 2016, the Board submitted a second report to the Secretary that covers its review of an additional 232 individual cases (Sets 6-13) and 14 blind case reviews. The current third report (2019) covers the review of an additional 166 individual cases (Sets 14 - 21), as well as an additional 18 blind case reviews. In sum, the Board has reviewed a total of 498 dose reconstruction cases and 32 blind reviews selected from the total of 48,089 dose reconstructions completed by NIOSH as of September 9, 2014 (Sets 1-21). This report provides background information on the methods used to select cases for review, the review procedures and methodologies, the findings of this review, and the Board's conclusions and recommendations.

#### **OVERVIEW OF REVIEW PROCEDURES**

The Subcommittee selects the dose reconstruction (DR) cases to be reviewed in consultation with the Board. The cases eligible for review include only claims that have been fully adjudicated by the Department of Labor (DOL). The cases for review are selected based on several criteria that have been modified over time to obtain better representation of covered facilities, employment periods, occupations and cancer diagnoses. The dose estimates of cases selected for review are most frequently close to the compensable level, with probabilities of causation in the range from 45 to 52 percent. The reviewed cases and their selection are described in more detail below.

The selected cases are referred to SC&A, which provides technical and scientific expertise to assist the Board in conducting its work. SC&A reviews the case files and then repeats the dose reconstruction procedures used by NIOSH for that case in an attempt to verify the NIOSH findings. SC&A then prepares a report on its findings and observations for each case, covering any concerns SC&A might have about how the DR was conducted. In turn this report is reviewed by NIOSH, allowing it an opportunity to respond to the findings and observations in the report. The Subcommittee then conducts a systematic review of the SC&A report and NIOSH comments, following a standard template and evaluation process that addresses concerns raised by both groups. The Subcommittee also considers the severity of the findings for each case (i.e., the potential impact of the findings on a claim's compensability). If during the review of cases, the Subcommittee identifies potential problems with the specific procedures or documents used in the DR, it may then refer these problems to Board work groups or other subcommittees for further evaluation. If it identifies potential problems with the review methods employed by SC&A or its findings and observations, it may amend them accordingly.

Preliminary to submission of SC&A's report to the Subcommittee each case is first presented to two Board members for initial review and discussion. Thus all Board members participate in this phase of the review process, with each assigned to review a limited number of cases. SC&A's report on each case may be modified in light of the Board members' reviews and sent to the Subcommittee for resolution, as indicated in the above paragraph. This process, preliminary to

the Subcommittee review, allows each Board member to become better aware of and involved in the review process, whether or not she/he is a member of the Subcommittee.

For a small proportion of the reviewed cases, SC&A is tasked by the Board to independently review the case as presented to NIOSH and to independently conduct the dose reconstruction and calculate the dose estimates, rather than just examining and assessing the procedures and decisions made by NIOSH. These are referred to in the report as "blind case reviews." SC&A prepares a written report on each blind case and shares it with NIOSH before submission for review and finalization by the Subcommittee and the Board.

#### **FINDINGS**

#### Cases Sent to NIOSH for Dose Reconstruction

As of Sept. 9, 2014, NIOSH had completed 48,089 DRs (Sets 1-21), from which the Subcommittee selected cases for subsequent review. All of the 48,089 DRs were returned to DOL with their Probability of Causation (POC) calculation for claims adjudication. The cases returned to DOL for compensation decisions included some claims that underwent DOL's claim adjudication process before HHS decided to add a class of employees to the Special Exposure Cohort (SEC) that would include those claims. Claims that are eligible for compensation through the SEC process do not require a dose reconstruction from NIOSH unless the claim also includes cancers that are not one of the 22 SEC cancers.

#### **Efficiency Measures for Dose Reconstruction**

To provide a reasonable dose estimate for individual cases, NIOSH uses one of three approaches to complete the process: 1) a best estimate; 2) an overestimate efficiency measure; or 3) an underestimate efficiency measure. NIOSH's overestimating approach (i.e., over-estimate DR) is an efficient way to process claims that are evidently non-compensable based upon cumulative program experience. The underestimation approach (i.e., under-estimate DR) is similarly a time-saving approach used for claims that are evidently compensable, without needing to take into account the entire work history of the employee whose dose is being reconstructed. Once the evidence of compensability is established during dose reconstruction, the dose reconstruction

work is curtailed because a more precise estimate of dose and resulting POC is not necessary. The best estimate approach (i.e., best-estimate DR) is used for cases that are not clearly compensable or non-compensable upon initial examination and gives the most precise estimate of dose and POC to support DOL's claim adjudication.

