Advisory Board on Radiation and Worker Health

Summary of Findings of the First 100 Dose Reconstruction Cases
Report prepared by the Subcommittee on Dose Reconstructions
May 2009

INTRODUCTION AND EXECUTIVE SUMMARY

This is a summary report of three separate reports to the Secretary 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.

The first set of 100 cases fall into three basic types of dose reconstructions: 1) 'best estimate' dose reconstructions; 2) 'over-estimated' dose reconstructions: and 3) 'under-estimated' dose reconstructions.

NIOSH's overestimating approach is a more efficient way to process claims which are non-compensable. This time saving method is only intended for non-compensable claims. The under-estimated 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. These are the cases for which a more precise estimate of dose is necessary in order to make a decision on compensation. NIOSH indicated that based on approximately 20,000 cases completed approximately 8% have been best estimate cases, 63% over-estimate, and 29% underestimate. Of the cases discussed in this report 7% were best estimate, 76% were over-estimate and 17% were underestimates.

In the seven (7) cases that were reviewed which incorporated a 'best estimate' approach for dose reconstruction, several findings related to professional judgment and consistency were made which may have impacted the overall outcome of the case. Explanations were offered, after the fact, of how and why the dose reconstructor arrived at the final dose reported. Reanalysis of the cases, based on modified procedures, was offered to the Subcommittee in response to findings. While the re-analysis appeared to demonstrate that the final decision was likely appropriate it raised concerns regarding other cases of this type completed during this time period.

There were seventy-six (76) cases that were completed using an over-estimating approach. This approach has been adopted by NIOSH to allow for faster completion of non-compensable cases. This approach, while logical and well-intended, does have problems. First of all, in the cases reviewed, NIOSH used this over-estimating approach for eight cases that were later

compensated. This is a rather serious quality assurance finding since it brings into question the fairness of the overall program. Additionally, unintended consequences have been created by this efficiency approach. One such consequence is that claimants that are diagnosed with an additional cancer after a decision has been made, and are therefore eligible to resubmit a claim, may receive a lower overall dose because NIOSH recalculated the dose using a best estimate approach rather than an over-estimating approach. While the dose reconstruction may be appropriate, this has created a credibility problem because the claimants do not understand how the doses and Probability of Causation (POC) could go down when a new cancer is diagnosed. A similar misunderstanding has occurred when NIOSH re-evaluates a case(s) based on a modified dose reconstruction method.

Finally, there were seventeen (17) cases that were completed using an under-estimating approach. This approach has been adopted by NIOSH to allow for faster completion of compensable cases. All of these cases were compensated. This approach was properly used for the cases reviewed.

Overview of the Board's Findings

- Dose Reconstruction final reports need modification to allow for more complete audit and better explanation of information to the claimant.
- Case Files (supporting data for the dose reconstruction) should include the internal guides or instructions used by the dose reconstructor and should include supporting data analysis. This will allow for a more complete audit process by assuring that there is an unambiguous description of how the dose was estimated.
- Several findings related to the claimant interview process were identified including questions about the adequacy of the interview, the use or consideration of the information provided in the questionnaire, and the explanation in the dose reconstruction report of how the information was considered.
- Several cases were identified in which NIOSH used an 'over-estimating' dose reconstruction methodology for compensable claims. This approach was developed to allow for faster claims processing but was not to be used for compensable claims.
- In the seven cases that were reviewed, which incorporated a 'best estimate' approach for dose reconstruction, several findings related to professional judgment and consistency were made which may have impacted the overall outcome of the case.

The Board is of the understanding that several procedures and policies have been or are being modified as a result of the findings summarized above and detailed in the full body of this report. [For example, the Board is aware of modifications to the Dose Reconstruction Final Report format, modification of the phone interview questionnaire and the procedures for conducting the questionnaire, and the revision of several dose reconstruction procedures (or Technical Information Bulletins)].

The Board believes that the audit and the finding resolution process, whereby the Board, NIOSH, and the Board's Technical Support contractor (Sanford Cohen and Associates) collectively resolve the findings, has been an effective means of improving the NIOSH dose reconstruction program.

