

THE NIOSH RADIATION DOSE RECONSTRUCTION PROJECT: MANAGING TECHNICAL CHALLENGES

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INTRODUCTION

Abstract—Approximately two years after promulgation of the Energy Employees Occupational Illness Compensation Program Act, the National Institute for Occupational Safety and Health Office of Compensation and Analysis Support selected a contractor team to perform many aspects of the radiation dose reconstruction process. The project scope and schedule necessitated the development of an organization involving a comparatively large number of health physicists. From the initial stages, there were many technical and managerial challenges that required continuous planning, integration, and conflict resolution. This paper identifies those challenges and describes the resolutions and lessons learned. These insights are hopefully useful to managers of similar scientific projects, especially those requiring significant data, technical methods, and calculations. The most complex challenge has been to complete defensible, individualized dose reconstructions that support timely compensation decisions at an acceptable production level. Adherence to applying claimant-favorable and transparent science consistent with the requirements of the Act has been the key to establishing credibility, which is essential to this large and complex project involving tens of thousands of individual stakeholders. The initial challenges included garnering sufficient and capable scientific staff, developing an effective infrastructure, establishing necessary methods and procedures, and integrating activities to ensure consistent, quality products. The continuing challenges include maintaining the project focus on recommending a compensation determination (rather than generating an accurate dose reconstruction), managing the associated very large data and information management challenges, and ensuring quality control and assurance in the presence of an evolving infrastructure. The lessons learned concern project credibility, claimant favorability, project priorities, quality and consistency, and critical path project activities.

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THE ENERGY Employees Occupational Illness Compensation Program Act (EEOICPA) was passed by Congress in 2000 (U.S. Congress 2000). Part B of the Act, supplemented by a Presidential Executive Order (2000), established a program for providing a lump-sum payment of \$150,000 and medical benefits as compensation to workers who have suffered, or are suffering, from certain types of cancer conditional upon the cancer being determined to be more likely than not the result of radiation exposures incurred during employment involving nuclear weapons-related activities at one or more facilities or sites operated by the U.S. Department of Energy (DOE), or its predecessor agencies. In cases where the claimant is deceased, the Act provides for payment of compensation to certain of his or her survivors. While the Executive Order assigned primary responsibility for administration of the program to the U.S. Department of Labor, the U.S. Department of Health and Human Services (HHS) was assigned the task of fulfilling several important supporting technical roles, including the performance of radiation dose reconstructions for workers applying to the program. Following this approach, the primary responsibilities for conducting the operational aspects of the program were assigned within HHS to the National Institute for Occupational Safety and Health (NIOSH). The Act and the Executive Order also contained provisions for establishing an Advisory Board on Radiation and Worker Health to provide an independent review of the activities to be conducted by HHS.

The NIOSH Office of Compensation and Analysis Support (OCAS) selected a contractor team to perform many aspects of the radiation dose reconstruction process under Part B of EEOICPA. The contractor prime was Oak Ridge Associated Universities (ORAU). The other core companies composing the ORAU Team were Dade Moeller & Associates and MJW Corporation. From the beginning, there were many challenges facing work on this project. This paper identifies those challenges and describes the resolutions and lessons learned.

The size and complexity of the project is reflected in the nature and diversity of the progress achieved during

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the first four and a half years of operations. To date, the Team has completed more than 19,000 approved radiation dose reconstruction reports of almost 27,000 referred to NIOSH, conducted 70,000 interviews, responded to 250,000 telephone inquiries for program information or claim status, prepared 144 technical documents comprising site profiles for 46 major facilities, prepared 50 technical information bulletins, completed 39 Special Exposure Cohort (SEC) evaluation reports, and reviewed more than 2 million pages of documentation on DOE and Atomic Weapons Employer (AWE) sites (Neton et al. 2008). To achieve these milestones, it was necessary to overcome initial and continuing challenges.

INITIAL AND CONTINUING CHALLENGES

The project was challenged from the beginning to process cases quickly. Unfortunately, at the time of contract award there was a backlog of nearly 10,000 cases to be processed for which technical methods and procedures had not yet been developed. This situation necessitated the eventual recruitment, training, and management of nearly 400 staff, including more than 100 professional health physicists working at more than a dozen locations within the United States. In addition to preparing dose reconstructions, health physicists were needed to conduct the associated reviews and evaluations, to prepare the site profiles necessary to provide the technical bases for the dose reconstructions, and to support the evaluations of petitions for SEC status (Ulsh et al. 2008). Professionals in numerous other disciplines were needed to establish and maintain an infrastructure to support the project tasks. Expanding these challenges was the necessity to recruit additional personnel specializing in fields such as information technology, communications, data entry, records management, and quality assurance. Furthermore, to achieve case processing goals required that these personnel be assimilated rapidly within congruous management, administrative, and logistical infrastructures.

