

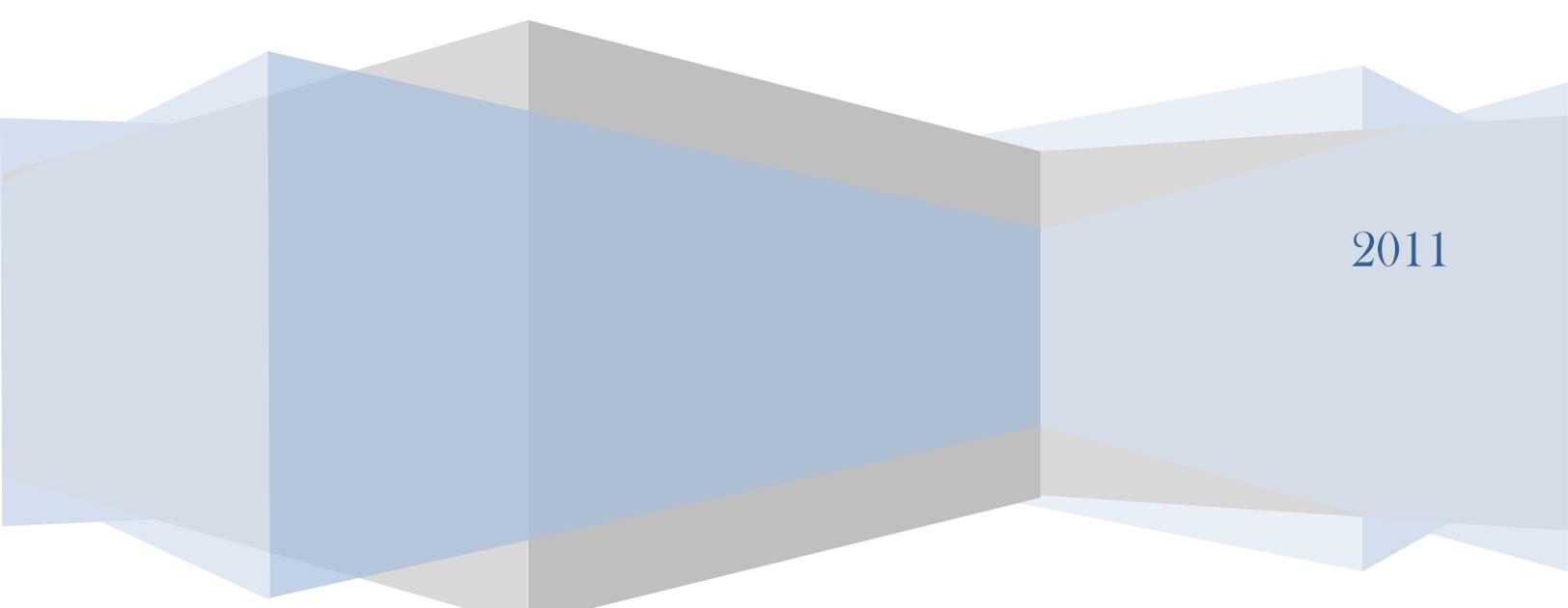
NIOSH Radiation Dose Reconstruction Program

Ten Year Review - Phase I Report

Recommendations

Excerpted from the Five Sections Phase I Report

Dr. Lewis Wade



2011

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Recommendations

Recommendations¹ Excerpted from the Five Sections of the Phase I Report

Submitted By

Dr. Lewis Wade

¹ In the opinion of the preparer of this recommendation document –These recommendations are excerpted from the NIOSH Radiation Dose Reconstruction Program Ten Year Phase I Report's five (5) Sections.

