

THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH RADIATION DOSE RECONSTRUCTION PROGRAM: COMMENTARY AND CONCLUSIONS

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INTRODUCTION

THE NATIONAL Institute for Occupational Safety and Health (NIOSH) Radiation Dose Reconstruction Program is a complex scientific effort that draws from most of the technical aspects of the health physics profession. As described in the papers of this special edition, these activities involve the assessment of internal and external doses for individuals who were exposed to workplace, environmental, and occupationally related medical sources of ionizing radiation at one or more of over 300 Atomic Weapons Employer (AWE) and U.S. Department of Energy (DOE) facilities. Workers were potentially exposed to one or more of 15 defined categories of ionizing radiation (NIOSH 2002a and b), further complicating the assessments because the records, if available, are often more than 50 years old, and their correct interpretation frequently necessitates detailed reviews of many historical program documents. In many respects, the dose reconstruction component of this program can be best described as *health physics archaeology*.

Throughout the development and conduct of activities under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), the NIOSH staff, in concert with its technical contractors, has adhered to four underlying principles: (1) all activities should be supported by a strong scientific foundation; (2) this foundation should be consistently and uniformly applied; (3) every effort should be made to perform the dose reconstructions in a timely, efficient, and equitable manner; and (4) the public should be provided ample opportunities to participate, that is, the program should be conducted in what is called as “transparent” a manner as possible while, at the same time,

maintaining the privacy of the workers and claimants. The methods through which these principles are being implemented are reflected in the sections that follow.

ESTABLISHING AND MAINTAINING A SCIENTIFIC FOUNDATION

It was realized at its inception that the program would require a strong scientific foundation and would need to be performed in accordance with regulations and formal guidelines. The technical bases for radiation dose reconstructions and probability of causation models were developed by NIOSH and included in two Federal regulations (U.S. DHHS 2002a and b). Care was taken to base the technical foundation for these regulations on the latest national and international scientific consensus standards developed by organizations such as the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP). Full advantage was also taken of the work of other nationally and internationally recognized groups such as the U.S. Committees on the Biological Effects of Ionizing Radiation (BEIR), the American National Standards Institute (ANSI), and the United Nations Scientific Committee on the Effects of Ionizing Radiation (UNSCEAR). As part of the formal rulemaking process, NIOSH requested and received feedback from a wide array of stakeholders on its proposed technical approaches and models. All public comments received by NIOSH were evaluated, and a discussion of the technical and scientific merits of each comment was published.

The formal guidelines, which were prepared by the NIOSH Office of Compensation Analysis and Support (OCAS), were of two types: those developed for implementation of the program, and those developed for operating the program. The first of these related to External and Internal Dose Reconstruction (NIOSH 2002a and b). As was the practice in preparing the regulations, these documents incorporated the latest national and international consensus standards. In addition,

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they were subjected to several levels of internal review and, in some cases, an independent external peer review.

Where shortfalls in the available scientific or technical information are identified, NIOSH is committed to applying an approach that ensures that the processing of the claim is supported by a “claimant favorable” policy (ORAUT 2005). That is, when there are two equally plausible exposure scenarios, NIOSH will select the scenario that provides the higher dose to the organ or tissue that developed cancer. This is exemplified by the care that is exercised in the assessment of inhalation intakes of uranium and transuranic radionuclides. In cases where the chemical form of the radionuclide can not be determined, the dose reconstruction will assume that the worker was exposed to the solubility type that provides the highest dose. Most often this means that respiratory tract doses are reconstructed using highly insoluble material (i.e., type S or Super S), while systemic organs are reconstructed assuming exposure to more soluble forms (i.e., type M or F) (Brackett et al. 2008).

ESTABLISHING AND MAINTAINING TRANSPARENCY

Recognizing that the outcomes of the dose reconstruction efforts are subsequently used by the U.S. Department of Labor (DOL) in adjudicating claims for financial compensation, the NIOSH program has been, and continues to be, subject to intense public scrutiny. From the standpoint of the claimants, such scrutiny is not only understandable but also fully justified. Desiring to respond to these needs, NIOSH has, from the beginning, been proactive in conducting its scientific deliberations in a manner that provides for public access to program documentation and encourages input from a variety of stakeholders. For example, the individual site profile documents have routinely been made available to the public. In a number of cases, as time permitted, draft documents were similarly made available with follow-up time for the submission of comments.

