

RADIATION DOSE RECONSTRUCTION PROGRAM OF THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH: OVERVIEW

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Abstract—Over the past 65 years, hundreds of thousands of workers have been engaged in nuclear weapons-related activities for the U.S. Department of Energy or its predecessor agencies. To date, almost 27,000 such employees (or their survivors) have filed claims under Part B of the Energy Employees Occupational Illness Compensation Program Act of 2000, which provides monetary compensation and medical benefits to energy employees who have developed certain types of cancer that have been determined, under the guidelines of the program, to have resulted from occupational radiation exposure covered under the Act. Although it is difficult to predict the number of cancer claims that will be evaluated under this program, the number could double or triple. In each case, the processing of a claim requires that the National Institute for Occupational Safety and Health reconstruct the radiation dose received by the employee followed by a determination by the U.S. Department of Labor as to whether the employee was “at least as likely as not” to have sustained the cancer as a result of his or her occupational exposure to ionizing radiation. Although some of the dose assessments are straightforward, many are extremely complex due to (1) missing, non-interpretable, or undocumented records; (2) a wide variety of external and internal exposure conditions; and/or (3) highly variable work assignments and work loads. The program objectives are to process claims in an effective, efficient, and timely manner. One of the initial challenges was to develop the necessary infrastructure to meet these objectives. Subsequent challenges included documenting that assessments are fair and scientifically consistent. Ensuring that each claimant receives the “benefit of the doubt” in any cases where the required background information and data are ambiguous or not available is also an important objective. Fortunately, there are some aspects of the processing requirements that have tended to reduce the complexity, two examples being that compensation is based on exposures that occurred during covered employment after a cancer has developed and that the required dose estimates are for individual body organs, not

effective doses. Throughout the process, every effort has been made to ensure that the dose assessments have the support of the best available science.

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INTRODUCTION

OVER THE past 65 years, hundreds of thousands of workers have been engaged in nuclear weapons-related activities for the U.S. Department of Energy (DOE) or its predecessor agencies, the Manhattan Engineering District, the Atomic Energy Commission, and the Energy Research and Development Administration.[‡] Additional thousands continue to be employed by DOE or its contractors. Through March of 2008, almost 27,000 cancer claims have been filed for compensation under Part B of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) promulgated by the U.S. Congress in 2000.[§] Considering that many workers who have developed cancer have not filed claims, and that many current workers eventually will develop cancer during their lifetimes, it is estimated that the number of Part B claims ultimately could double or triple. The processing of each claim requires that the National Institute for Occupational Safety and Health (NIOSH), a component of the Centers for Disease Control and Prevention, reconstruct the dose received by the organ or tissue in which the cancer was diagnosed and that the U.S. Department of Labor (DOL) make a determination as to whether the energy employee was “at least as likely as not” to have developed the cancer as a result of exposure to ionizing

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[‡] For purposes of simplicity, all such agencies will be referred to collectively as “DOE” in the discussion that follows.

[§] Cancer claims submitted under Part B of the Act require a dose reconstruction to enable the U.S. Department of Labor to determine whether the claim qualifies for compensation. Additional cancer claims have been filed under Part E and do not require a dose reconstruction.

radiation in the performance of occupationally related duties. This paper presents an overview of the NIOSH Radiation Dose Reconstruction Program. Details on each of the more important aspects of the program are presented in the papers that follow.

Although radiation dose reconstruction efforts have been ongoing in the United States for several decades, the earlier investigations were confined primarily to exposures received from radionuclide releases into the general environment (Till 1996).^{**} To fulfill the needs of the program described here, it was necessary to expand these efforts not only to include exposures received in conjunction with the onsite occupationally related duties of the energy employees, but also to provide the information necessary to allow DOL to render a decision on whether the claimant should be compensated. Nonetheless, the earlier work has served as a valuable resource in developing procedures for the program described here.