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Recommendations

Dose Reconstruction

1. NIOSH, guided by the nature of the findings from the first 178 DR reviews, must undertake a rigorous review of its internal quality control quality assurance procedures followed by a committed effort to improve those procedures to reduce the deficiencies found in Board reviews.
2. Not only must Overestimating approaches be used with great care, but thought should be given to the continued use of such techniques at this stage of the program's evolution given the confusion to claimants as stated by the Board, "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."
3. The number of findings (538 resulting from procedures reviews and more than 700 resulting from Site Profile Reviews) reinforces the need for NIOSH to focus on its internal quality control/quality assurance efforts.
4. The significant amount of work still to be completed, i.e. 20 site profiles under active review by Work Groups, 11 Site Profiles Reviews without a Work Group assigned; only three of seventy five site profiles closed out: and more individual DR reviews to reach the 2.5% goal, underscores the need for NIOSH to develop and implement a detailed resource management plan to ensure that finite NIOSH resources are deployed in ways consistent with program priorities.
5. NIOSH needs to conduct an analysis of completed reviews to identify if there are reoccurring issues that appear in a number of reviews and if so these issues should be given a high priority to be corrected.
6. NIOSH Leadership needs to focus on this tension and take steps to minimize the confusion that surrounds such changes while maintaining the use of the best available science and ensuring that individuals that warrant compensation consistent with the best available science receive compensation.
7. While Full Best Estimate dose reconstructions take longer, as measured by calendar time passed, than Overestimates and Underestimates (in the majority of years evaluated) that difference is not that great particularly in recent years, 2006 through 2008. For that reason NIOSH needs to explore whether or not it should continue to use Overestimating and Underestimating techniques given the confusion that their use causes with claimants.

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Recommendations

8. Unless partial dose reconstruction is attempted for cases that are in part covered by an SEC but are for a cancer not on the list of 22, that individual would have no hope of being considered for compensation. Therefore the process of partial dose reconstruction should be continued and if possible expanded upon, i.e. with a more precise definition of the doses that cannot be reconstructed in an SEC definition it would be possible to include more components of dose in a partial dose reconstruction.
9. All parties, NIOSH, the Advisory Board, and the Department of Labor should undertake a detailed review of past SEC class definitions to determine, (1) how to better define classes in the future (that would allow for robust partial dose reconstructions) and, (2) if any of those class definitions could be rewritten to allow for the consideration of addition dose in a partial dose reconstruction.
10. The Department of Labor should be consulted with in the development of SEC class definitions to better ensure that such class definitions can be effectively administered.

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Recommendations

Timeliness

1. NIOSH should set aggressive targets for the average time that an initial claim is with NIOSH. Any such target needs to take into account allowing for a reasonable amount of time to secure the appropriate records from DOE and others.
2. NIOSH should consider a target of 90 days or less to complete the dose reconstruction once the information is in their hands.
3. NIOSH should give a higher priority to returned claims in setting its goals for the timely completion of claims
4. NIOSH should explore additional efficiency measures in the DR process to decrease the time a claimant waits for their DR.
5. NIOSH Leadership should consider establishing a DR target of six months or less.

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Recommendations

Special Exposure Cohort (SEC)

1. Using the NAS definition of equity in RECA compensation suggests that the criteria for inclusion or exclusion from the SEC should be explicit and applied consistently. NIOSH should seek to develop consistent, objective criteria which it can apply across SEC petitions to ensure fairness and uniformity. . Expert judgment is not an objective criterion.
2. NIOSH should revisit its interpretation of the statutory phrase “with sufficient accuracy” to give fuller effect to the role of scientific uncertainty.
3. NIOSH should recognize that SEC petitions often raise science policy questions, where science can inform NIOSH's policy choice, but science may not provide “facts” to govern those choices. NIOSH should clearly articulate these policy choices. It should compare the policy choices it makes in reconstructing radiation dose across SEC petitions and against other occupational health policy choices. Where radiation dose reconstruction justifies different policy choices than NIOSH relies on in other areas of occupational health, NIOSH should explain why the different choice is appropriate.
4. NIOSH should consider relying on a multi-disciplinary approach to SEC evaluation. By relying on a broader range of experts to evaluate the data on radiation exposures at a site, NIOSH can take steps to minimize any unconscious bias in the SEC evaluation process. A multidisciplinary approach would also ensure that NIOSH applies consistent science policies across its programs.
5. NIOSH should recognize that scientific expertise can be used to mask professional bias and take steps to minimize that effect. All professionals have some form of unconscious biases. Because DCAS is staffed overwhelmingly with health physicists, the biases of that profession dominate NIOSH's evaluations. Broader participation of other disciplines in SEC decision would likely bring with it a broader range of policy perspectives.
6. NIOSH should rely on the authority in 42 CFR 83.13(b) in appropriate cases to declare that data will not be available for dose reconstruction.
7. When evaluation of a SEC petition is complex, NIOSH could present a detailed, petition-specific evaluation plan to the Board and seek its agreement on how to proceed.
8. NIOSH should consider limiting the number of revisions it makes to its SEC petition analysis.