The most challenging and complex undertaking from a management perspective has been to complete transparent and defensible dose reconstructions at an acceptable production level. Achieving and sustaining such a rate has been problematic as several project priorities proved to be in conflict. Resolution of several of these conflicts is discussed below as lessons learned. Other issues created additional challenges. These included establishing scientifically defensible methods and tools within the framework of EEOICPA; managing the resource-limited pool of health physicists; and managing the contributions to the project of other staff members—the non-health physicists.

Finally, as with any large project requiring significant communications, an effective and efficient project infrastructure was essential.

MANAGING THE CHALLENGES

The challenges identified above derailed the project for a period of time. The resolution of many of these issues is not ground-breaking management, as they are typical of large scientific projects. However, some were unique and of interest because of the unusual, individualized nature of the dose reconstruction and SEC processes.

To determine compensability on an individual basis, radiation dose reconstructions are prepared using data covering personal dosimetry; the site, facility, and environmental characteristics and monitoring; job type and hazards; years and duration of employment; and other relevant factors. This has required the development and use of new methods for individualized dose reconstructions to support compensation determinations (Maher et al. 2008). The magnitude of the project and volume of work to be performed has necessitated development and use of efficient methods, tools, and techniques.

The objective of the project has always been to achieve dose reconstructions that result in defensible compensation determinations combined with a rate of production that would process the cases in a timely manner. The project cannot claim the use of best-available or good science without bias because the EEOICPA requirements govern the conservatism or claimant favorability applied to the assumptions, methods, and techniques used. In EEOICPA terms, claimant favorability means that the worker has received the benefit of the doubt. The project can claim that the science used in dose reconstructions is transparent and consistent with the intent of the compensation program. All efforts have been aimed at striking a balance between the need for achieving production and the defensibility of the resulting dose estimates and compensation determinations.

USE OF HEALTH PHYSICISTS ON THE PROJECT

One challenge was that there were more health physics tasks than health physicists available to work them. Their primary roles were to understand and interpret data and dosimetry information; prepare technical basis documents that included site profiles for numerous DOE and AWE sites; and develop the methods and procedures required for assessing the associated dose contribution from internal, external, medical, and environmental sources. In addition, health physicists

were needed to support the review of SEC petition applications.

In the initial months of the project, the dose reconstruction approach was to have one health physicist process one case at a time from beginning to end. This required the health physicist to research the DOE or AWE site; assess the nature of the worker's occupation(s); enter his or her dosimetry data into electronic spreadsheets for analysis; develop an individualized method to estimate internal, external, medical, and environmental radiation doses received by the worker; and prepare an individualized dose reconstruction report for the case. The health physicist also needed to provide a quality assurance review and an edit of the final product. At the time, all of these tasks were being performed by the health physicist assigned to each case. As a result, while the quality was good, the level of production was slow and the backlog was increasing. To become more efficient without sacrificing quality, project tasks were restructured and assigned to Team members with specific expertise in data entry, technical editing, communications, case management, records management, database management, information technology, mathematical modeling, quality assurance and control, and data and information gathering. This change freed many health physicists to focus on peer reviews, AWE dosimetry, tool development, internal dosimetry, medical dosimetry, external dosimetry, dose reconstruction, site profile development, SEC petition evaluations, and technical information bulletins. This division of tasks resulted in increased productivity for the entire project.

The health physics activities were eventually organized based on task functions. The assignment for each health physicist was made on the basis of the individual's technical strengths in these functional areas. Many health physicists were also cross-trained on numerous activities. There was a major demand for health physicists to prepare site profiles and the supporting technical basis documents as these were needed to ensure consistency and quality of the dose reconstructions, especially for the large DOE sites. Eventually, more than 150 staff members were preparing the technical basis documents for the 13 original site profile documents. This task represented a significant and schedule-sensitive activity, one that involved staff with expertise in many disciplines (Kenoyer et al. 2008).

The outcome of these efforts is evidenced by the fact that, while the first 1,000 dose reconstructions required 26 months to complete, the next 1,000 were completed within 14 weeks.

ORGANIZATIONAL STRUCTURE

As with any project of this size and complexity, the organizational structure has continually evolved to meet project needs. This is evident at all levels of the project. At the task level, this has included how the dose reconstruction work was organized. At the subtask working level, temporary groups have been formed to meet specific or critical project needs such as performing data capture, developing site profile documents, and preparing preliminary calculations on cases for workers with certain types of cancer. The nature and number of larger tasks being managed have changed significantly.