In accordance with the Federal Advisory Committee Act (FACA) (U.S. Congress 1972), the meetings of the Presidentially appointed Advisory Board on Radiation and Worker Health (Ziemer 2008), which was established to advise NIOSH on its implementation of the program, are open to the public. To ensure transparency, the law that established the Board specifies that its membership “shall include affected workers and their representatives, as well as representatives of the scientific and medical communities.” Again, in line with its established goals of openness, NIOSH has gone well beyond the requirements of the FACA. This includes, for

example, producing complete *verbatim* transcripts of all meetings of the Board, including those of the various working groups that have been established. These transcripts, as well as most program documentation, are subsequently posted on the program’s Web site at <http://www.cdc.gov/niosh/ocas/> (a notable exception is any information covered by the provisions of the Privacy Act).

To assist in the development of site profile documents (Kenoyer et al. 2008), various worker outreach meetings were convened. These, again, are designed to ensure that workers have input to the process and that important workplace processes and operations have not been overlooked. Another aspect that helps to instill public confidence is the internal and external review process to which program documentation is subjected. With the assistance of an outside contractor, the Board is also reviewing the majority of the program’s site profiles and operational guidelines, as well as a representative sampling of all dose reconstructions. As in the examples cited above, the results of these reviews are held in an open forum with opportunities for comment, supplemented by detailed minutes and transcripts made publicly available.

CONSISTENCY AND UNIFORMITY

To ensure that all dose reconstructions are performed in a consistent and uniform manner, a hierarchical document system has been established. This system has as its foundation the previously cited Federal regulations (U.S. DHHS 2002a and b), which were promulgated prior to the initiation of the dose reconstruction program. Flowing from these requirements are the various implementation guidelines, technical information bulletins, site profiles, and all associated procedures that are used by the distributed network of dose reconstructors. This practice has proved to be extremely effective and beneficial in documenting that all dose reconstructions are performed in accordance with currently approved technical approaches. Throughout this special issue, there are examples of how these various controlled documents were developed and how they are applied to the dose reconstruction process. In particular, the development of site profiles has helped to ensure that dose reconstructions apply consistent exposure scenarios, including the uniform application of source terms, detection limits, and a variety of exposure conditions.

DATA VALIDATION AND VERIFICATION (QUALITY ASSURANCE AND CONTROL)

The quality and scientific accuracy of the reconstructed doses are highly dependent on the availability

and validity of the original data. For that reason, NIOSH directed major attention to the associated collection, processing, validation, verification, quality assurance, and quality control of the data. Closely supporting these activities was the insistence that the data be tailored to the uses to which they are to be applied. The discussion that follows illustrates and documents the continuing effort to improve the outcomes of all such activities.

Assessments of internal exposures necessitate the careful consideration of a multitude of processes and technologies. These include the manner in which the bioassay sample was collected, the interpretation of the outcome of the available analytical techniques, and the sensitivity of the instruments required for performing the associated radionuclide assessments. Equally important is the necessity of fully understanding the manner in which the body metabolizes the chemical form of each individual radionuclide. Providing support to the evaluation of internal dose are the multiple publications of the ICRP (1991, 2005), ably supported by the NIOSH-OCAS Claims Tracking System (NOCTS) and the Site Research Database (SRDB) (Martin et al. 2008). These record systems play a major role in documenting that the accompanying assessments can be both validated and verified.[†]

In the case of the assessments of external exposures, key factors that must be recognized in validating and verifying the associated data include the continuing changes in personal monitoring devices during the working lifetime of the claimant. Depending on the time period under investigation, the common methods for assessing such exposures were pocket dosimeters, then film badges and, more recently, thermoluminescent dosimeters (TLDs). The data yielded by each of these have accompanying radiation specific detection limits and uncertainties. Although the use of TLDs reduced the measurement uncertainties, it did not eliminate them (Merwin et al. 2008). Particularly difficult to evaluate are the doses due to x-ray screening examinations because of the lack of documentation of the x-ray exposure records and the continuing changes due to updates of the x-ray equipment (Shockley et al. 2008).