#### **Dose Reconstruction Cases**

As of September 9, 2014, NIOSH had completed 48,089 DRs covering review Sets 1-21. The distribution of DRs based on the use of efficiency measures and partial DRs is as follows (Table 1):

Table 1. Types of Dose Reconstruction for the First 48,089 DRs\*

Best estimate	Overestimate	Underestimate	Partial**	Total***
1,881 (3.9%)	33,682 (70.1%)	8,918 (18.6%)	3,608 (7.5%)	48,089 (100.1%)

<sup>\*</sup> DRs for Sets 14-21 completed by NIOSH on September 9, 2014. Reviews of these DRs by Subcommittee were completed on August 16, 2018.

As indicated above a majority of the claims submitted (70.1 percent) were overestimated DRs, the second largest portion were underestimated DRs (18.6 percent), and only 3.9 percent of cases were reconstructed based on the more precise but also more elaborate and time-consuming best-estimate methods of DR.

Partial dose reconstructions are conducted for claims from facilities and time periods that have SEC class designations but the claim is not eligible for coverage under the requirements of the SEC; these comprised the remaining 7.5 percent in Table 1. For these claims, NIOSH will estimate the limited set of radiation doses that remain feasible to estimate, enabling DOL to make a compensation decision based on those radiation doses.

The results in Table 1 are similar to those presented in the Board's 2016 Report, except for the best-estimate DRs, which appear to have decreased from 7.8% in the 2016 Report to 3.9% here. However, this decrease is an artifact of a change by NIOSH in determining which cases are

<sup>\*\*</sup> Partial dose reconstructions are conducted for claims involving facilities and work periods that have SEC class designations, but for which claimants are not eligible for inclusion.

<sup>\*\*\*</sup>Percentage exceeds 100% due to round-off errors.

designated as best estimates. An examination by NIOSH of all cases determined to be best estimates since the program's inception indicates that in the early years of NIOSH's dose reconstruction program many cases were completed using the best-estimate approach for administrative reasons that were independent of an assessment of the claim's compensability; whereas for at least the past seven years the best-estimate approach was reserved for selected cases with probability of causation (POC) between 45 and 52 percent. Using the latter criterion NIOSH has found that the percentage of best-estimate cases with POCs between 45 and 52 percent since the program's inception is 3.9 percent, as reported in Table 1 above, rather than the greater (and inflated) value of 7.8 percent reported in 2016.

#### **Dose Reconstruction Cases Reviewed**

Of the DR cases reviewed for this report, the Subcommittee, under the direction of the Board with technical assistance from SC&A, and NIOSH, with its contractor, Oak Ridge Associated Universities (ORAU), has been able to undertake more reviews of best-estimate DRs. Although best-estimate DRs are relatively infrequent among all DRs completed under the program (Table 1), they are particularly important in that assumptions in the best-estimate DRs have greater impact on compensation decisions than assumptions involved in efficiency measures. Also best-estimate DRs require much more extensive calculations and involve professional judgment to a greater extent than for over- and under-estimated DRs. Hence reviews of best-estimate cases test more of the critical elements of the DR process with respect to supporting the accuracy of DOL's compensation decisions.

Cases for review in this report were selected significantly, but not solely, from among bestestimate DR cases already adjudicated by DOL. The criteria used in selecting these cases were POCs between 45 and 52 percent and with appropriate representation of Department of Energy and Atomic Weapons Employer facilities (i.e., covered facilities), claimant occupations, career duration, chronological decades worked, and cancer diagnoses. More recently, gender has also been included as a selection criterion.

In the 2016 Report, the 232 cases examined reflected the Board's desire to focus intensively on reviews of best-estimate cases because of the sensitivity of their compensation decisions to the

parameters in the DR calculations. Thus, in the 2016 Report, 83 percent of the 232 cases were best estimates. Remarkably only one of the cases of dose reconstruction undertaken by NIOSH until then (2016) had been found, upon Subcommittee and Board review, to need to have its initial compensation decision changed. This resulted in a rate of compensation change of 0.3 percent among all cases reviewed since EEOICPA's inception. Furthermore the need for this change was triggered not by any error of analysis or interpretation, but by new information gathered between the time the dose reconstruction was completed by NIOSH and the time of its review by the Subcommittee and Board.