SUMMARY OF FINDINGS OF THE FIRST 100 DOSE RECONSTRUCTION CASES

I. CASE REVIEW METHODOLOGY

This report summarizes the findings of the first one hundred dose reconstruction cases reviewed by the Advisory Board. This is a summary of the findings outlined in three previous reports to the Secretary 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). EEOICPA Section 3623(d) (42 U.S.C. § 7384n(d)(2)(B)) directs that: "[t]he President [delegated to the Secretary, HHS] shall establish an independent review process using the Advisory Board on Radiation and Worker Health to verify a reasonable sample of the doses established under paragraph (1) [the dose reconstruction methods]." Additionally, Section 3624 (b) (42 U.S.C. § 7384o(b)(2) directs that the Board shall advise the President on the "scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program."

To implement these requirements, the Advisory Board plans to audit approximately 2.5% of all cases for which NIOSH completes a dose reconstruction, as well as the site profiles for at least 16 of the facilities. Cases must be fully adjudicated through the Department of Labor (DOL) before they are eligible for selection by the Advisory Board. At the time of the case selection for the fifth set of cases (cases 80 thru 100) 8,120 cases had been adjudicated and therefore available for Board review. The cases reviewed had dose reconstruction (DR) completion dates ranging from 4/10/03 to 12/2/05.

The Board's case selection criteria are designed to include a representative sample of DOE and AWE facilities, time periods, years worked, and cancer sites. Attached are five (5) tables which show a breakdown of the cases by site, decade first employed, years of employment, type of cancer, and Probability of Causation (POC). Table 1 shows that a wide variety of sites (37 different facilities) have been covered in this review. Tables 2-4, likewise, indicate a broad sampling of cases by decade first employed, years of employment and type of cancer. Table 5 shows that a relatively small number of cases (5 cases) of primary interest to the Board (POC between 45% and 49.9%) were reviewed.

II. SUMMARY OF FINDINGS

This Board's report is based on its review, supplemented by the comprehensive audit reports developed by Sanford Cohen and Associates (SC&A, Inc.) which were provided as attachments to the previous three reports.

1. Method for Ranking

The SC&A reports include a ranking of the individual findings based on the effect that it could have on the case. The Board has also developed a methodology by which the findings would be scored which allowed for ranking based on how the finding may have broader

programmatic impact (Site/Program Ranking) (e.g., finding may effect other cases from the same site, finding may effect other cases throughout the DOE complex, etc.).

The Board subcommittee used this methodology to develop matrices to track the deficiencies, the type of deficiency, the resolution of deficiencies and the actions taken as a result of the deficiencies. The deficiencies listed in the matrices have been linked to the SC&A tables for purposes of continuity. The utility of the Board's matrices is the ability to track the resolution of findings and provide a more in-depth description of the finding. In the near future all this data will be available in a database format.

2. Summary of Findings Impacting Estimates of Individual Doses

There were 386 deficiencies found in 100 cases audited. With respect to the impact on the dose for the individual cases, the majority of the deficiencies (341 of 398) were low-level deficiencies which likely would not significantly affect the individual dose evaluation; however, there were 46 scored as medium-level deficiencies and 11 as high-level deficiencies.

3. Summary of Findings Which Have Program Wide or Site Wide Impacts

The Site/ Program Wide ranking considers the broader potential impact and resulted in 73 high level deficiencies, 179 medium level deficiencies, and 146 low-level deficiencies. It is noted that there was a greater number of high level and medium level deficiencies when considering the Program Wide or Site Wide impact. This is due to the fact that many of the low level findings identified for AWE cases impact all cases for those AWE sites since the approach for dose reconstruction are often based on a site wide models. Therefore, a low level case finding could have a higher level Site Wide ranking because it could have an impact on many cases.