Experience to date has shown that, while some of the dose reconstructions are straightforward, many are extremely complex due to (1) missing, non-interpretable, or undocumented records; (2) a wide variety of external and internal exposure conditions; and/or (3) highly variable work assignments and workloads. The techniques employed by NIOSH to account for these factors are discussed in detail elsewhere in this issue (Brackett et al. 2008; Merwin et al. 2008b). In many instances, the ensuing search of the records and clarification of the reported data are extremely tedious and time-consuming. Adding to these challenges is the need to interview claimants who, in some cases, are aged and/or ill or are relatives of a deceased worker. Lastly, there is the relatively large number of claims to be processed. To our knowledge, this program is the largest such effort that has ever been undertaken.

In all cases, the energy employee has developed at least one cancer in a specific body organ or tissue. As such, the desired endpoint is an estimation of the radiation dose received by the affected organ or tissue. Unfortunately, the worker doses that were recorded for regulatory compliance purposes during employment were generally not organ-specific, nor were they reported by DOE in the detail required for this program. For purposes of making a compensation decision, the radiation dose to the organ must be reconstructed on an annual basis from the date of cancer diagnosis to the termination of exposure. Further, the annual exposure information must be separately quantified for each type of radiation (i.e., alpha, beta, gamma, x ray, or neutron). In some cases, energy spectral data are also required.

A common example of missing detail is the lack of separate bioassay information for each of the different radionuclides that might contribute to internal exposure and, in the case of external exposure, the lack of descriptive information on the types, energies, and exposure geometries for external radiation sources. In addition, in the case of internally deposited radionuclides, the regulatory guidelines prior to the late 1980's did not require that detailed organ doses be calculated. At that time, it was sufficient for DOE facility operators to demonstrate that the quantities of radionuclides deposited in the bodies of workers were less than the recommended maximum permissible body burdens. For purposes of radiation dose reconstruction under EEOICPA, information is required to document the organ-specific equivalent dose received from the time of the first exposure to the time of the diagnosis of cancer. In addition to the scientific and technical program requirements, there are other factors that must be considered. These include the widespread interest in, and visibility of, the program; the accompanying public scrutiny; and the need for transparency throughout the dose reconstruction process, given the level of distrust in government by former DOE workers.

The program that has been developed to accomplish this mission involves essentially every aspect of the fields of radiobiology, radiation dosimetry, and health physics, including the interpretation of supporting data derived from records based on personal monitoring and in vitro and in vivo bioassays (i.e., urinalyses and whole body counting). Essential to this effort is the need to (1) consider potential errors in the monitoring methods that were used; and (2) ensure that all assessments are fair, consistent, and well grounded in the best available science. At the same time, NIOSH must take care to implement the intent of EEOICPA and the regulations contained in Title 42 CFR Part 82 (U.S. DHHS 2002b) that each claimant receive the "benefit of the doubt" when the available information is inadequate to differentiate between two equally plausible exposure scenarios.

GENESIS OF THE PROGRAM

The genesis of the NIOSH Radiation Dose Reconstruction Program (U.S. Congress 2000), EEOICPA, was enacted after epidemiologic research indicated associations between work-related exposures and illness at DOE facilities and claims for work-related illnesses were not being accepted by local workers' compensation authorities (NEC 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

^{**} A notable exception is the Nuclear Test Personnel Review program conducted by the Defense Threat Reduction Agency, an agency of the U.S. Department of Defense.

suffered, or are suffering, from designated illnesses (i.e., cancer, chronic beryllium disease, or silicosis), provided these were shown to have developed from exposures incurred during employment involving nuclear weapons-related activities at one or more facilities or sites operated by DOE or its predecessor agencies. In cases where the energy employee is deceased, the Act provides for payment of compensation to certain of his or her survivors. The Act also included employees of commercial facilities that were contracted by DOE to perform work related to the nuclear weapons programs. Under the Act, these facilities have been designated as Atomic Weapons Employers.^{††} A complete listing of all facilities covered under Part B of EEOICPA can be viewed at the following Web address: <http://www.hss.energy.gov/healthsafety/fwsp/advocacy/faclist/findfacility.cfm>.

