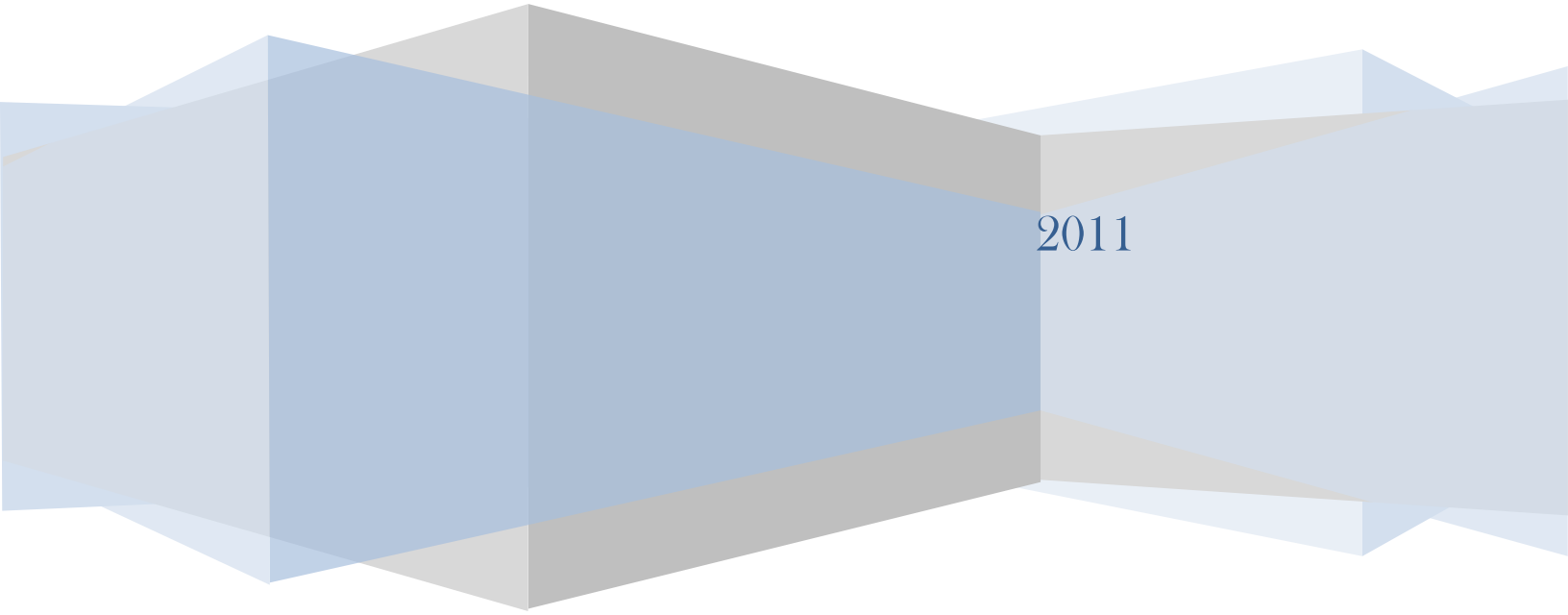
NIOSH Radiation Dose Reconstruction Program

Ten Year Review – Phase I Report

Quality of Science

Robert Daniels
Henry Spitz



2011

Quality of Science

Quality of Science

Submitted By

Robert Daniels and Henry Spitz

Contents

Tables

Figures

Quality of Science

Background

Part B of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), establishes a compensation program for workers with certain cancers determined more likely than not to be the result of employment in nuclear weapons-related activities managed by the U.S. Department of Energy (DOE), or its predecessor agencies [U.S. Congress 2000]. In carrying out the Act, the U.S. Department of Health and Human Services (HHS) was tasked with several policymaking and technical roles, including the development and application of methods to estimate radiation doses for individuals applying for benefits under EEOICPA (Executive Order 13179). The exposure estimates are necessary for science-based adjudication, whereby claims are awarded to individuals who are ''at least as likely as not,'' to have developed cancer caused by their exposure to ionizing radiation during their employment in the U.S. nuclear weapons production program. Regulations promulgating these methods were published in 2002 (42 CFR Part 82), effectively establishing a program of "dose reconstruction" required by EEOICPA and delegated to the National Institute for Occupational Safety and Health (NIOSH).