4. Summary of Audit Contractor Findings

SC&A concluded that 94 of first 100 dose reconstructions reviewed were considered to be sufficient for the purpose of determining the probability of causation (POC). The majority of the cases reviewed in the first 100 cases were either maximizing cases or minimizing (compensable) cases (only 5 Best Estimate cases were reviewed) and therefore it was unlikely that mistakes in the dose reconstruction would impact the compensability determination. This is reflected in the case statistics provided in this report which show that only 5% of the cases had a POC between 45% and 49.9%.

While the outcome of nearly all of the cases reviewed will likely not be impacted by the findings in this review, concerns were identified that could have a broader impact on the overall dose reconstruction program.

5. Resolution Process

The Board, NIOSH and SC&A went through an iterative process over the course of several months which included: 1) Initial review of cases by SC&A and assigned Board workgroups, 2) factual accuracy review involving NIOSH and SC&A, 3) draft report discussion (SC&A and NIOSH and Board members either at the meeting or by conference call), 4) NIOSH's response to findings within draft, 5) Expanded review meeting (comment resolution discussions) involving Board representation, SC&A, and NIOSH, and 6) final issuance of SC&A report to the Board. The Board reached the following conclusions:

III. CONCLUSIONS AND RECOMMENDATIONS

1. Dose Reconstruction (DR) Final Reports

After reviewing 100 cases it is apparent that the DR reports which NIOSH provides to the claimants and the auditor need to be reformatted and expanded to include more specific information about the claim and an auditable trail that identifies the origin of each line of the dose input tables used for IREP (e.g., based on co-worker data, missed dose calculated based on TIB, etc.). The Board previously recommended that this report be revised. This enhanced DR report remains under development by NIOSH and ORAU. The suggested improvements are necessary to allow for a more efficient quality assurance process as well as to give the claimants a report that more thoroughly explains the conclusions. NIOSH has indicated that some of these changes have already been made to the template that was used at the time of the completion of this review.

2. Internal Quality Control

There were several deficiencies noted during this phase of the audit that suggested a broader concern that the internal quality control procedures and processes at NIOSH and ORAU are inadequate (findings related to organ selection, selection of hypothetical internal dose model, and dose conversion factors). One technique that ORAU has used to avoid such deficiencies has been the use of electronic workbooks (spreadsheets) associated with specific procedures or sites which are designed to aid the dose reconstructor in parameter selection and dose calculation. Findings associated with the use of workbooks and associated guidance, in this early phase of the use of workbooks, accounted for a high percentage of the findings. Another method that NIOSH has employed to assure consistency is the establishment of site specific DR Notes or DR Guidelines. These 'notes' or 'guidelines', however, are not formalized in procedures nor included in the case supporting documents file available to the Board and it's contractor. This has hindered the audit process since it is difficult, in some of the more complex cases, to determine what approach was used to derive the assigned dose. The Board has requested that NIOSH include the 'notes' or 'guidelines' in the case files. The Board further requests that NIOSH include all analytical files in the case file. Finally, NIOSH has employed a peer review process, which includes two reviews of each dose reconstruction. The Board requests that NIOSH include the peer review reports with the case

supporting documents file and that NIOSH should report back to the Board on trends identified in the peer review reports.

3. External Dose Issues

There were several deficiencies noted during this phase of the audit that involved issues related to the use of the dose conversion factor (DCF - used to correct dose based on geometry factors and the organ of concern). This issue remains unresolved; however, NIOSH has indicated that in the interim the most practical and claimant-favorable geometry factor will be applied. Additionally, NIOSH is currently conducting a program evaluation review (PER) assessing all cases that may be affected by incorrect implementation of DCF's.

4. Overestimating approach used for compensable cases

Several cases were reviewed in which the dose reconstruction was completed using OTIB-0004. This procedure was intended to be used only for likely non-compensable claims however, several cases were identified for which this approach was used and the case was compensable. NIOSH has developed TBD 6000 and 6001 to allow for a more realistic approach to this type of dose reconstruction case. A separate Board working group has been established to review these TBDs.