Of the 166 cases reported here for Sets 14-21 (Table 2), 140 (84%) were best estimates, 26 (16%) were overestimates and none were underestimates. The percentage of cases reviewed that were best estimates reported here is consistent with the 83% reviewed in the 2016 Report. These best estimate cases were highly oversampled from among the 48,000 DRs conducted by NIOSH since the program's inception (Table 1), reflecting the priority given by the Board to reviewing best-estimate cases, since this tests more of the critical elements of the DR process than does the Board's review of over- or under-estimated dose reconstructions. Overall, as reflected in the bottom line of Table 2, of all 498 cases reviewed by the Board during the life of this program, two-thirds (68%) were best-estimate cases, about one quarter (27%) over-estimates, and 5 percent underestimates.

Table 2. Changes Over Time in Board Utilization of Dose-Reconstruction Efficiency Measures

Cases Reviewed (Yr. of Report to Secretary)	Best Estimate	Over- Estimate	Under- Estimate
First 100 cases (2009)	7 (7%)	76 (76%)	17 (17%)
Next 232 cases (2016)	193 (83%)	32 (14%)	7 (3%)
Next 166 cases (2019)*	140 (84%)	26 (16%)	0 (0%)
Total Cases reviewed: 498	340 (68%)	134 (27%)	24 (5%)

<sup>\*</sup>Reviews of these DRs completed August 16, 2018.

#### **Findings among Reviewed Cases**

Findings among reviewed cases are discussed first by the respective staffs of NIOSH and SC&A and then by the Subcommittee. Upon examining the 166 cases from Sets 14-21, the Subcommittee reviewed a total of 243 findings (Table 3), an average of 1.46 findings per case. This is about half (54 percent) the level of 2.70 per case reported in 2016.

Since the 2016 Report, the Subcommittee has continued to assess and categorize findings by type of issue resulting in the finding. These are presented for the 166 cases in Table 3. The largest single category, which accounts for 30 percent of the 243 findings, is incorrect use of external dose models and related assumptions, followed by 12 percent in the category of incorrect internal dose models and related assumptions. Both of these percentages were smaller than the corresponding rates reported in the 2016 Report (40 percent and 21 percent, respectively). These decreases result from overall improvement in the dose reconstruction program.

Against the background of an overall decrease in the rate of findings, some categories of findings did increase proportionately: For example, quality concerns, related to dose reconstructors not properly carrying out mandated programmatic procedures, rose to 23% of the total number of issues compared to 15% in the 2016 Report. However in terms of absolute numbers, 55 instances of quality concerns were observed here among 166 review cases here (55/166 = 33%) compared to 95 instances among 232 review cases (95/232 = 41%) in the 2016 Report – so the *rate* of quality concern findings among reviewed cases has *fallen* from 41% to 33% since the 2016 Report.

Finally the large percentage of findings (30%) that did not fit into any of the specific issue categories in Table 3 suggests a need to re-examine the reviews for this 30% of cases to determine if another category of issue or issues should be added to such a Table in the future. The Subcommittee will undertake this with assistance from NIOSH and SC&A.

Among the total 498 cases reviewed by the Subcommittee, 50 cases (10 percent) were filed either by female energy workers or survivors of female energy workers. This percentage is less than the 13.4 percent of claims involving a female energy worker among the 48,089 total claims. Among the current sets of cases being reviewed (Sets 14-21) and going forward, the

Subcommittee has paid greater attention in its selection of cases to improved representation among covered facilities and a wider range of other characteristics, including gender. Thus there is good reason to expect that the percentage of female claimants' cases reviewed will increase as this program continues.

Table 3. Findings by Type of Issue for Sets 14-21\*

Type of Issue	No. Of Findings** (Percent)
Was the proper judgment made regarding placing a person physically at a work location?	1 (0.4%)
Were all exposure scenarios considered (i.e., neutron, thorium)?	14 (6%)
Were the correct external dose model and assumptions used?	72 (30%)
Were the correct internal dose model and assumptions used?	28 (12%)
Was there a quality concern?	55 (23%)
Issues not covered by any of the above categories	73 (30%)
Total	243 (101%)***

<sup>\*</sup>NOTE: Some cases had more than one type of issue.

As a result of discussion and review of these 166 cases, none of the compensability outcomes for Sets 14-21 was changed. Thus of the grand total of 498 cases reviewed by the DRRSC since the program's inception, only one had its compensation decision changed, resulting in a decrease of the changed decision rate from 0.3% to 0.2% of reviewed cases.

Note that whenever an issue is identified to potentially have an impact on other similarly-situated DR cases, NIOSH will conduct a system-wide review of such cases. Based on its evaluation, NIOSH may issue revised DRs as needed and coordinate with DOL in the event that the revised DRs might impact the claims' compensability. Indeed, NIOSH utilizes the same process of reconsidering and revising DRs upon its own review and improvement of DR data and methods, independent of the Board's and the Subcommittee's reviews.