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Recommendations

9. NIOSH's heavy reliance on expert judgment to evaluate SEC petitions is an inherently subjective criterion, in the sense that reasonable experts can reasonably disagree about the outcome of any petition. NIOSH should consider developing objective criteria to limit the exercise of expert discretion so that similarly documented exposures are treated similarly across sites. NIOSH regulations do not anticipate such an inquiry.
10. Applying an equally rigorous effort to reconstruct dose across SEC petitions may be one measure of "fairness and equity" but other measures, such as developing objective criteria to guide science policy decisions or increasing the use of presumptions in SEC evaluation, are available as well. Application of an equal measure of scientific rigor to SEC petitions may not ensure that similarly situated workers – in terms of year of exposure, type of exposure, or degree of risk – are treated similarly
11. NIOSH should develop objective criteria to guide when it relies on surrogate data and, if it does so rely, what type of data is accurate enough to serve that purpose. NIOSH has begun taking steps internally to do so. It should continue those.
12. NIOSH should review whether its reliance on surrogate data is consistent across SEC petitions, in the sense that workers with comparable exposure records are treated similarly. NIOSH should be more aware of whether its decisions are uniform and fair across SEC petitions.
13. NIOSH should also consider whether its use of surrogate data in the radiation dose reconstruction program is consistent with its treatment of such data in other areas of occupational health. Any differences in the way it approaches such data across programs should be consistent with relevant statutes or justified by explicit policy choices.
14. NIOSH should better explain its judgments about the use of surrogate data.
15. NIOSH should evaluate whether its reliance on surrogate data speeds or delays resolution of claims.
16. NIOSH should reconsider whether its heavy reliance on expert judgment to decide when to rely on upper bound estimates and, if so, how it decides how claimant friendly to make its assumption is uniform or fair.
17. NIOSH should develop objective criteria, where possible, to guide the exercise of expert judgment.

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Recommendations

18. NIOSH should give greater consideration to the uncertainties associated with its dose estimates.
19. NIOSH should consider creating presumptions to be applied across all SEC petitions. Such presumptions should be based on objective criteria. Increased use of presumptions would create more timely, uniform decisions on SEC petitions.
20. In developing presumptions under EEOICPA, NIOSH should take steps to ensure that its policy choices under this program are either consistent with its policies on related issues in other occupational health contexts or justified by the different statutes and regulations for each program.
21. NIOSH should continue and expand its efforts to cooperate with petitioners. Such efforts increase petitioners' knowledge of what is needed to gain SEC approval and should aid NIOSH in more quickly obtaining whatever information petitioners have about exposures and practices at potential SEC sites.
22. For SEC petitions requiring complex analysis, NIOSH should submit a comprehensive plan to evaluate a SEC petition for Board approval and evaluate a petition consistent with that plan. 42 C.F.R. §83.12(c).
23. NIOSH should utilize the authority provided in 42 C.F.R. 83.13(b) and avoid delay when data necessary to evaluate a petition is not forthcoming in a timely manner.
24. NIOSH should reduce delay between filing of a claim and a decision that a petition under 83.14 is proper by setting an internal deadline on when it will decide that DR is not feasible and a section 83.14 SEC should be considered.
25. NIOSH should consider the use of summary reports on its evaluation of petition under section 83.14 to reduce the size and complexity of the evaluation reports it produces for each SEC petition.
26. DCAS should prioritize completion of site profiles, particularly in cases where the absence of a final site profile has delayed resolution of individual dose reconstructions or decisions on SEC petitions.
27. NIOSH should minimize revisions to site profiles while a SEC petition is pending.