Although the Executive Order assigned primary responsibility for administration of the program to DOL, the U.S. Department of Health and Human Services (HHS) was assigned the task of fulfilling several important supporting technical roles. NIOSH is named under EEOICPA to assist the Secretary of HHS in implementing his or her responsibilities under the Act. 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 conducted by HHS. The responsibilities and activities of the Advisory Board are covered elsewhere in this issue (Ziemer 2008).

THE CLAIMS MANAGEMENT PROCESS

To ensure that all claims are processed by NIOSH in accordance with the regulatory requirements, a rigorous system has been established to manage and track the flow of claims. The claims process for NIOSH begins when DOL forwards a claim to NIOSH for dose reconstruction. By this point in the process, DOL already has verified that the employee (1) worked at a covered facility during a period of time covered under the Act; and (2) was diagnosed with cancer (other than chronic lymphocytic leukemia) during or after the time of covered employment. In addition, cancers of the skin require that ethnicity be established, and cancers of the respiratory tract require a determination of the employee's history of cigarette smoking.

Once a case is received by NIOSH, all applicable information is entered into the NIOSH Office of Compensation Analysis and Support (OCAS) Claims Tracking System database. In addition, a request for radiation

exposure information is sent to the DOE site(s) at which the employee was employed. This request, which is generated automatically within the tracking system, requires that sites provide all available records regarding the individual's internal and external radiation monitoring, any radiological incident in which the individual may have been involved, and any x-ray examinations required as a condition of employment (Shockley et al. 2008). Once received, these records are scanned into the database and are made available electronically for all future aspects of dose reconstruction and case management. This is covered in more detail elsewhere in this issue (Martin et al. 2008).

THE DOSE RECONSTRUCTION PROCESS

As discussed elsewhere in this issue (Ziemer 2008), some claims do not require a dose reconstruction because they qualify for compensation automatically under the Special Exposure Cohort provision contained within the Act (U.S. DHHS 2004). For claims that require a dose reconstruction, it is not possible on the basis of a medical evaluation to prove or disprove unequivocally that a specific cancer was caused by a specified radiation exposure (NCRP 1992). Hence, a dose reconstruction and calculation of the associated probability of causation (PC) are used under EEOICPA to determine compensability for these claims. The steps in this process are discussed in the paragraphs that follow.

As an initial step, individuals who have filed eligible claims are contacted to schedule a voluntary interview. By this point in the process, the claimants already have received a hard copy of the questions that they will be asked. These computer assisted telephone interviews, which are conducted by trained support contractor staff, are designed to supplement the exposure data received from DOE with personal accounts of job duties and incident involvement. They also are used to verify employment periods and cancer diagnoses. Each interview is documented and forwarded to the claimant for his or her review, and changes are made as requested by the claimants.

To provide supporting information to dose reconstructors, the specific radiation environments to which the worker was exposed are characterized on the basis of information contained in technical basis documents that relate to the site where he or she was employed. The collection of these documents, prepared for a single site, compose what is called a site profile. The process of preparing these profiles is described elsewhere in this issue (Kenoyer et al. 2008). Once the site profile has been completed and applied to the conditions under which the energy employee worked, the accompanying exposure

^{††} For purposes of the discussion that follows, these workers will be referred to by the collective term "DOE employees" or "energy employees."

data and related information are used to estimate annual radiation doses to the specific organs or tissues relevant to his or her cancer. This process, for which NIOSH is responsible (U.S. DOL 2005), employs a hierarchy of methods, depending on the nature of the exposure and the type, quality, and completeness of the data available to characterize the environment of the worker. Using data for the energy employee, information from the interview, and documented methods and procedures, a trained expert prepares a draft dose reconstruction. Once complete, this document is independently reviewed and, upon completion of the peer review process, a NIOSH health physicist reviews and approves the final document for release to the claimant. Thereafter, the claimant is provided the opportunity to review the report for factual accuracy and to ensure that all relevant information he or she provided to NIOSH has been incorporated. Once this step has been completed, a telephone call is scheduled to answer his or her questions. Following this step, the claimant is asked to sign and return a form to NIOSH that indicates that he or she has no additional information to provide NIOSH on this case. Once this form is received, the dose reconstruction is forwarded to DOL for final adjudication. The major steps involved in processing a claim for dose reconstruction are provided in Fig. 1.