5. Approach used not appropriate for site where claimant worked

Several cases were identified where a procedure (OTIB-0004) which was written for a certain purpose was inappropriately used beyond its intended application. OTIB-0004 was developed for use for dose reconstruction cases for a particular class of facilities; however, several cases were identified in which the OTIB-0004 approach was used for cases involving work at facilities that were not included in OTIB-0004. NIOSH has now published site specific technical documents to remedy this issue.

6. Issues regarding Scientific Judgments and Assumptions

Due to the nature of best estimate cases, professional judgment becomes an important factor in completing the dose reconstruction. Issues of consistency and the degree to which an individual dose reconstructor applies favorable assumptions are most apparent in the best estimate cases. A small percentage of the first 100 cases were best estimate cases (7%) however in this limited number of cases several findings related to judgments were made which may have impacted the overall outcome of the case including: 1) when specific job or workplace details were unknown the dose reconstructor did not consistently give the benefit of the doubt to the claimant and 2) assumptions related to intake dates for internal exposures.

7. Computer Assisted Telephone Interview (CATI)

In several cases SC&A reviewers indicated that there was either inadequate follow-up on items raised in the CATI interview or that incidents identified were not considered in the DR report. The Board believes that it is important to consider the identified information in the

final report that is provided to the claimant. The Board believes that the final DR report must incorporate all relevant facts that contribute to potential dose in order for the DR to be credible. There may be instances where the information provided in the CATI interview may significantly affect the overall dose estimates. NIOSH has stated that the current dose reconstructions address all information provided in the CATI and NIOSH has modified their dose reconstruction reports to assure that incidents or accidents identified by the claimant are addressed in the final dose reconstruction report. The CATI review process and the CATI questionnaire are currently being considered by the Procedures Workgroup.

8. Validation and Verification

In several cases summary data (such as annual summary reports) provided by DOE or DOE contractors was used solely for the dose estimates. It was not evident that any verification or validation of these summary data against source or raw data was performed by NIOSH or ORAU. The Board believes that an essential element of the dose reconstruction process is the independent calculation or estimation of doses. The Board believes that validation of the underlying data is essential and the method by which the data used for dose estimates is verified and validated should be documented within the DR reports. The Board has requested that NIOSH provide an overview of their approach to data validation and verification.

FIRST 100 DOSE RECONSTRUCTION CASES

SUMMARY TABLES

Included herein are five tables that summarize the characteristics of the dose reconstruction cases audited by the Advisory Board with the assistance of the Board's technical support contractor, SC&A. These tables are as follows:

