Advisory Board on Radiation and Worker Health

Findings for 232 Dose Reconstruction Review Cases (Sets 6-13) and Comparisons to the First 100 Dose Reconstruction Review Cases (Report prepared by the Subcommittee on Dose Reconstruction Reviews)

July 2016

INTRODUCTION

Under the Energy Employees Occupational Illness Compensation Program Act 0f 2000 (EEOICPA), the Advisory Board on Radiation and Worker Health (the Board) is required to "verify a reasonable sample of the doses" calculated by NIOSH through their 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 established a subcommittee to select cases for review and oversee the reviews which were conducted by our technical contractor. The Board initially established a target of reviewing 2.5% of the individual dose reconstructions conducted by NIOSH, but later modified this target to 1%. This reduced target was base was based on amount of effort required to reach the original target and the judgment of the Board that a 1% sample would be adequate.

The Board's last report to the Secretary of Health and Human Services (the Secretary) was issued in 2009 and covered the first 100 cases reviewed by the Board. The current report covers the review of an additional 234 individual cases. The following report encompasses some background information on the methods used to select cases for review; on the methods used for dose reconstruction; and the review methodology; the findings of this review; the Board's conclusions; and the Board's recommendations.

CASE SELECTION

The Board selects cases for review based on several criteria, and these criteria have been modified over time to obtain better representation of all facilities, work eras, occupations or type of work, and cancer type. For the cases reviewed in this report, selection was targeted to include the more comprehensive dose calculations (so-called best estimates) and estimates that were closer to the compensable level (calculated Probability of Compensation greater than or equal to fifty percent).. The reviewed cases are described in more detail below. The cases

eligible for review include only claims that have completed the full compensation administrative process at the Department of Labor.

REVIEW PROCEDURES

The Board's Dose Reconstruction Review Subcommittee selects the cases to be reviewed in consultation with the full Board. The cases are referred to the Board's technical contractor who then reviews the case files and repeats the dose reconstruction procedures utilized by NIOSH for that case and recalculates the NIOSH findings. For a small proportion of the reviewed cases, the Board follows a slightly different procedure in that the Board's contractor independently calculated the dose estimates (rather than just verifying the NIOSH calculations.) The contractor then prepares a report on their findings including any errors found in how the dose reconstruction was conducted. The report presents a systematic review of the findings following a standard template and evaluation process that also addresses the severity of the finding. Findings with the greatest potential impact on the dose reconstruction calculation are rated as being more serious. The contractor's report is first presented to two Board members for initial review and discussion. All Board members participate in this phase of the review process but only for a limited number of the cases being reviewed. The contractor's report on each case is modified in light of the Board members' review and sent to NIOSH for comments and/or clarification. Then the report on each case is presented to the Subcommittee for review and discussion. The Subcommittee resolves any differences between the contractor and NIOSH or the contractor and the Subcommittee regarding the review findings. The Subcommittee finalizes a report on the findings on each case review.

In addition to the specific case review findings, the review process may also reveal potential problems with the specific procedures or documents used in the dose reconstruction process. These may be referred to NIOSH or to other Board work groups or subcommittees for further evaluation.

FINDINGS

(Part A)

Cases Sent to NIOSH for Reconstruction

As of November 1, 2015 the Department of Labor (DOL), which administers EEOICPA, 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 for a compensation decision, 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 SEC classes. In claims for facilities with SEC classes for which the cancers declared are not among the 22 that are compensable under the SEC provisions of EEOICPA, a partial dose reconstruction is undertaken, enabling DOL to make compensation decision based on the fraction of radiation doses that remain feasible to reconstruct.]

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 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-	Partial
		Estimate	
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 were reconstructed based on the more precise but more time-consuming best-estimate method. Partial dose reconstructions comprised the remaining 6.4 percent.

Following the initial Report to the Secretary in 2009, the Board directed DCAS to decrease the percentage of cases involving over-estimates (resulting in denial of compensation) through more frequent use of best estimates. However overestimates remain in frequent use in order to complete dose reconstructions on a timely basis within available resources.

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 (Sets 6-13), the Dose Reconstruction Reviews Subcommittee, with technical assistance from NIOSH/DCAS, its subcontractor ORAU (Oak Ridge Associated Universities) and the Board's contractor (SC&A, Inc.), 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 being advised to make 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 reviews of best estimates test the dose reconstruction process more effectively and intensively.

Cases for review were selected primarily from among best-estimate dose reconstruction cases, typically already adjudicated by DOL. The criteria used in selecting these cases were Probabilities of Causation (POCs) between 45 and 55 percent (more recently between 45 and 52 percent), appropriate representation of facilities (DOE and AWE), diversity of occupations among persons selected for review, work era decades, lengths of tenure and diversity of cancer types. More recently representation by gender has also been included for selection consideration.