<sup>\*\*</sup> Unresolved findings were assigned their preliminary classification

<sup>\*\*\*</sup> Percentage exceeds 100% due to round-off errors.

#### **Rate of Dose Reconstruction Cases Reviewed**

In 2016, the Board established the goal of reviewing one percent of all DRs. As of August 16, 2018, the Board had reviewed a total of 498 DRs of the 48,089 DRs which NIOSH had processed and completed for Sets 1-21 since the program's inception. Thus, the Board has completed reviews of 1.04 percent (=498/48,089) of all claims requiring dose reconstruction as of this Report, thus continuing to achieve its current goal of reviewing one percent of all DRs completed. This result is consistent with the 1.05 percent reported in 2016.

#### **Blind Case Reviews**

To further assure the scientific validity and quality of DRs performed, the Board conducts independent blind case reviews in a limited number cases by tasking SC&A independently to conduct DRs for cases already completed by NIOSH. The Board's goal is to further and more meticulously examine a subset of NIOSH dose reconstructions to identify possible DR deficiencies. The Subcommittee compares SC&A's and NIOSH's results to assure that dose reconstruction cases were properly evaluated by NIOSH and that professional decisions made by NIOSH were grounded in the best available science and information at the time. While this blinds case review process is resource-intensive, it provides an additional avenue to evaluate how consistently two independent dose reconstructors can interpret the same data and move through the various decision points that might result in variations in the DRs which could potentially impact the claim's compensability.

Some variability in the paired POC values for each blinds case is expected, particularly due to professional judgments, which must be made in light of inadequacies in the exposure data and/or in interpreting such data. However if the instruction given to the dose reconstructors and the procedures mandated are appropriate, then the vast majority of blinds cases should result in identical paired compensability outcomes. To more sensitively test the reliability of these paired comparisons, most of these blinds cases were selected from among NIOSH best-estimate review cases.

As shown in Table 4 below, a total of 32 cases have been reviewed using these procedures and for 31 (97%) the compensation decisions were identical. Fully 87 percent (= 27/32) of these cases were selected from best-estimate cases.

The one case for which the compensation decisions by NIOSH and SC&A did not agree (Case 3 in Table 4), was singular in that no exposure measurements were recorded, nor was there a site profile for this small site. The Subcommittee referred this case to the Surrogate Data Working Group for review. The Working Group accepted the NIOSH approach. Thus these 32 blind DR case reviews have not identified *any* deficiency in the NIOSH dose reconstruction procedures that have impacted the compensability outcome. [NOTE: NIOSH conducts all DRs under EEOICPA, whereas SC&A conducts only a very limited number of DRs for the Board as part of its review process. Thus as noted above the main goal of this blinds process is to seek out possible deficiencies in *NIOSH's* DR procedures – and so far none have been identified.]

**Table 4. Blind Case Reviews** 

Blind Case No. (Facility)	POC by SC&A	POC by NIOSH/DCAS
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 & Dye*	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%
D. Set 22 Blinds		
15. ANL-E	42.63%	46.19%

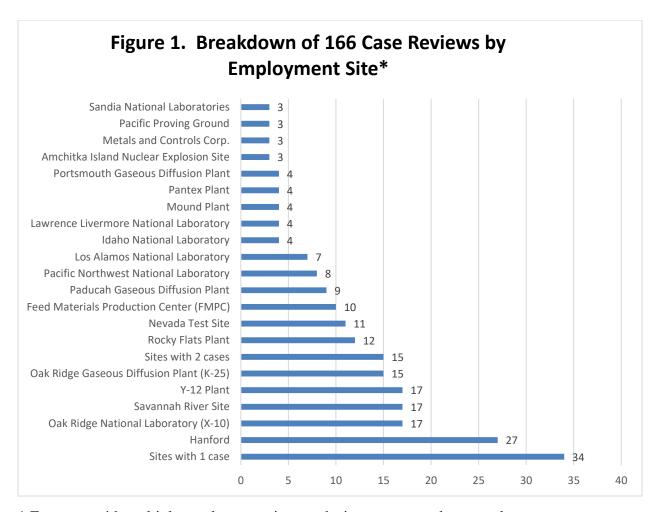
16. GJOO	47.92%	48.08%
17. LANL/NTS	42.43%	46.44%
18. Metals and Controls Corp	49.78%	46.60%
19. Rocky Flats Plant	50.19%	50.08%
20. SNL- ABQ	51.50%	50.57%
E. Set 23 Blinds		
21. Nevada Test Site	44.57%	46.10%
22 FMPC	40.47%	48.64%
23. Hanford/PNNL/IOP	49.19%	47.31%
24. LLNL	50.73%	50.83%
25. Rocky Flats Plant	45.69%	48.44%
26. Sandia National Laboratories	43.08%	44.33%
F. Set 24 Blinds		
27. Rocky Flats Plant	46.39%	47.19%
28. WR Grace	50.99%	51.56%
29. Mallinckrodt Chemical Co.	46.25%	45.40%
Destrehan St	40.2370	43.40%
30. FMPC	49.30%	47.90%
31. NTS/REECo	50.09%	51.61%
32. FMPC	45.89%	41.93%