Table 1

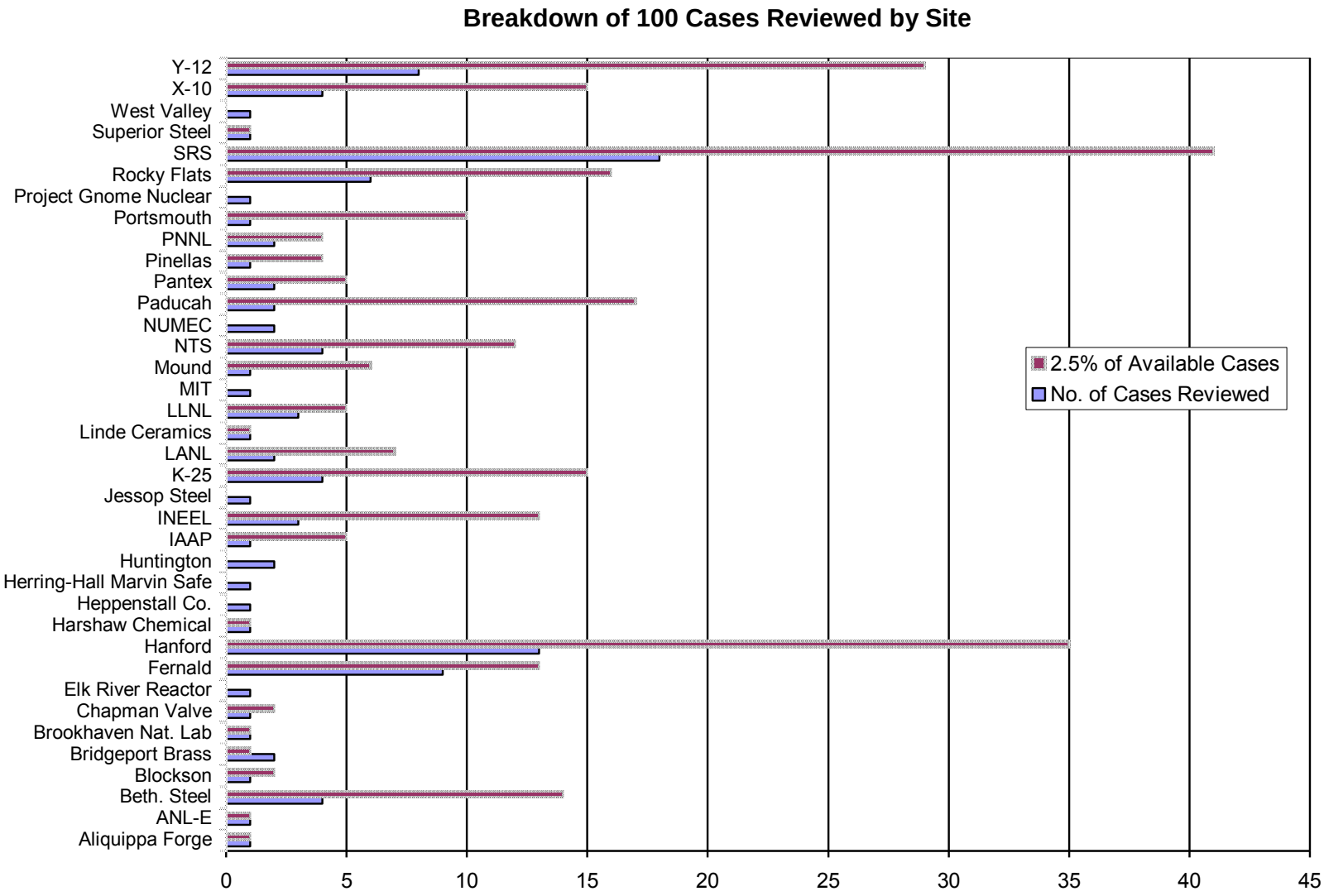

Breakdown of 100 Cases Reviewed by Site
Y-12
X-10
West Valley
Superior Steel
SRS
Rocky Flats
Project Gnome Nuclear
Portsmouth
PNNL
Pinellas
Pantex
Paducah
NUMEC
NTS
Mound
MIT
LLNL
Linde Ceramics
LANL
K-25
Jessop Steel
INEEL
IAAP
Huntington
Herring-Hall Marvin Safe
Heppenstall Co.
Harshaw Chemical
Hanford
Fernald
Elk River Reactor
Chapman Valve
Brookhaven Nat. Lab
Bridgeport Brass
Blockson
Beth. Steel
ANL-E
Aliquippa Forge
0
5
10
15
20
25
30
35
40
45
2.5% of Available Cases
No. of Cases Reviewed

Table 2

Percent of 100 Cases by Decade First Employed

Selection Goal: 40s (10%), 50s (25%), 60s (25%), 70s (25%), 80s (10%), 90s (5%)