Of the 232 recently reviewed cases, 193 (82%) were best estimates, 32 (14%) were overestimated and 7 (3%) were under-estimated. [Two cases originally assigned to Sets 6-13 were not reviewed because it was determined they qualified for a rework under a Program Evaluation Report (PER).] 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 Reviews

Nr. Of Cases Reviewed	Best	Over-	Under-
(Yr. of Report to Secretary)	Estimate	Estimate	Estimate
First 100 cases (2009)	7 (7%)	76 (76%)	17 (17%)
Next 232 cases (2016)	193 (83%)	32 (14%)	7 (3%)

The review of the first 100 cases comprised dose reconstructions that were largely processed as over- and under-estimates. This reflects the imperative at the time 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
 document research and visits by staff and Board members, and much of this work has
 been reviewed through the establishment of 37 different site-specific Board Work
 Groups, and
- Many more analytical procedures have been developed, documented, and automated
 where feasible, based on staff input and the activities of the Board's Procedures Review
 Subcommittee so that dose reconstruction decisions are now better regularized and more
 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, Inc., 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 232 cases from Sets 6-13, the Dose Reconstruction Reviews Subcommittee reviewed a total of 626 findings (an average of 2.70 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 626 findings, 513 (82%) were found to be of low impact on the compensation decision, 91 (15%) had a medium impact, and 22 (4%) had a high impact.

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 recommendation related to a Probability of Causation was noted to be changed in only one case (0.3% of cases reviewed by the DRSC Subcommittee). In this case the NIOSH dose reconstruction resulted in a positive compensation decision, whereas the determination of the Subcommittee would have denied compensation. The claimant-favorable assumptions made by NIOSH in response to the original claim were the best information available when the assessment was made and were used to give a timely answer to the claimant even though it was known that later information and calculations might show a reduction in POC.

As might be expected, the above result of 2.70 findings per case is 32 percent less than the 3.98 per case reported in 2009. However the distribution of impacts in this report (82%L, 15%M and 4%H) is quite similar to those from the 2009 report (86%L, 12%M and 3%H). While this result might at first appear anomalous, it may reflect the fact that the dominant over- and underestimations 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. 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 of 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 the 232 cases in Sets 6-13 are presented in Table 3.

Table 3. Findings by Type of Deficiency for Sets 6-13*

Category	Type of Deficiency	Nr. Of Findings
A	Was the proper judgment made regarding placing a	13 (2%)
	person physically at a work location?	

В	Were all exposure scenarios considered (i.e., neutron,	28 (4%)
	thorium)?	
С	Were the correct external dose model and assumptions	253 (40%)
	used?	
D	Were the correct internal dose model and assumptions	134 (21%)
	used?	
Е	Is it a quality concern?	95 (15%)
F	It does not meet either of the above criteria.	103 (16%)
	Total	626*

^{*}NOTE: Some of the 232 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 disagreement between NIOSH and SC&A about the radioactive materials to which an energy employee was exposed. If a discrepancy is found in a reviewed case on the part of NIOSH, all cases present and former that have not already been compensated, are reconsidered by NIOSH, and provided a new dose reconstruction when appropriate. Noncompensation decisions are reversed by DOL 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 a discrepancy is found on the part of NIOSH, all affected cases that have not been compensated are re-considered and provided a revised dose reconstruction when appropriate, the results of which are communicated to the DOL if compensation is called for. It should also be noted that NIOSH utilizes the same process of reconsidering and revising dose reconstructions upon its own review and improvement of dose reconstruction data and methods, independently of the Board's review.

Observations among Reviewed Cases

In addition to the findings under review, SC&A consultants 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 comments or 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 appropriately. Thus none of the 206 observations recorded resulted in a change of POC.

Number of Dose Reconstruction Cases Reviewed

As of November 1, 2015, the Dose Reconstruction Reviews Subcommittee had reviewed since its inception 332 cases among the 31,534 claims filed which required dose reconstruction. Thus this Subcommittee has completed reviews of 1.05 percent of all such claims filed as of this date, achieving its current goal of 1 percent of all such claims reviewed. Initially the DRSC and the Board had set a goal of 2.5 percent, 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 precise 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 all 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.

<u>Distribution of Dose Reconstruction Sites across Employment Sites</u>

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 Sets 6-13 is presented in Figure 1. Sites with only one or two cases reviewed are represented collectively with 38 sites having one case reviewed and 26 having two.

These reviewed cases cover the array of claims filed under EEOICPA. In Figure 2 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 1 percent of all DRs reviewed for that site. [NOTE: The Board's goal is 1 percent reviewed of the total of all claims involving dose reconstruction cases, not 1 percent of all claims for any given facility. Some facilities, for example, may deserve greater attention due to the complexity of the DRs involved.] In Figure 2 the second bar next to each site is the sum of cases which have been reviewed, combining those for first 100 cases (in red) and those for the next 232 cases (in green). Thus if the height of the red-green bar for the reviewed

exceeds that of the blue bar, then the Board has accomplished its goal of 1 percent of DRs reviewed for that site.

As indicated for the 26 named sites in Figure 2, the DRSC has met or exceeded the measure of one-percent reviewed for 11 of them and has not met this measure for the 15 other named sites. (See NOTE above.) For sites with very small numbers of claims (Figure 2, bottom line) the DRSC has far exceeded 1 percent reviewed, with 82 reviews completed when 53 were needed to achieve one-percent reviewed. This gives evidence that sites with small numbers of claims were appropriately covered in the review process.