The radiation dose reconstructors originally were organized according to their ability to perform internal vs. external dose estimates. Within months, the organization was changed to strive for greater efficiency by having dose reconstructors focus on specific sites and types of cases. This organizational approach was also responsive to the production of site profiles, which significantly aided the dose reconstruction process.

A site profile document evolved to ultimately include five technical basis documents covering the site description, and internal, external, medical, and environmental dose estimates. This evolution of these documents led to further organizational changes. Collecting, verifying, managing, and disseminating the information and data for each worker, including performing data capture at DOE records repositories (Martin et al. 2008), became a separate task. Preparing and managing the site profile documents became a second task whose activities were often the critical path for completing large numbers of cases at the major DOE sites (Kenoyer et al. 2008; Rollins 2008). Records management became a third task dedicated to establishing and preserving necessary records for each case.

INFRASTRUCTURE

Effectively using the strengths of nearly 400 individuals working on the project required a robust infrastructure. Logistical needs included office space, computers, Internet access, and telecommunications. Other infrastructure needs included tools, systems, and provisions for project management, human resources, equal employment opportunity assurance, contracts, cost accounting and accrual, and travel. Project policies and procedures were necessary for many of these functions. As would be expected, the orientation, development, and training of employees engaged in supporting activities proved to be vital.

Quickly establishing a sound infrastructure was an operational necessity. For example, the adequacy, compatibility, and reliability of computers and software

Internet communications were critical to maintaining productivity. For most facilities, dedicated computer hardware systems, secure Internet servers, and high-speed transmission lines were installed to improve reliability. In reality, the scope of this project could not have been attempted in the pre-computer or pre-Internet age.

Some infrastructure needs were met with the establishment of the ORAU Team's Cincinnati Operations Center. Located in close proximity to OCAS, the Center is the hub for Team operations and serves as the meeting point for most significant Team activities. In addition to staff performing the wide variety of task activities on the project, it is also the base for conducting telephone interviews of workers or their survivors. A large number of claimant interviews have been performed and documented for use by dose reconstructors.

LESSONS LEARNED

Any discussion of lessons learned has to be within the context of improving the project's ability to meet the objectives of EEOICPA. This began with establishing an open project, preparing credible technical documents, and generating understandable, defensible, and claimant-favorable dose reconstructions in a timely manner. These straightforward objectives continue to guide the project. One primary characteristic of a successful organization is to identify and benefit from the lessons learned resulting from both operational successes and failures. The lessons learned from this project may assist managers of similar scientific projects, particularly those requiring significant data needs, technical methods, and calculations. Five examples are discussed below.

Establishing and maintaining credibility

A first lesson learned is that the use of defensible science was essential to establishing and maintaining technical credibility. Never give anyone a reason to lose confidence in the technical approach. This project was vulnerable to criticism because of the number and complexity of new approaches and methods that had to be developed to perform individualized dose reconstructions. Compounding the problem was that the new methods were not easily explained to those lacking health physics knowledge. Two credibility issues have been particularly challenging. The first related to the accuracy of a dose reconstruction vs. the defensibility of a compensation determination. The purpose of this project is the latter. Often, determining the recommendation did not require an accurate dose reconstruction. For example, a method that grossly overestimated the actual dose received could be sufficient to confirm a non-compensable determination; that is, even with significantly

more radiation exposure the worker would not have been recommended to be compensable. The second issue related to bounding the radiation dose potentially received by a worker in the absence of dosimetry records. Regarding both of these issues, the project has been criticized on the basis that the dose reconstruction was not as accurate as possible. For neither issue would an accurate dose determination yield a dose that would have changed a compensation determination. The reality is that these operational approaches and methods were founded on defensible science within the provisions of EEOICPA and were claimant favorable.

Ensuring transparency and claimant favorability

A second lesson learned is that project credibility is dependent upon the work being presented in an understandable manner to stakeholders including, for example, complex technical issues and the meaning of claimant favorability in EEOICPA. Many aspects of EEOICPA, with its different requirements and outcomes, are confusing to claimants. The project staff needed to help stakeholders understand that the resulting compensation determinations are fair because claimant favorability is fundamental to the methods and assumptions being used. Under EEOICPA, the determination of likelihood is made at the 99% confidence interval. In other words, there is only one chance in 100 of having a false negative; that is, of wrongfully denying compensation for a case that is as likely or not (50% probability) to be compensable. As described in another paper in this issue (Merwin et al. 2008), claimant favorability goes far beyond just the designation of a 99% confidence interval. Claimant favorability is considered in the selection of all approaches and methods used, including many data and assumptions in which it is not intuitively obvious that claimant favorability would be affected. Project activities are independently reviewed by the Presidential Advisory Board on Radiation and Worker Health and its contractor (Ziemer 2008). Despite this approach, the program is often criticized by some as not being fair to the workers and their survivors. Through public meetings, more information on the project is being provided directly to stakeholders. Furthermore, detailed information on the technical approach and methods is being documented by the project (i.e., in site profiles and technical information bulletins) and in this issue of *Health Physics*.