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Recommendations

28. Because NIOSH did not give added meaning to the phrase “with sufficient accuracy” in the SEC regulations, it has created a “zero sum game” where approval of a SEC petition is beneficial for some while at the same time limiting the dose considered in the claims of others. NIOSH should revisit whether this policy choice is reasonable.
29. NIOSH should explain the rationale for its decisions, and its change of position, clearly and succinctly. The rationale behind its choices should be transparent.

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Recommendations

Quality of Science

1. DCAS should consider processes and tools aimed to improve accuracy and minimize inconsistencies between and within documents used in dose reconstruction. For example, reference maps have been used in some settings to identify document linkages and parent-child relationships. Likewise, a relational database could be developed to manage document interrelationships and provide for easy document searches. Furthermore, periodic reviews by subject matter experts may help to systematically and expeditiously uncover inconsistent and erroneous text in technical documents.
2. DCAS, in conjunction with the ABRWH, should develop a process whereby document inaccuracies are readily identified and corrected in a timely manner without causing delay in claims processing.
3. DCAS should reexamine its policy on peer review of dose reconstruction documentation. At a minimum, DCAS should consider seeking external review on those documents that have not been reviewed by the ABRWH. DCAS should consider conducting stakeholder reviews prior to the issuance of future documents, especially documentation of indirect exposure methods, to ensure that all reasonable attempts for gathering site-specific information have been exhausted.
4. DCAS should consider expanding the use of its procedures database to provide a comprehensive report on its technical documents and associated reviews. The database should include status on resolutions to comments from all sources, including science reviews by the ABRWH and its subcontractor as well as reviews conducted by other scientists, affected workers and worker advocates.
5. DCAS should develop methods to systematically assess the internal and external validity of indirect exposure assessment methods. These validation methods should provide reasonable evidence that resultant dose estimates are bounding and provide insight into the degree in which claimant-favorability is achieved.
6. DCAS should consider methods to examine between- and within-worker variance components in current coworker models.
7. DCAS coworker models should consider additional strata based on work history information, which may elucidate if an individual is likely to be routinely or intermittently exposed.

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Recommendations

8. DCAS should develop data validation methods that readily quantify coverage, temporal and spatial variance, and existing anomalies in data selected for coworker analyses. These methods should include well-defined gold-standards for comparisons.
9. DCAS coworker models should prefer facility data to other sources of information in lieu of evidence of significant systematic errors in the dose of record. In the event that CEDR data are used, the analysis should: 1) cite the actual file(s) used (e.g., K25EXP from the ORMULA05 Data File Set); 2) describe the study cohort characteristics in relation to the full cohort; 3) provide information on adjustments (if any) previous researchers used to prepare the dataset; and 4) discuss any limitations expected from the use of these data.
10. DCAS should consider future research to better characterize the degree of claimant-favorability that is afforded by current methods for adjusting doses for measurement biases, including the bias from exposures below detection. Moreover, the current comparison between substitution and maximum likelihood methods shown in ORAUT-OTIB-0020 lacks the scientific rigor necessary to fully support the assertion of claimant-favorability. This analysis should be revised or its use discontinued.
11. Where possible, DCAS should address outstanding questions concerning the use of surrogate data by adopting plausible upper bounds on the exposure that can be used in determining compensation.
12. The U.S. EPA has a protocol for the use of surrogate data that may be useful to DCAS in deciding upon when surrogate data can be used to estimate exposures to groups and individual workers, DCAS should review and where appropriate consider the impacts of the EPA document on DCAS's use of surrogate data.