Distribution of Probabilities of Causation among Cases Reviewed

The chart in Figure 3 shows the distribution of Probabilities of Causation among cases reviewed in Sets 6-13. 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 recommendation from non-compensated to compensated or *vice versa*. 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 slight errors in this subgroup have not resulted in erroneous compensation decisions. As a matter of policy when such errors are found, the inappropriately-compensated claimant is not asked to return his/her compensation money. However finding such errors can help both the Board and 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 under-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 over-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 reconstruction can change the compensation decision, hence seeking further to minimize errors in the final compensation decision.

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 SC&A independently to conduct dose reconstructions for cases already reconstructed by NIOSH and comparing the results, which are then reviewed by the Dose Reconstruction Reviews Subcommittee. While this process is resource-intensive it is the best and most appropriate way to quantify how well two independent dose reconstructors can interpret the same data and identify decision points that can result in inconsistencies in assessment and compensation. 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, of which thirteen reviews have been completed and one is still under examination. All thirteen completed reviews are in agreement with respect to their compensation decisions. (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 calculations and the

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 & Dye	DR under review	DR under review
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%

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

For the 13 completed cases in Table 4 the median of the absolute value of the difference between POCs = |POC(SC&A) – POC(NIOSH/ORAU)| = 1.8%. The average value of these absolute differences = 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 9 of these 13 were. For all these assessments both results were either above or below the 50% and hence agreed regarding compensability.

Distribution of Dose Reconstruction Reviews by Years of Employment

Figure 4 shows the distribution of dose reconstructions by years of employment. As noted two-thirds (67%) of the 232 persons 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 (average 24.1 years).

The present results 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 (average 22.4 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 for 5-year relative survival rates of cancer victims have continued to rise, allowing claimants more years of employment before they file their claims if they so choose.

<u>Distribution of Cases Reviewed by Risk Model</u>

Figure 5 presents the breakdown by type for 28 cancers in Sets 6-13. 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). Half of the urinary tract cases are cancers of the bladder and the other half cases 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 presents the distribution of 232 cases 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 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 cases reviewed from before 1960 (72%) compared to 51% in the earlier report.

Other Board Review Activities

In interpreting the findings of these individual case reviews, it is important to consider this review process in the context of other reviews conducted by the Board. The dose reconstructions are based a large number of technical documents that provide a description and history of the activities at each facility covered by the legislation and potential sources of radiation exposure for people working at that facility over time. In addition, there are a large number of other technical documents and procedures that are used in the dose reconstruction process. These documents are continually being revised and updated to reflect newly available information and adapted to improve the dose reconstruction process. The Board has reviewed or is in the process of reviewing nearly all of these documents and often recommends changes to these documents that are then implemented by NIOSH.

In addition, there have been many petitions to add people working at specific facilities during designated time periods to the Special Exposure Cohort. NIOSH evaluates these petitions to determine if there is adequate information available to conduct individual dose reconstruction. If

not, the group is added to the Special Exposure Cohort, and those people are eligible for compensation for specific cancers without individual dose reconstruction. The Board then reviews the NIOSH evaluation and makes a recommendation to the Secretary of DHHS whether or not to add the group to the Special Exposure Cohort.

These other review activities by the Board have a large indirect effect on the Board's verification of dose reconstructions. Often while the individual case is being reviewed or after the review, a procedure or other technical document used in the dose reconstruction may have changed due to the availability of new information or in response to a recommendation from the Board's review, or the claimant may be added to the Special Exposure Cohort. The Board's review of the individual case does not reflect those potential changes. It relies only on the procedures and information in place at the time that the original dose reconstruction was done and does not attempt to incorporate any subsequent modifications.

Conclusions

- 1. The Board's review of 232 individual dose reconstructions yielded 626 findings. Only 22 (4%) of these findings had the potential for a significant impact on the outcome of the individual dose reconstruction. These findings indicate that the NIOSH dose reconstruction process has improved compared to our earlier findings based on the initial review of 100 cases.
- 2. Most of the findings with the potential for a significant impact on dose reconstruction were due to the limited availability of exposure and other data from the facility where the individual worked.
- 3. The limited number of more comprehensive reviews (so called Blind Reviews) also show good agreement between the NIOSH dose calculations and those of the Board's contractor. One of the more comprehensive case reviews was deferred until a more complete review of all of the data from the facility where the claimant worked could be conducted.

Recommendations

Based on the findings of this review and further deliberation by the Board, the Board recommends the following:

- 1. The Board should continue the individual review process consistent with the current goal of reviewing one percent of the dose reconstruction cases.
- 2. The Board should modify the review process to make it more efficient by focusing on the more critical parts of dose reconstruction evaluation.
- 3. The Board should continue the more comprehensive (so-called blind) reviews.
- 4. The Board should initiate a process to conduct reviews focused on evaluating the consistency and accuracy of dose reconstructions for claims where individual judgment on the part of the person doing the dose reconstruction is required.