As of April 2010, nearly 32,000 cases had been referred to NIOSH for dose reconstruction under Part B. Of these cases, a dose reconstruction was completed for 23,827 (75%). Dose reconstruction under Part B is arguably the most complex and dynamic element of the program; requiring expertise in the gathering and analysis of information necessary to determine a probability of causation from occupational exposures. Thus, it is not surprising that dose reconstruction is a key determinant in the timeliness and expense of claim processing. On average, dose reconstruction adds nearly two years to the claim process at annual costs in excess of $55 million [GAO 2010]. Given its critical role in adjudication, NIOSH dose reconstruction has also been subject to intense criticism. To date, the majority of complaints received by the U.S. Department of Labor's (DOL's) Office of the Ombudsman concerning its program under Part B of EEOICPA are related to dose reconstruction [DOL 2009]. Most issues raised are related to the timeliness and complexity of dose reconstruction; most notably, questions have surfaced on the reliability and validity of the methods used to estimate doses when information is sparse [GAO 2010; DOL 2009].

Within NIOSH, the Division of Compensation Analysis and Support (DCAS)[1] carries out the responsibilities of dose reconstruction to obtain "reasonable" estimates of radiation doses to covered employees seeking compensation. Here, the term reasonable refers to estimates that are well-based in science, timely, and fair. Scientifically based estimates include assurances of objectivity, reliability, and validity in the methods used. However, dose reconstruction must be timely as well as accurate and precise because of its critical role in serving persons suffering from severe illnesses. Finally, estimation methods are intended to be fair, indicating that claimant-favorable assumptions will be made when

[1] Formerly known as the NIOSH Office of Compensation Analysis and Support (OCAS)

exposures are uncertain. Given that dose reconstruction requires a balance of science, timeliness, and fairness, results used in adjudicating an individual's claim under EEOICPA are not likely to be the most precise or accurate estimates of his or her true radiation dose.

Ideally, dose reconstruction incorporates information from detailed records of personal radiation exposure monitoring that was conducted during a covered period of employment. However in practice, individual exposure monitoring data are often incomplete or inadequate to stand alone as reasonable estimates of dose. Under the final rule, NIOSH is responsible for evaluating the completeness and adequacy of individual monitoring data (42 CFR 82, §82.15) and, when practical, providing a remedy for information gaps (42 CFR 82, §82.15). There are three categories of exposure information that are unequivocally identified as appropriate supplemental monitoring information for covered individuals under EEOICPA:

1. Monitoring data from coworkers, if NIOSH determines they had a common relationship to the radiation environment (42 CFR 82, §82.17(a));
2. A quantitative characterization of the radiation environment in which the covered employee worked, based on an analysis of historical workplace monitoring information such as area dosimeter readings, general area radiation and radioactive contamination survey results, air sampling data (42 CFR 82, §82.17(b));
3. A quantitative characterization of the radiation environment in which the employee worked, based on analysis of data describing processes involving radioactive materials, the source materials, occupational tasks and locations, and radiation safety practices (42 CFR 82, §82.17(c)).

These sources are listed in order of preference of the best available information for use in dose reconstruction in the absence of individual monitoring data (42 CFR 82, §82.2). Moreover, these sources are not mutually exclusive; sources can be used in combination to improve dose estimates as long as the hierarchy is not violated.