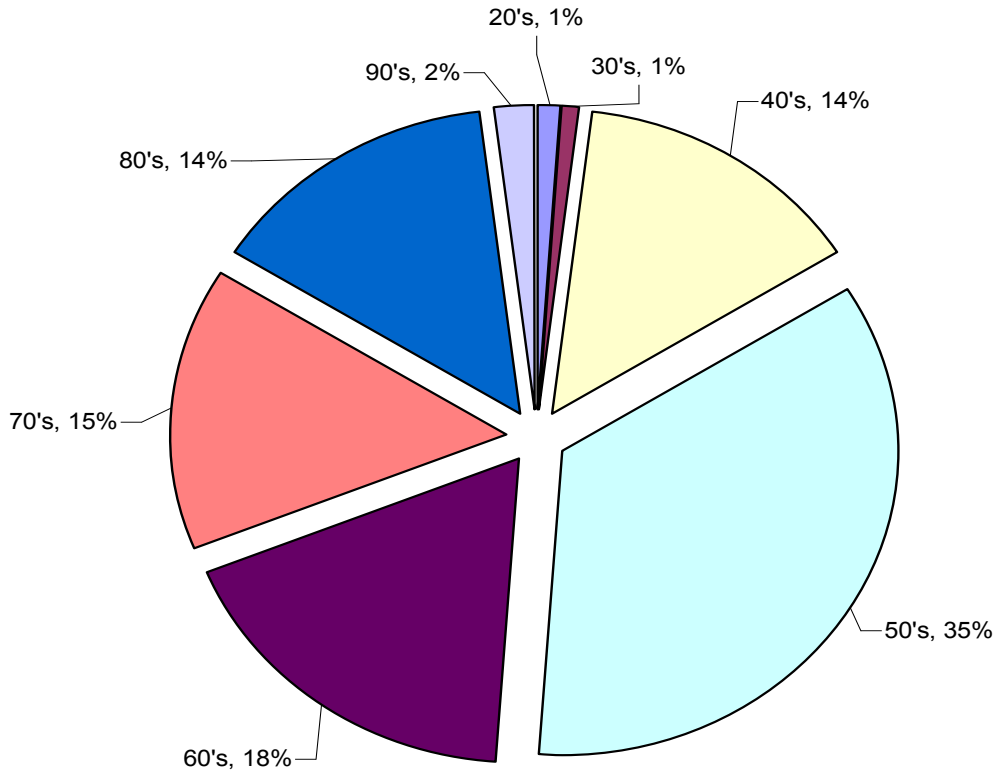


Table 3

Percent of 100 Cases Reviewed by Years of Employment

Selection Goal: 0-1 (15%), 1-5 (25%), 5-10 (25%), 10-20 (25%), >20 (10%)

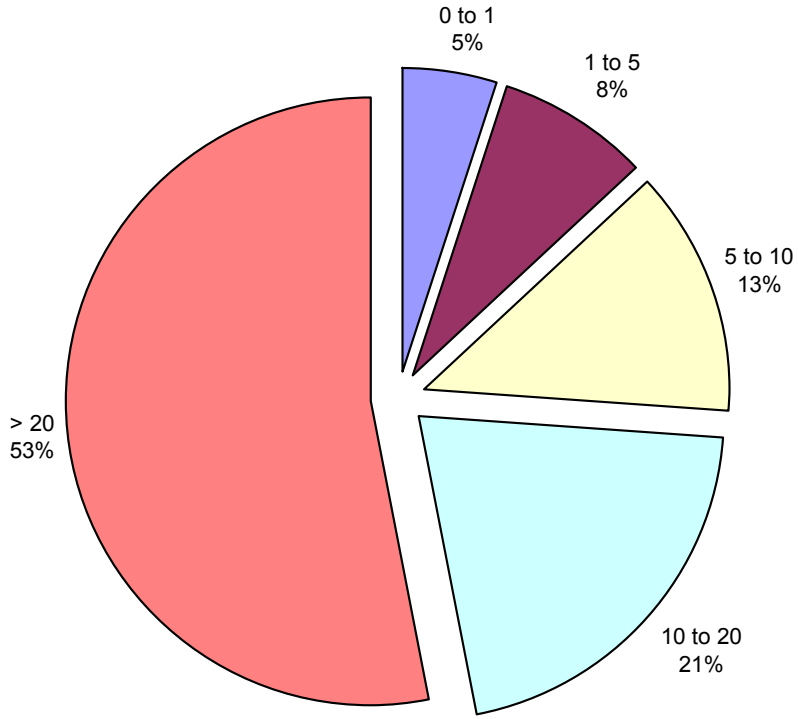


Table 4:

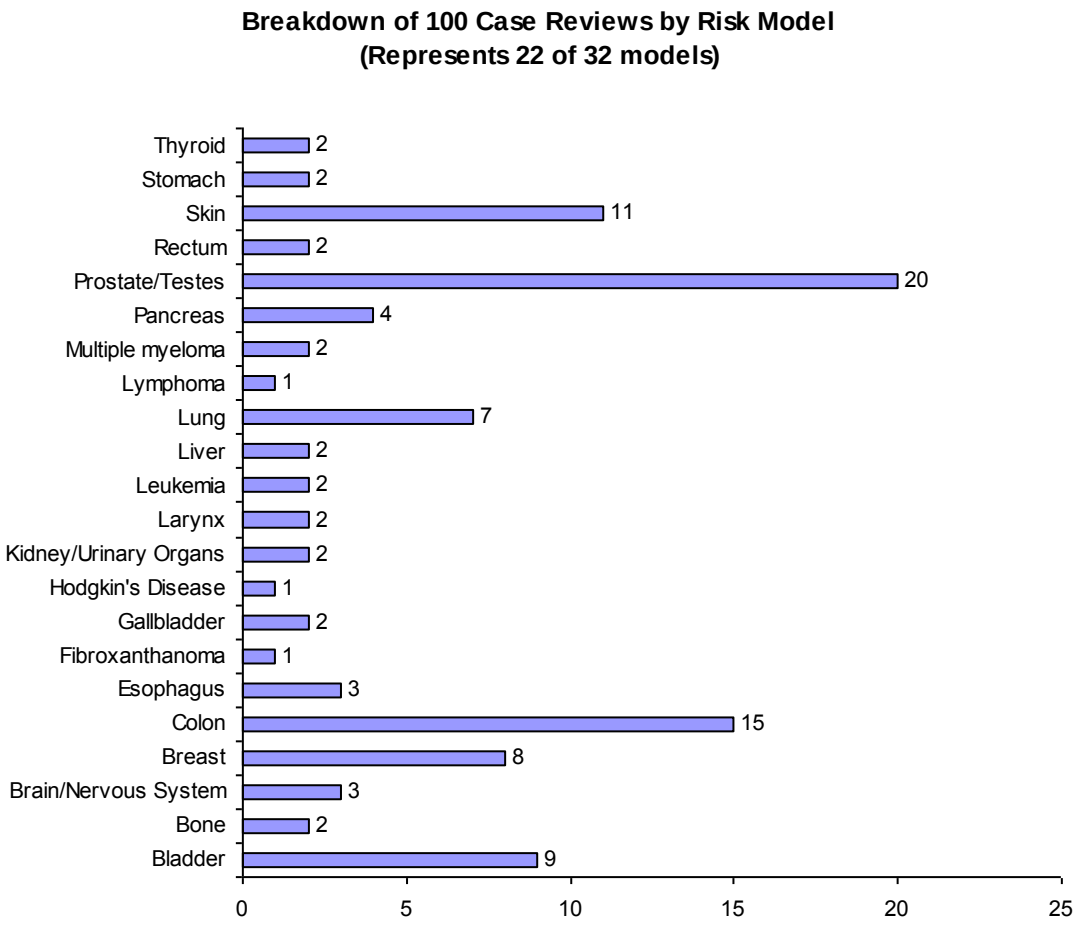
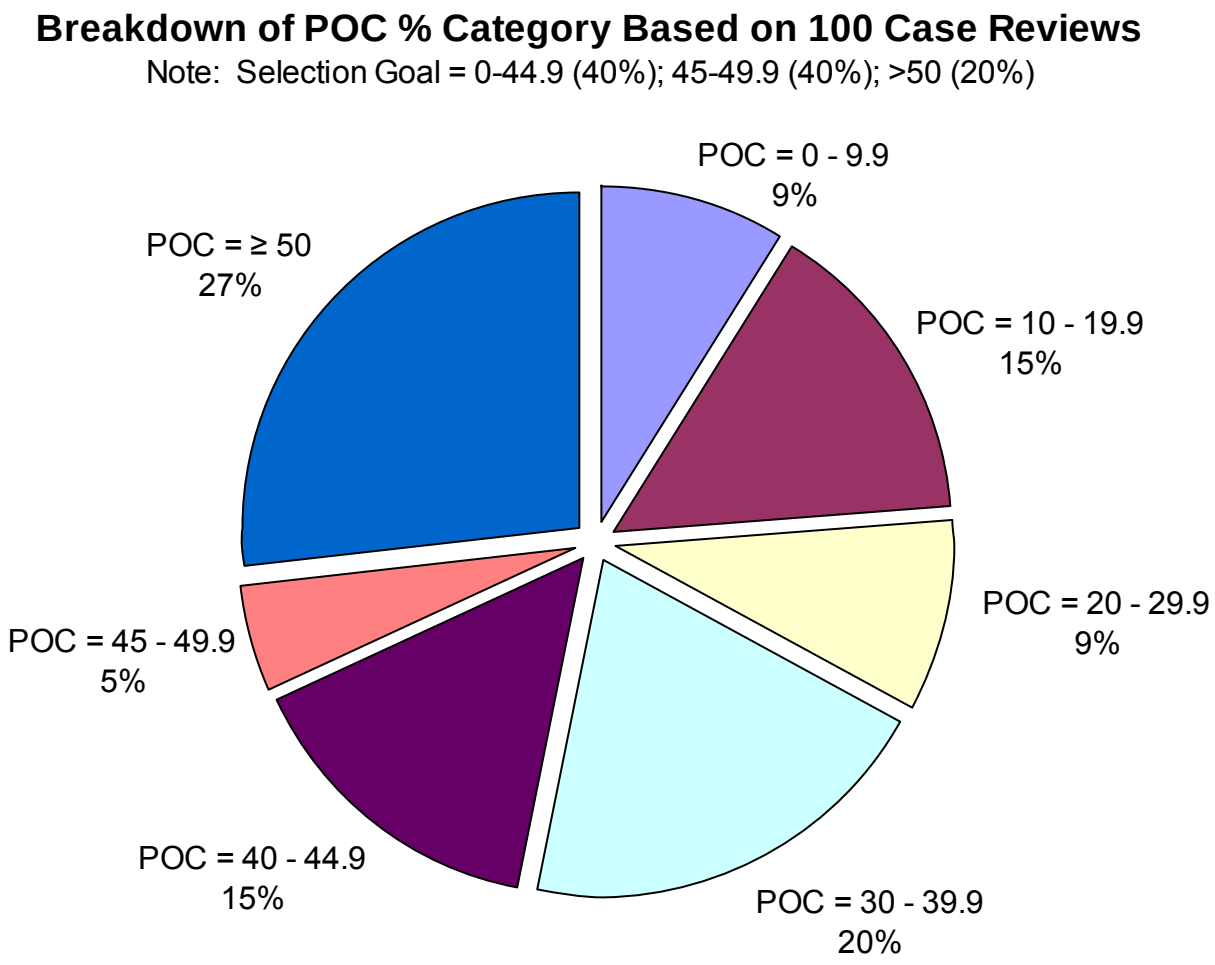

Breakdown of 100 Case Reviews by Risk Model
(Represents 22 of 32 models)
Thyroid 2
Stomach 2
Skin 11
Rectum 2
Prostate/Testes 20
Pancreas 4
Multiple myeloma 2
Lymphoma 1
Lung 7
Liver 2
Leukemia 2
Larynx 2
Kidney/Urinary Organs 2
Hodgkin's Disease 1
Gallbladder 2
Fibroxanthanoma 1
Esophagus 3
Colon 15
Breast 8
Brain/Nervous System 3
Bone 2
Bladder 9
0 5 10 15 20 25

Table 5:


Breakdown of POC % Category Based on 100 Case Reviews
Note: Selection Goal = 0-44.9 (40%); 45-49.9 (40%); >50 (20%)
POC = 0 - 9.9
9%
POC = 10 - 19.9
15%
POC = 20 - 29.9
9%
POC = 30 - 39.9
20%
POC = 40 - 44.9
15%
POC = 45 - 49.9
5%
POC = ≥ 50
27%