<sup>\*</sup> The Subcommittee accepted the scientific approaches both by NIOSH and SC&A as reasonable ones. When the NIOSH review was referred to the Surrogate Data Working Group, it agreed with the approach used by NIOSH. [See NOTE above this Table.]

These results, agreement in compensation decisions in 31 of 32 blind cases, give the Board confidence that the instruction and procedures given to the program's dose reconstructors are reliable and result in consistency among the DRs evaluated by them.

#### **Distribution of Dose Reconstruction Cases among Covered Facilities**

The Subcommittee, under the Board's direction, has worked assiduously over the years to assure that cases selected for review represented an appropriate cross-section of covered facilities. The breakdown of covered facilities represented in Sets 14-21 is shown in Figure 1. As indicated, 34 sites had only one case reviewed and 15 had two. Those with three or more review cases are represented individually. The total number of sites in Figure 1 is 246 and thus the average number of sites per case is 1.48 (=246/166).

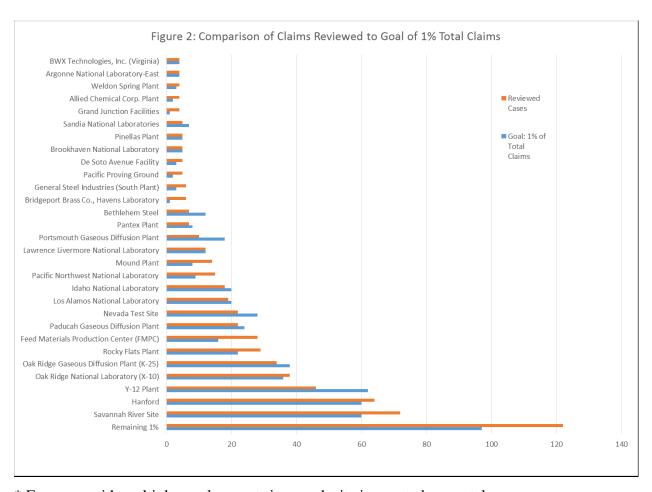


<sup>\*</sup> For cases with multiple employment sites, each site was counted separately.

In Figure 2, the blue bar next to each of the 29 individual sites displayed represents the number of cases needed to be reviewed in order to achieve one percent of all DRs reviewed for that site. These 29 sites are ones for which at least four cases reviews would be needed to achieve the one percent goal for that site. All other covered sites are combined into the "Remaining 1%" category [NOTE: The Board's goal is to review one percent of the total of DR claims, not one percent of all DR claims from any given facility. Some facilities may require greater attention due to the complexity of the DRs involved.]

The orange bar next to each named site displayed in Figure 2 is the sum of cases reviewed by the Subcommittee and Board from that site among the 498 total cases reviewed. The "Remaining 1%" category is the sum of cases from all sites with three or less cases reviewed. Thus if the

length of the orange bar exceeds that of the blue bar, then the case reviews undertaken by the Subcommittee and Board have exceeded one percent of the DRs for that site.

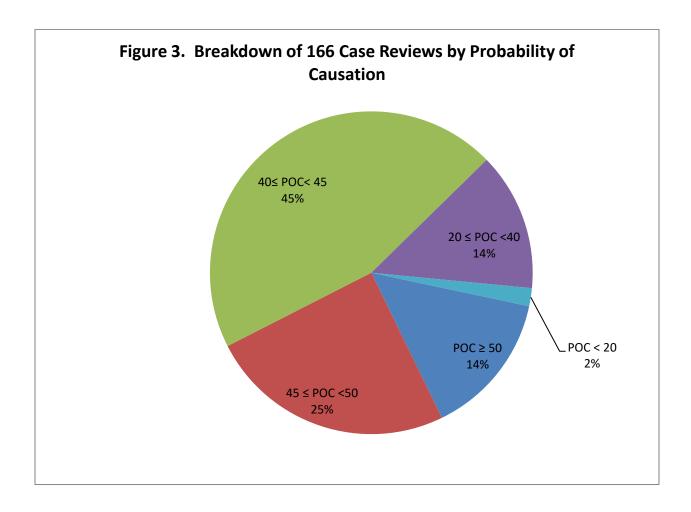


<sup>\*</sup> For cases with multiple employment sites, each site is counted separately.