Purpose and Scope

NIOSH is committed to conducting the highest quality of science in its programs by applying state-of-the-art scientific methodologies and practices. In addition, NIOSH recognizes the importance of program transparency and responsiveness to the needs and concerns of program stakeholders. Thus, In February, 2010, NIOSH initiated a comprehensive program review and solicited public comment on its Radiation Dose Reconstruction Program that is conducted pursuant to requirements under the EEOICPA [U.S.

Congress 2000]. The purpose of the review is to gauge the effectiveness, relevance, and responsiveness of the program. The review focuses on five program elements:

- The quality of science practiced in the program;
- The timeliness of accomplishing program tasks;
- The appropriateness and the consistency of decisions regarding petitions to add groups of claimants to the Special Exposure Cohort (SEC);
- The appropriateness and the consistency of decisions on individual dose reconstructions; and
- The responsiveness to claimants and petitioners, and their representatives under the program.

The current report addresses the first of these elements, namely the quality of science demonstrated throughout the program's ten-year evolution. In evaluating this program element; reviewers investigated a number of key questions regarding science quality, such as:

1. When reconstructing employee radiation exposures where records are incomplete or missing, has NIOSH relied on the type of data that provides the most accurate estimate of a worker's exposure?
2. In the absence of measurement data on individual claimants, has NIOSH relied on scientifically valid surrogate data (such as dose measurements for other workers who were employed in the same work location or in similar work processes) to calculate exposure estimates?
3. Has NIOSH appropriately accounted for the possibility that instruments used to measure employee exposures in given instances may not have been sufficiently sensitive to detect low levels of radiation?

These questions focus on NIOSH's approach to handling instances of incomplete or inadequate monitoring data when performing dose reconstructions. Therefore, the scope of this review is limited to assessing the quality of science related to the use of supplemental information in dose reconstruction. In particular, we examined current and past practices of using coworker and surrogate data in estimating doses when direct monitoring data were unavailable. NIOSH distinguishes between these general sources of proxy information, whereby "surrogate data" refers to exposure information from facilities other than the site where the affected worker was presumably exposed and "coworker" information is exposure data from similar workers (i.e., comparable exposure risks) within the exposure site.

Quality of Science

Review Structure

Two researchers were assigned to conduct this phase of the review; one reviewer focused on issues related to coworker models while the other examined the use of surrogate data. Each reviewer was provided with complete access to DCAS technical documents and information contained in databases supporting dose reconstruction, such as the Site Research Query Interface (SRQI), Document Control and Tracking Application (DCTA), and the NIOSH OCAS Claim Tracking System (NOCTS). Telephone and in-person interviews were conducted with the staff responsible for dose reconstruction. The reviewers also accessed public comment regarding the review, which was available from NIOSH Docket 194.

This review consists of four parts. The first part discusses general areas of the DCAS dose reconstruction program in the conduct of indirect methods of exposure assessment. A summary of findings is provided at the end of the discussion for each area examined. Many program elements were broadly examined, including:

- The statutory authority for the methods used;
- The scientific precedence and state-of-the-art exemplified in research and other compensation programs;
- The quality of documentation; and
- The transparency the program.

Clearly, these program elements serve more than the quality of science in indirect exposure assessment; therefore, the findings and recommendations from our review may have relevance in other program areas.

The second part of the report summarizes the results from our review of external coworker analyses. Key aspects examined included:

- The data sources relied on for exposure inference;
- The soundness of methods used to construct models and estimate doses; and
- Examinations of reliability and validity of the methods chosen.

We discussed the three basic steps to developing coworker models for estimating external doses; namely data selection, adjustments made to the data, and analysis and reporting of results. Although, these details are specific to external coworker models, the findings and recommendations may be applicable to internal coworker models and other dose reconstruction methods given similarities in the models used. Findings and recommendations for program improvement are summarized at the end of the discussion on each step.

This part also includes a replication of the coworker model for external doses at the Oak Ridge Gaseous Diffusion Plant (ORGDP) using information from a previous epidemiologic study [Yiin et al. 2009] and methods outlined in the associated DCAS TIBs [ORAU TEAM 2006a; ORAU TEAM 2008c]. The purpose of this analysis was to examine the reliability of estimates from coworker analyses, which is an important measure of the quality of science.