The more complex the case, the more time and effort is required to search through the dosimetry records, clarify information regarding the nature of the radiation sources, and confirm the exposure situations with regard to locations and time. In general, exposures involving the internal deposition of radionuclides are more complicated than those involving only external exposures. This is especially true when the exposures occurred in conjunction with facility processes of a complex nature; where there are uncertainties in the monitoring methods that were used; and/or where there was a potential for the

intake of radionuclides through a combination of pathways, such as ingestion, inhalation, and absorption through intact skin or wounds.

ENSURING EFFICIENCIES

A primary objective in developing the dose reconstruction program has been to ensure that the processing of claims would be effective, efficient, and timely. While it was essential to ensure that each claim received adequate attention, it was equally important that unwarranted time not be devoted to a claim for an energy employee whose radiation dose is obviously at an exposure extreme; that is, the individual was exposed to an amount of radiation either well above or below the level required to be awarded or denied compensation. If these policies were to be successfully implemented, every opportunity for incorporating efficiencies into the reconstruction process had to be identified and incorporated. The existing program accomplishes these objectives through the following approaches:

- In cases where it is evident from the record of external radiation exposures alone that a DOE employee incurred a sufficiently high dose to qualify for compensation, NIOSH will complete the dose reconstruction without spending the time and effort that would be required to estimate the additional dose contribution from internal exposures. Likewise, when internal doses alone qualify the claim for compensability, external doses need not be reconstructed;
- If records and information appear to indicate that an employee incurred radiation doses well below a level that would result in compensation, the dose reconstructors will substitute a bounding value constant dose. The bounding value is based on worst-case assumptions in lieu of performing additional research and

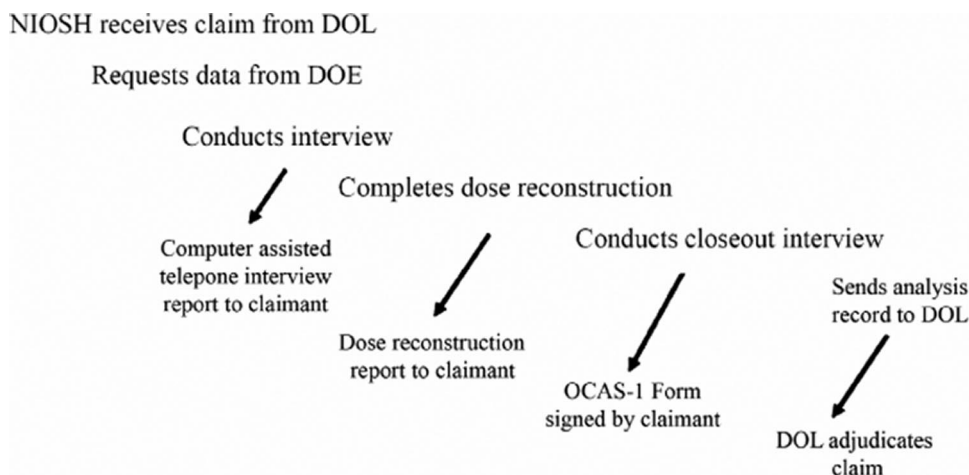


Fig. 1. Schematic presentation of the major steps involved in processing a claim for dose reconstruction.

produce a distribution of PC estimates. The decision whether compensation is warranted is based on this PC calculation (U.S. DHHS 2002a). Other terms used for expressing this concept are “assigned share” and “attributable risk percent.” For purposes of the NIOSH radiation dose reconstruction program, the PC is calculated by dividing the risk of cancer attributable to the radiation exposure (RadRisk) by the sum of the baseline risk (BasRisk) of cancer for the general population plus the RadRisk. In each case, the input values for each of these factors are for the specific cancer that the claimant has suffered. To express the result as a percentage, the outcome (quotient) is multiplied by 100%:

$$PC = \frac{\text{RadRisk}}{\text{RadRisk} + \text{BasRisk}} \times 100\%.$$

In terms of perspective, an evaluation that yields a PC of less than 10% means that there is very little likelihood that radiation caused the cancer; an outcome of 70–80% means that there is a very high probability that radiation caused the cancer.