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Recommendations

Quality of Service

1. These comments indicate that there should be more explanation of NIOSH policies on how it evaluates, corroborates, and incorporates information from different sources. This could foster more accurate expectations of how the information will be used and reduce misunderstandings about use of information from DOE, workers and survivors, and others.
2. Without specific procedures, there is no observed NIOSH policy requiring that worker comments be recorded and action taken on the comments.
3. Developing criteria for following up on worker information, policies on following up, and deadlines could be useful steps toward ensuring that worker concerns are addressed and that worker information is taken into consideration.
4. It may be useful for NIOSH to highlight the changes that have been made since the SC&A evaluations and take further actions as needed to improve worker outreach procedures and actions
5. The number of cases (15) in which claimant-provided incident information was not fully acknowledged in the dose reconstruction report suggests both a need to better capture information, and quality control to ensure that interviewee comments are noted in dose reconstruction reports.
6. Follow-up on the incident information seemed to consist of only searching for DOE information. It would be informative to discuss any other follow-up that was conducted, such as interviewing coworkers and using information from those interviews.
7. Not making changes to the dose because no DOE records were found seems to indicate that DOE records are more accurate than worker comments. NIOSH may wish to consider providing information on the validity and reliability of DOE recordkeeping and how decisions are made regarding which source to use when there is conflicting information.
8. The NIOSH response to most information was to state that dose estimates were overestimates and were claimant-favorable. This does not seem to directly respond to claimant comments. Customer service would be improved by providing more detailed, case-specific responses.
9. In none of the 100 cases reviewed did NIOSH indicate that a change was made to the dose estimate based on claimant-provided incident information. There could be more clarity if the reports highlighted any changes that were made to dose reconstruction reports based on information provided by workers or survivors.

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Recommendations

10. Respondents suggested that NIOSH provide tutorials, workshops available to all, and access to independent health physicists or advocates.
11. NIOSH should explore ways in which the process and information can be more disability friendly to better address the needs of the claimant and petitioner population.
12. To be better understood by a greater number of people, dose reconstruction reports, webpages, educational materials, as well as other documents (SEC petition evaluation reports, etc.) should be written at or below the 12th grade reading level. It may be helpful to provide short, easy to read summaries.
13. Although CATIs and submission of work history information are voluntary, there is concern that the program places on claimants and petitioners the responsibility of proving exposure.
14. Based on comments from respondents that NIOSH requested "specific dates" and "excerpts," better explanations could be provided regarding information requests, the mandatory information needed from claimants and petitioners, and the role of NIOSH in obtaining information for dose reconstructions and petition evaluations.
15. NIOSH should take into consideration circumstances faced by workers and survivors, such as the passage of time, burdens of illness, lack of technical expertise, fear of retribution by current energy employers, and systematic lack of information sharing given national security concerns.
16. To reduce burden, it was suggested that NIOSH request information only if the information will be used. Two respondents believed that some dose reconstructions and interviews seem unnecessary. NIOSH should examine its procedures and eliminate any steps that are redundant or are barriers to timely, effective dose reconstructions and petition evaluations.
17. Based on these comments, access to the information used by NIOSH to make decisions could be increased by addressing barriers such as cost, inconvenience, and lack of timeliness. NIOSH should provide the information in a manner that would facilitate use of the data/information by others.
18. Providing full, free, immediate, and convenient access to information may increase trust in the program and NIOSH. In making information more available, NIOSH would need to address issues related to the time it takes NIOSH to complete tasks, privacy protections, and the understandability of information.
19. There seems to be inconsistency in the personal communications by staff in terms of friendliness, helpfulness, and responsiveness. It may be useful to provide more staff training in risk communication and conflict resolution.

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Recommendations

20. The quality of written communications can be improved to reduce errors, which may increase credibility and trust.
21. To address concerns from three respondents regarding DOL, NIOSH could try to work with DOL to consider ways to reduce mistakes.
22. It was suggested that a position or entity be developed to respond to complaints and obtain feedback from and communicate with the community.