The third part of the report discusses information from recent public comment on issues relevant to the quality of science and provides a summary of the findings and recommendations stemming from our review.

Finally, we summarize our review pertaining to the use of surrogate data in Appendix A. This portion of the review provides a more in-depth discussion on the methods currently used by DCAS researchers to estimate exposures to claimants when direct measurement data for the individual or affected site are unavailable. Additional recommendations pertaining to the use of surrogate data are presented at the end of the appendix. It is important to note that the review presented in Appendix A was conducted by a second reviewer working independent of, and concurrent with the reviewer who wrote the main body of the report; therefore, there is some redundancy in the information presented.

General Review Areas

Authority

Authority for using coworker data as supplemental information is explicitly stated in the final rule (42 CFR 82, §82.17(a)). The use of these data in dose reconstruction is acceptable if DCAS determines that a common relationship exists between the coworker and the claimant with respect to the radiation environment. For the purposes of assessing commonality, DCAS defined coworkers as "…workers at a site (potentially grouped by work location, job description, or other appropriate category) whose measured doses are considered representative of those that were received by one or more claimants with no individual monitoring data" [ORAU TEAM 2008c].

The use of surrogate data in dose reconstruction is not explicitly addressed in current EEOICPA regulations. Instead, DCAS interprets that these data are acceptable to assist in characterizing the radiation environment of an affected facility, as addressed in [42 CFR 82, §82.17(c)], provided that the exposure conditions under which the surrogate exposure data originated are representative of conditions in the affected facility at the time of the claimant's exposure [OCAS 2008]. Furthermore, in addressing the feasibility of estimating individual doses, current regulations specify that NIOSH must use *some* information from the site where the individual worked but is not limited to information obtained exclusively or primarily from the affected site [42 CFR 83, §83.13(c)(i)]. For dose reconstruction, DCAS

stipulates that, at a minimum, the affected site information must be sufficient to identify the radionuclide(s) or radiation generating equipment that was present.

Summary

The use of information from coworkers in dose reconstruction is clearly authorized under the rule [42 CFR 82, §82.17(a)]. Thus, as long as the prescribed hierarchy of data is maintained, coworker data can and should be used in dose reconstruction. In contrast, the authority for using surrogate data is equivocal and continues to be a matter of considerable debate. On the one hand, the rule clearly charges NIOSH with filling information gaps, where feasible (42 CFR 82, §82.15). Moreover, dose reconstruction is judged infeasible based on a rigorous assessment of information sources that are not restricted to the affected facility [42 CFR 83, §83.13(c)(i)]; therefore, surrogate data appears to be a viable source of exposure information for dose reconstruction. On the other hand, surrogate data are not explicitly mentioned in the hierarchy of information used in dose reconstruction. It has been argued that, without explicit mention in the rule, surrogate data are inappropriate in dose reconstruction [ABRWH 2010; McKeel 2010].

We find that that the debate surrounding surrogate data is centered on policy interpretation rather than issues of science. We acknowledge that it is often difficult to reconcile opposing legal and scientific viewpoints; thus we understand that decisions regarding the use of surrogate data must be dealt with judiciously. Nevertheless, we are mindful that a tenet of exposure assessment is to improve the reliability and validity of estimates using any and all information that is made available. Thus, in a purely technical sense (i.e., without regard of legitimacy or policy), we find no fault in using surrogate data in dose reconstruction provided that the data complement, but not supplant, information from preferred sources clearly listed in the rule.