As indicated in Figure 2, the Board has met or exceeded the goal of one percent of cases reviewed for 19 of the 29 sites, and has not met this measure for the other 10 named sites. For sites with zero to three reviewed cases (Figure 2, "Remaining 1%") the Subcommittee's review far exceeded the one percent goal – at 1.26 percent with 122 reviews completed when 97 would have been needed to achieve one-percent reviewed. This gives evidence that sites with small numbers of total claims were accorded appropriate attention during the review process.

#### Distribution of Probabilities of Causation among Cases Reviewed

Figure 3 shows the distribution of POCs among the 166 cases reviewed in Sets 14-21. Cases with POC between 45 and 52 percent have long been targeted for review.

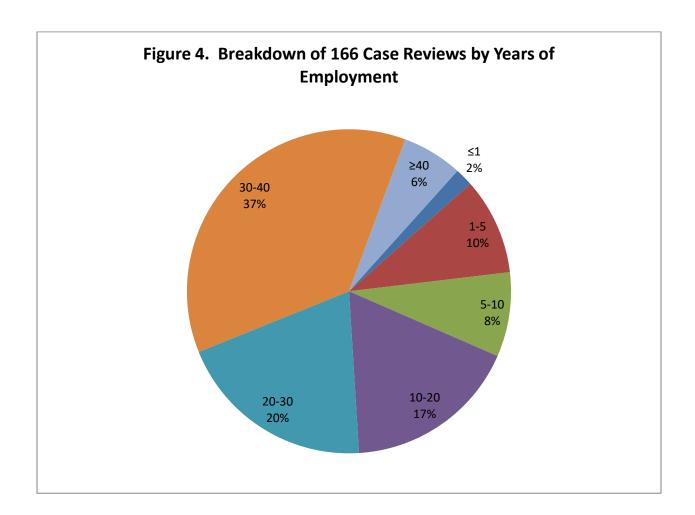


Since a pie chart reflects percentages of a particular population or group under scrutiny and all of these percentages add up to 100%, this means that if, as in this case, both POC segments at or above 45% have declined since last report (from 51 to 39 percent), then the sum of all segments below 45% must necessarily increase – and this is observed. However among the three segments observed below POC = 45% (i.e., POC 40 to <45, 20 to <40 and <20), only the segment 40 to <45 increased – and it did so dramatically at 45% in this report compared to 22% in the previous report (2016). Both of the other two segments below POC = 45% (POC 20 to <40 and <20) declined. This increase in percentage in only one of the three expected POC categories appears

simply to reflect a difference in the particular population of claimants in this report compared to that in the 2016 Report.

## **Distribution of Dose Reconstruction Reviews by Years of Employment**

Figure 4 shows the distribution of dose reconstructions by years of employment. Fully 63 percent of the 166 cases reviewed have employment at covered facilities for 20 years or more. This is slightly below the 67 percent reported in the Board's 2016 Report. For lesser employment periods, 17 percent of the cases have employment for 10 to 20 years and 20 percent for less than 10 years. The former figure is four percent larger than the corresponding one in the 2016 Report and the latter identical. The decreased percentage of claims with 20 years of employment or greater (four percent less) thus resulted in an equal and opposite percentage increase for those below 20 years (four percent more).



#### **Distribution of Cases Reviewed by Cancer Risk Model**

Figure 5 presents the breakdown of cases reviewed for 27 cancer risk models used with dose reconstructions. There were 287 risk models used among 166 cases, for an average of 1.73 risk models used per claim. The most frequently used risk models were: Non-melanoma Skin (111 cases, of which 59 were cases of basal cell carcinomas and 52 of squamous cell carcinomas), All Male Genitalia (52 cases) and Lung (22 cases). These cancer risk models among reviewed cases were also the most frequent among the cases reviewed in the 2016 Report. However the proportions of cases among these three differ: In this report, there are approximately twice as many cases of skin cancer as cancers of the male genitalia, whereas in the 2016 Report, skin cancer cases exceeded male genital cancers by 40 percent. Also in this report, male genital cases are more than double the number of lung cancer cases, whereas in the 2016 Report the numbers of these two types were nearly equal. The differences in the proportions of these risk-model types between the two samples of reviews may be a result of the Board's samples not being representative of the population of all cases and not being consistent from one sample to the next.