In accordance with the requirements of EEOICPA, U.S. DHHS (2002a and b) promulgated regulations that can be used by DOL to determine whether an energy employee who had developed a cancer was, as previously noted, “at least as likely as not” to have sustained it due to occupational exposure to ionizing radiation. Under terms of this requirement, an individual would warrant compensation if the PC calculation indicated that the cancer had “a 50% or greater probability” of having been caused by the estimated radiation doses incurred under the described circumstances. To ensure that a claimant’s compensation decision would consider the uncertainty inherent in the risk models and dose estimates, Congress stipulated that the PC be evaluated at the upper 99% credibility limit (U.S. Congress 2000). Additional information on the NIOSH-IREP code and the implications of the 99% credibility limit value is provided in subsequent papers in this issue (Kocher et al. 2008; Merwin et al. 2008a).

As may be noted from the equation above, a PC estimate of 50% means that the estimated radiation dose was sufficient to yield a probability of the development of a specific cancer that is equivalent to the baseline rate (BasRisk). Interestingly, the BasRisk is highly dependent on the lifestyle and living habits of each individual employee. In IREP, the only adjustment made for lifestyle choice is for cigarette smoking. Because a cigarette smoker has a higher BasRisk of lung cancer than does a nonsmoker, the dose to the lungs necessary to yield an estimated PC equal to or greater than 50% for a smoker is higher than that for a nonsmoker.

OPERATING GUIDELINES

NIOSH has indicated that it may periodically revise the compensation procedures to incorporate new scientific information. Such revisions may involve adding, modifying, or replacing cancer risk models, adopting new dosimetry models recommended by the International Commission on Radiological Protection (ICRP), adjusting the modeling of uncertainty, and improving the functionality and user interface of NIOSH-IREP. Such changes may be recommended by NIOSH, the congressionally established Advisory Board (Ziemer 2008), DOL, independent organizations such as the National Academy of Sciences-National Research Council, and members of the public. Prior to adoption by NIOSH, changes that would substantially affect estimates of the PC will be submitted to the Advisory Board for review. If NIOSH changes any components of the risk or dose calculation models, previously completed dose reconstructions will be reviewed. If this confirms that a case, previously determined not to warrant compensation, would be sufficiently affected by such changes as to increase the PC so that the new value would equal or exceed 50%, the dose reconstruction will be reevaluated and the new dose reconstruction submitted to DOL. This is to ensure that all claimants are provided the same level of consideration regarding the compensation determination.

ENSURING THE “BENEFIT OF THE DOUBT”

One of the foundations of the dose reconstruction program is to consistently and reasonably provide claimants the “benefit of the doubt” whenever the available technical information is so ambiguous that there are two or more equally plausible exposure scenarios. This is especially relevant to policy decisions and technical procedures involving factual or scientific unknowns and uncertainties. Some of the changes made by NIOSH in the original IREP, prepared by the National Cancer Institute, reflect this philosophy. Other examples of the application of the “benefit of the doubt” are:

- For best estimate dose reconstructions, analysts take into account the uncertainties associated with the radiation dose estimates. These uncertainties, as well as the uncertainties in the risk models, are reflected in the estimate of PC provided by IREP (U.S. DHHS 2002a);
- One early stage cancer, commonly known as carcinoma-in-situ (CIS), is evaluated as a malignant neoplasm at the specified site. This is because, while current risk models do not specifically include cancers detected in their early stages, the risk factors for CIS frequently are similar to

those for its corresponding malignant neoplasm. There also is increasing evidence that CIS represents the earliest detectable phase of malignancy;