Scientific precedence

Epidemiologic Studies

In occupational epidemiology, one relates the occurrence of disease in a study population to some exposure measure. Ideally, exposure levels are quantified for each study participant by sensitive, specific, precise and accurate measurements [Checkoway et al. 2004]. However, adequate individual exposure monitoring for most hazardous substances encountered over the course of employment is rarely available in industrial settings. Thus, indirect methods of retrospective exposure assessment have become commonplace in occupational studies. The job-exposure-matrix (JEM) is a widely used method of inferring exposures whereby employment information (e.g., job title, department, and plant) is systematically linked with available coworker exposure information (e.g., area and personal monitoring data) and time of exposure [Benke et al. 2000; Hoar 1983]. These methods have been used in

conjunction with algorithms and statistical models to fill in gaps in exposure information during time periods when monitoring data were unavailable [Dement et al. 1983; Eisen et al. 1984; Hallock et al. 1994; Hornung et al. 1994; Woskie et al. 1988].

The origin of the JEM is debatable given that linking exposures, occupations, and disease is the very essence of occupational epidemiology. Nevertheless, Hoar [1980] is generally credited with developing the first JEM that systematically linked hazardous substances to job titles for an epidemiologic study. JEM methods rapidly developed shortly thereafter, resulting in methods relating measurements to other exposure determinants in models serving a wide variety of industrial settings. Notable early works involved exposures to silica [Eisen et al. 1984; Rice et al. 1984], asbestos [Dement et al. 1983; Gardner et al. 1986], solvents [Blair et al. 1986; Ford et al. 1991] and benzene [Rinsky et al. 1987; Wong 1987]. Efforts have continued from this foundation as evidenced by several recent studies on benzene exposures in the petroleum industry [Armstrong et al. 1996; Glass et al. 2000; Lewis et al. 1997; Panko et al. 2009]. There are several comprehensive reviews on data sources, assessment methods, uncertainties, and validation techniques available [Checkoway and Eisen 1998; Goldberg et al. 1993; Kauppinen 1994; Seixas and Checkoway 1995; Stewart and Dosemeci 1994; Stewart et al. 1996].

Unlike chemical hazards, monitoring data are typically available for occupational ionizing radiation exposures; thus, indirect exposure assessment methods are less prominent in epidemiologic studies of nuclear workers. Nevertheless there are notable examples of using coworker or other proxy information in exposure assessment for radiation epidemiology. For example, in studies of nuclear test participants, Grimson et al. [Grimson et al. 1983] estimated doses for unmonitored military units present during weapons testing based on nonparametric statistical assessments of monitored personnel. In early Oak Ridge facility studies, Watson et al. [1994] assigned exposures to unmonitored workers using a combination of "nearby" and coworker methods. Nearby methods [Strom 1983] have been used in several radio-epidemiologic studies to interpolate exposures in unmonitored periods using the worker's existing dosimetry data from adjacent periods [Brown et al. 2004; Richardson et al. 1999; Richardson and Wing 2007; Schubauer-Berigan et al. 2007; Watson et al. 1994; Yiin et al. 2009]. When nearby coverage was incomplete, Watson et al. [1994] used the dose distributions from available monitoring data of similar workers (i.e., typically characterized by occupation, gender, and calendar year of employment) as the basis for dose estimation. Dupree et al. [1995] linked uranium air sampling data to employment information (i.e., job, location, and time) to estimate exposures for a study examining the relation between uranium dust exposures and lung cancer. Watkins et al. [1997] estimated exposures for unmonitored X10 and Y12 workers using employment histories and exposure information on coworkers. Eheman et al. [1999] developed a JEM for a population based case control study of occupational radiation exposure and non-Hodgkin's lymphoma. In that study, researchers estimated annual dose distributions for a range of occupational and industrial groups using published data.

Similarly, Simon et al. [2006] estimated annual doses to radiation technologists prior to 1960 based on a synthesis of data from peer-reviewed literature reports of quantitative film badge results and in-place radiation protection standards. Most recently, Hamra et al. [2008] estimated tritium doses to unmonitored workers at the Savannah River Site using a JEM that linked qualitative information on job, area, and time to available measurement data. Similar estimation methods are referenced in other radiation-related epidemiologic studies [Kubale et al. 2008; Schubauer-Berigan et al. 2007; Yiin et al. 2009].