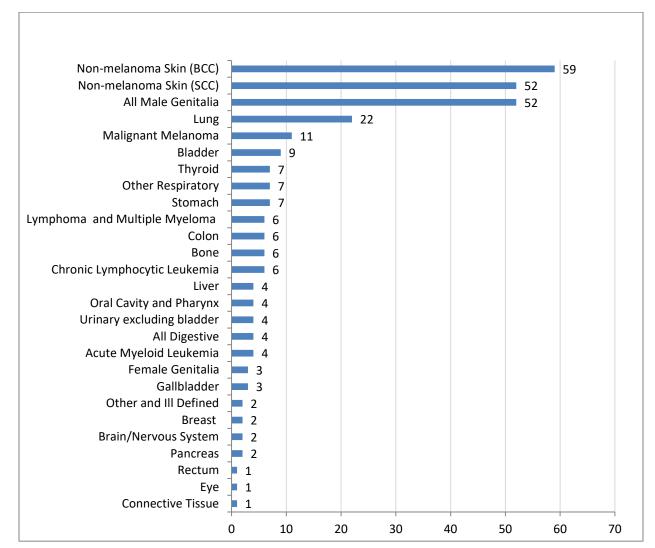


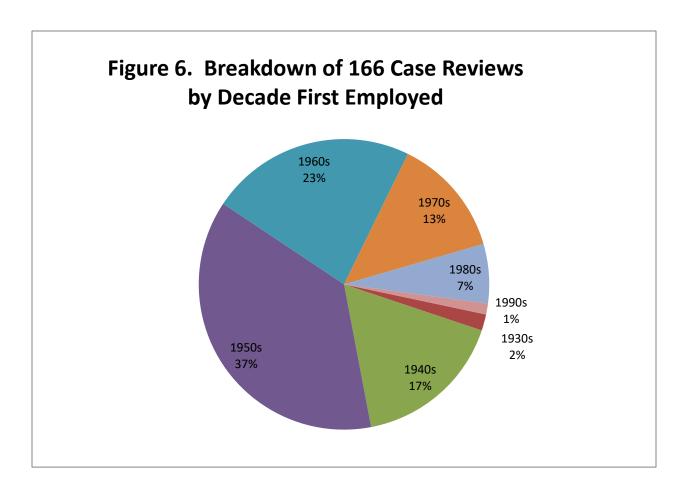
Figure 5. Breakdown of 166 Case Reviews by Types of Cancer Risk Model\*

\*For claims using multiple cancer risk models, each risk model was counted separately. [NOTE: Among skin cancers, BCC is an abbreviation for basal cell carcinomas and SCC for squamous cell carcinomas.]

#### **Distribution of Cases Reviewed by Decade First Employed**

Figure 6 presents the distribution of the 166 cases reviewed in this report by decade first employed. Over half (56 percent) of the cases reviewed involve energy workers who were first employed before 1960, down from 72 percent in the 2016 Report. Similarly, among these 166 cases the percentage of cases involving energy workers who first started working in covered facilities in the 1960s has increased to 37 percent from 18 percent in the 2016 Report. And in the 1970s and 1980s the percentages of claimants from these decades are up to 13 percent and 7

percent, respectively compared to 6 percent and 4 percent in 2016. There were no claimants who started work in the 1990s in the 2016 Report, whereas there is now 1 percent. Such trends may in part be the result of having established more SEC classes during the earlier decades and is likely to continue as the claimant population ages.



#### **Administrative Changes to Enhance Review Efficiency**

In the midst of its reviews of cases in Sets 14-18, the Board modified one aspect of its procedures in order to improve review efficiency – namely, NIOSH and SC&A were approved and encouraged to engage more actively in technical discussions to address concerns raised by SC&A upon examination of NIOSH case reviews. If such joint technical discussions successfully resolve these issues, then NIOSH and SC&A present these suggested case-review resolutions to the Subcommittee for review and approval -- these are called Type 1 review cases. These can be resolved relatively quickly, which saves the Subcommittee time and allows it to focus on the more complicated review cases (Type 2 issues), in which the differences cannot be

resolved during NIOSH and SC&A talks. In either circumstance, all review cases are discussed and finally resolved by the Subcommittee.

This modified procedure was then continued for all review cases in Sets 19-21, saving considerable Subcommittee time, and will be used in all further review sets. Data on the distribution of issues resolution since adoption of this procedure are presented in Table 5. As noted, two-thirds of the 278 findings and observations reviewed by the Subcommittee are of the more rapidly resolved Type 1 issues.