- A method was established to ensure that cases without an identified primary cancer location, but with information on secondary cancer site(s), can be evaluated. To accomplish this, NIOSH has developed a table that identifies the sites of the primary cancers that produce a majority of the secondary cancers diagnosed among members of the U.S. population (U.S. DHHS 2002a). In cases where a secondary cancer, but no primary cancer, is identified, evaluations are made of all the likely primary cancer sites to determine the one with the highest PC at the ninety-ninth percentile;
- Whenever possible, the estimated dose for skin cancer is based on the location on the skin where the cancer occurred. However, in cases where the location of a cancer has not been specified, the maximum skin dose at any location on the body is used as input for estimating the PC (NIOSH 2002);
- For situations where the solubility class of a radionuclide cannot be determined, the class that results in the highest dose to the organ will be used (Brackett et al. 2008); and
- In some cases, information on the energies of the neutrons involved in certain exposures is not available in DOE records. In these cases, NIOSH assigns the energies to be used in evaluating the claims. To ensure that the claimant receives the "benefit of the doubt," NIOSH ensures that the energy selected is the most favorable to the claimant, while being consistent with the available information (Merwin et al. 2008b).

Details of the claimant-favorable methods, assumptions, and parameters inherent in the program (including a tabulation of more than 30 such sources of claimant favorability), their overall impacts on the reconstructed doses and the calculated PCs, and the associated implications are discussed elsewhere in this issue (Merwin et al. 2008a).

DEVELOPING AND APPLYING INNOVATIVE CONCEPTS

In the course of the radiation dose reconstruction program, a number of innovative concepts have been developed and applied. One is to ensure that the methodologies being applied in the program reflect, on a continuing basis, the latest advances in the scientific principles of risk assessment and radiation dose reconstruction. For example, assessing internal exposures incorporates current knowledge, concepts, and data, such as those generated by the ICRP, from ongoing research on the metabolic properties of radioactive materials. A

second innovation is the concerted effort to ensure that all sources of radiation exposures in the work environment of each employee are addressed. As part of this effort, dose contributions from diagnostic medical x-ray examinations, required as part of the claimant's employment, are included. Under the recommendations of the ICRP (1991) and the National Council on Radiation Protection and Measurements (NCRP 1993), for purposes of dose assessments for regulatory compliance, this would not have been the case. In a similar manner, exposures to radon and its decay products, incurred in conjunction with the work of an employee, likewise are being included for those sites and job locations where the exposures were elevated above background levels by DOE operations. A third innovation is the careful consideration, where appropriate, of ethnicity in relation to the dose necessary to warrant a favorable decision on compensation. Care is taken to ensure that appropriate adjustments are incorporated into the determination of PC for both malignant melanomas and non-melanoma skin cancers according to ethnicity.

COMMENTARY AND CONCLUSION

While many of the dose assessments have been straightforward, some have proved to be extremely complex due to missing, non-interpretable, and/or undocumented records; a wide variety of external and internal exposure conditions; and highly variable workloads on the part of the claimants. Another example of this complexity is that, for purposes of dose reconstruction, estimates of the doses due to internally deposited radionuclides are limited to those that were actually delivered during the time between the first exposure and the diagnosis of the cancer, not on the basis of the 50-y committed dose that normally is used for purposes of radiation protection. Fortunately, there are other aspects of the processing requirements that have tended to reduce the complexity of the reviews and analyses, including the fact that the required dose estimates are for individual body organs, not the whole body.

The number of claims that the NIOSH Radiation Dose Reconstruction Program ultimately could process may double or triple. This work will include reviewing the applicable records, filling data omissions, estimating the doses that occurred, computing PCs, and submitting the results to DOL to render a compensation decision. Although this was recognized as a formidable challenge even prior to the initiation of work, it also was realized that success depended on the development of the necessary infrastructure to ensure that the processing of claims would be efficient, effective, and timely. The result of this program is the development of a radiation dose reconstruction process that is based on the

best available science with every effort being made to ensure that each claim is reviewed and evaluated thoroughly.

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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