Balancing preparation of tools and methods with timely case production

At the time the contract was awarded to ORAU, nearly two years had passed since Congress had established EEOICPA. From the initial stages, the project was playing catch up to reduce the backlog of claims. From a

management perspective, one of the most challenging aspects of the project was the immediate need to balance documenting the scientific bases of the methods being employed and preparing dose reconstruction tools with the demand for timely, sustained case production. Within months of contract award, the ORAU Team was required to complete dose reconstructions that were defensible. This challenge was likened to “painting a moving train.” It would have been easy to manage the project if years had been available to establish the methods and document the information relevant to performing radiation dose reconstructions at the multitude of DOE and AWE sites. Given the objective to prepare timely compensation decisions, there was no time for delays. Difficult cases could not be processed without first developing new, sophisticated methods. The lesson learned is to focus on what you can do and to never stop looking for efficiencies and innovations. By effectively screening and triaging cases, the project was able to process hundreds of cases early on. Examples include those for which the worker had clearly received significant radiation exposures, lacked the potential for meaningful radiation exposures, or had a type of cancer that was inconsistent with an occupational exposure being more likely than not to have caused the cancer (e.g., cancer latency period inconsistent with detection of the cancer). The initial screening approach allowed for these easier cases to be processed, which enabled production to be increased dramatically. This provided time for the new methods to be developed and documented prior to processing the more difficult cases. Other innovations were developed to optimize the involvement of health physicists, reduce calculational processing time, and increase efficiency.

Maintaining quality and consistency

A fourth lesson learned addresses the need to establish and maintain the quality and consistency of reports and project deliverables. Early on, each dose reconstruction report was prepared as a unique document. The initial lack of a uniform approach and adequate formats, templates, and report controls resulted in some embarrassing errors. These mistakes included incorrect worker name, cancer types, and years and locations of employment. No mistake is acceptable that appears to be insensitive or non-compassionate to a worker or his or her survivors. Interestingly, many of these errors were related to the use of computers. There was a tendency for dose reconstructors to reuse a previous report as a template for preparing a new one. To alleviate this source of errors, a dose reconstruction report template was developed for each of the sites and the specific types and complexities of cases. In addition to eliminating such errors, solving this problem also greatly

improved the consistency of reports and the productivity of the dose reconstructors. Using single entries for key data, the templates automatically repeated information such as the name of the worker. Editing and quality control reviews were proceduralized. Furthermore, text was developed for use by dose reconstructors to describe the methods and assumptions for specific types of cases, the presence of certain conditions, and the nature of the dose estimates or conclusions determined. Because these texts were available, dose reconstructors were able to spend more time documenting aspects of the dose reconstruction that were specific to the worker. The use of templates was shown to actually increase the individualized nature of the dose reconstruction report. The improvements demonstrated that standardizing a method, procedure, or report does not have to be inconsistent with the objective of providing individualized, personal attention to each activity.

Identifying critical path activities and balancing resources

A fifth lesson learned is that critical path activities must be identified and their objective and purpose evaluated early in the project planning process. A primary example was the site profiles developed for a given DOE or AWE site. Initially, the critical path objective of the site profile documents was to provide data and assumptions for dose reconstruction. A second objective was to document the activities at the site, the dosimetry data available for workers, the radiation exposure conditions, the occupational environment, and the general (or ambient) environment. As evidenced by this list, a site profile ended up containing a large amount of information, which resulted in a large document. However, certain information in the site profiles was needed immediately for dose reconstruction. Early on, cases could not be processed until the document was finally completed and approved. This conflict was resolved by recognizing that the site profiles were serving two important, but distinct, purposes. Further delays were avoided by issuing the essential data as a separate user’s guide well ahead of the site profile. Off the critical path, each site profile went through a significant preparation, editing, comment, and review cycle. Other scientific projects likely face similar conflicts when critical path items have multiple objectives or purposes.

SUMMARY

Those managing the work performed under Part B of EEOICPA have faced many challenges that have required planning, integration, and conflict resolution. The key challenge has been to complete defensible radiation dose reconstructions that support timely compensation determinations

at an acceptable rate of production. A defensible dose reconstruction does not necessarily mean it is accurate, rather that it supports a compensation determination consistent with the intent of EEOICPA, which requires that methods, tools, and techniques used in the process be claimant favorable. Maintaining defensible science has improved project credibility, which is further enhanced through transparency. The lessons learned may be useful to managers of similar scientific projects, especially those requiring significant data needs, technical methods, and calculations.

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