Table 5. Classification of Review-Case Issues\* Among a Subset of Cases within Sets 14-18 and All Cases within Sets 19-21\*\*.

Type of Issue	Nr. cases (Pct.)
Type 1 Issues	189 (68%)
Type 2 Issues	89 (32%)
Total	278 (100%)

<sup>\*</sup>Includes both findings and observations for reviewed cases. Since there may be more than one issue (finding and/or observation) for each case, the number of issues resolved exceeds the number of cases reviewed.

#### **Other Board Review Activities**

In interpreting the results of these individual case reviews, it is important to consider the review process in the context of other reviews conducted by the Board. The DRs are based on a large number of technical documents which provide a description and history of the activities at each covered facility and potential sources of radiation exposure over time for people working at that facility. In addition, a large number of other reference documents have been developed for use in the dose reconstruction process. These documents are continually revised to reflect newly available information. The Board has reviewed nearly all of these documents and its recommendations are implemented by NIOSH.

In addition, there have been many petitions to add classes of energy employees at specified facilities and during specific time periods to the Special Exposure Cohort (SEC). NIOSH first

<sup>\*\*</sup>Classification applied midway through issues resolution of Sets 14-18 and includes all issues among Sets 19-21.

evaluates these petitions to determine whether adequate information is available to estimate doses for all workers at that particular site and during the time periods specified. If NIOSH determines that it does not have sufficient information to estimate these with sufficient accuracy, then it recommends adding the class of evaluated workers to the SEC. The Board independently evaluates NIOSH's findings and transmits its recommendation to the Secretary on whether or not to add a class of workers. The Secretary then makes the final decision on this matter. Energy employees who are members of an SEC do not need to undergo the dose reconstruction process in order to receive monetary and medical benefits under Part B of EEOICPA for those 22 "specified cancers" covered by the SEC requirements.

These and other review activities by the Board have a direct effect on the Board's verification of dose reconstructions. Often while an individual case is being reviewed or after the review, a procedure or other technical document used in the dose reconstruction is revised in light of the newly available information or in response to a recommendation from the Board's Subcommittee on Procedure Reviews. The Board's review of an individual case may not reflect these changes. It relies only on the procedures and information in place at the time that the dose reconstruction was completed. However, on its own initiative NIOSH reviews and revises, if needed, individual DRs that may be impacted by a change in procedures or other technical documents used in the dose reconstruction and notifies DOL if the revised DRs may affect their compensability.

#### **CONCLUSIONS**

- 1. The Board has continued to reach its goal of reviewing one percent of all DR claims during this third report to the Secretary.
- 2. Since the 2016 Report, the Subcommittee has reviewed another 166 DR cases, which yielded a total of 243 findings (1.46 findings per case reviewed), a drop in findings rate of almost 50 percent from the 2016 Report. This review shows that none of the findings resulted in revisions to the completed DRs to the extent that they would subsequently change the compensation decisions made by DOL.

- 3. The Subcommittee continues to solicit blind-case reviews, in which dose reconstructors from SC&A independently conduct DRs on cases already completed by NIOSH and reports its results back to the Subcommittee for review. As of this report, 32 blinds cases have been reviewed. Findings from all these cases affirm that the DR procedures undertaken by NIOSH were properly and professionally carried out. This is a strong validation of the consistency of dose reconstructions performed under this program.
- 4. The above three conclusions along with the Board's ongoing reviews of the NIOSH dose reconstruction procedures provides the Board with a high level of confidence that the dose reconstruction process now in place is scientifically sound and consistent among various dose reconstructors. However, it should be noted that the methods and information used for dose reconstruction process are not static. As new information becomes available on the many sites covered by this program and procedures are further developed, the DR methods used in this program will also be improved to better reflect this new information and improved procedures.

#### **RECOMMENDATIONS**

Based on the findings of this report and the Board's further deliberations, the Board recommends the following:

- 1. The Board should continue to review at least one percent of the total DR cases.
- 2. The Board should continue to conduct blind-case reviews at the current rate.
- 3. The Board should modify the review process to make it more efficient and timely by focusing more effort on the critical parts of dose reconstruction evaluation. In particular, the Board should initiate a process to conduct reviews focused on evaluating the consistency and accuracy of dose reconstructions for cases where the dose reconstructors must make professional judgments about exposure data or other information used for conducting dose reconstructions. The Board will work with the

Subcommittee, NIOSH and the technical contractors to identify key targets and methodologies to implement these more focused reviews.