EFFICIENCY AND EFFECTIVENESS

Due to the large number of cases and the need to provide timely completion of the dose reconstructions, every effort is made to process them as efficiently as

[†] Oak Ridge Associated Universities Team. Verification and validation process for the tools development group [internal procedure]. Cincinnati, OH: ORAUT-PROC-0094; 2005.

possible. At the same time, care is taken to ensure that the accuracy and quality of the information provided to DOL are sufficient to adjudicate the claims in a manner that instills confidence in the outcome. This was particularly important in the initial phases of the program when claims were being processed prior to the development of the supporting operational and implementation guidelines. To achieve this goal, primary attention was directed to cases having either relatively high or low anticipated dose estimates. If those cases with an anticipated low dose did not appear to justify compensation, even when deliberately overestimated, and those with an anticipated high dose still appeared to justify compensation, even when underestimated, they were completed and the results submitted to DOL. This approach enabled the dose reconstructors to process the cases efficiently and effectively, especially during the early phases. This emphasizes the point that the goal in estimating the doses in conjunction with the NIOSH Radiation Dose Reconstruction Program is not to produce what might be termed an "accurate dose;" it more properly is to produce an estimate that will enable DOL to adjudicate the claim.

As the program progressed, other efficiency measures were identified, perfected, and applied. Providing overall support to these activities was the adoption of a questioning attitude, complemented by a policy of seeking continuous improvement. A significant outgrowth of these efforts was the establishment of a separate group, composed of dosimetrists and computer modeling experts, whose goal was to develop new computer tools (such as the Chronic Annual Dose Workbook (CADW) (Maher et al. 2008). This computer tool has the capability to process claims at rates hundreds to thousands times faster than previously possible. In addition to being able to process hundreds of radionuclides simultaneously, through all routes of intake, this system was designed to account for far more input factors, while simultaneously reducing the rates of error. Further enhancing these tools were features that enabled them to be automated. The products of these efforts enabled the dose reconstructors to achieve a quantum leap in their output.

CLOSING COMMENTS

The objective of this review has been to highlight certain hallmarks of the NIOSH Radiation Dose Reconstruction Program. While the technical and scientific details of the individual components of the program have been addressed in the preceding papers, the objective of this concluding commentary is to emphasize that the

overall program is based on sound science that has been adapted to meet the unique needs of the compensation decisions made under EEOICPA. That is, the scientific decisions are made using an efficient process that has been optimized to produce consistent results. To instill stakeholder confidence, a high degree of emphasis has been placed on conducting activities as transparently as possible.

While these goals and desires are important in their own right, they exemplify the underlying objective of interacting with the workers on an individual basis. This includes engaging them in periodic telephone discussions and enhancing their opportunities to be involved and to comment on changes in the program and the associated methods of analyses. Closely intertwined with these objectives is an effort to ensure that the processing of the claims is supported by a “claimant favorability” policy. Another major consideration is to ensure that the claims are processed as rapidly as possible. Still another example is the evaluation of facilities to be added to the Special Exposure Cohort, a group of claimants for whom it has been determined that (1) “it is not feasible to estimate with sufficient accuracy” their radiation dose, and (2) there is a reasonable likelihood that their dose “may have endangered” their health (U.S. DHHS 2002c). In these cases, compensation is granted for 22 specified cancers under certain conditions, without the necessity of reconstructing their doses. Finally, recognizing the changing nature of the scientific elements underpinning this program, all claims where dose reconstruction results in a denial from DOL are subject to rework when new technical approaches are adopted.

As a result of these efforts, the science of radiation dose reconstruction has been moved forward in a number of areas. In fact, each step in the process, from the acquisition of data, the computer tools available for their processing, and the interpretation and applications of the outcomes, has been improved through the use of techniques that not only were previously unknown, but also are innovative and efficient.

Disclaimer: The findings and conclusions in this paper have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.

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