Notable Differences between Health Studies and Dose Reconstruction:

In some health studies in which quantitative individual or aggregate estimates are not feasible, researchers have relied on qualitative exposure estimates (e.g., low, medium, high) or self-reported information, neither of which is acceptable in EEOICPA dose reconstruction. In other cases, aggregate data are used to estimate exposures to populations or groups of workers that may poorly represent exposures to a particular individual because of variance heterogeneity. Thus, some methods deemed appropriate in the context of examining the relation between disease and agents within an exposed population, are not translatable to an individual worker for the specified purpose of compensation.

JEMS used in epidemiologic studies typically include strata to represent spatial variance, such as job and location variables, in addition to adjusting for temporal factors. These strata reduce Berkson error induced by aggregate exposure estimates and also provide a means to account for exposure heterogeneity. In contrast, DCAS coworker models include few exposure determinants. These models are based on an assessment of annual exposure distribution at the facility level; therefore, the underlying assumption is that the average exposure for every person under observation is the same within that year. Studies have shown that exposures between and within workers can vary widely [Johnston et al. 1986; Kromhout et al. 1993; Rappaport et al. 1993; Rappaport et al. 1995]. For example, Johnston et al. [1986] examined annual dose distributions of 25 groups of nuclear workers (n=1810) from five countries. That study found correlations between annual doses between subgroups and within individuals. Furthermore Johnson et al. [1986] found within-worker correlations that persisted for several years, suggesting that some workers may be "dose-prone". Thus, it is conceivable that quantiles drawn from the data for the population under observation may differ markedly from quantiles pertaining to data from subgroups within the population. Many of the datasets used for coworker analyses include employment information. Also, methods for examining variance heterogeneity have become commonplace with the onset of statistical modeling, especially the use of mixed models in exposure assessment [Burstyn et al. 2000; Friesen et al. 2005; Nylander-French et al. 1999; Peretz et al. 2002; Rappaport et al. 1999; Symanski et al. 1996]. Thus, the apparent lack of analyses examining between- and within-worker variance components in DCAS coworker models is remarkable. At the very least, a rigorous examination of the internal validity of coworker models may buttress claims of

claimant-favorability by demonstrating that methods currently used are robust to the effects of variance heterogeneity.

In addition to internal validation, contemporary epidemiologic studies that rely on surrogate exposure information typically include a rigorous and systematic evaluation of the external validity of exposure assessment methods. Here, external validity refers to the transportability of exposure information from the characterized exposure scenario to the exposure scenario under evaluation [Lyles et al. 2007; Tielemans et al. 2002]. Of course, it is understood that validation, in the formal sense, is not feasible because information on true exposures is not available in most cases. We also acknowledge that recent emphasis on validation methods in epidemiologic studies are most likely a direct consequence of a shift in study aims from hazard identification to quantification of risk. Thus, using a graded- approach to validation methods may prove that quantitative validation may be less valuable in situations in which obviously bounding assumption are used, or when the conduct of validations may cause unnecessary delays in claimant-favorable adjudication. Nevertheless, methods to systematically assess the external validity of indirect exposure assessment methods against a defined gold standard only serve to strengthen confidence in exposure estimates.

Finally, exposure assessment methods in epidemiologic studies are meant to reduce random error and systematic biases that may affect risk estimates for a population under study. Nevertheless, it is generally accepted that some uncertainty in the exposure to an individual or even a group of individuals is not likely to significantly affect estimates of relative risk in a study population provided the sources of uncertainty are not differentially associated with the outcome under study. In contrast, we must be mindful that EEOICPA dose reconstruction is conducted to assess the probability of causation for *the individual* and even a small bias may play a large role in a compensation decision. Thus, fairness dictates caution when translating methods meant for assessing aggregate risks to that of assessing individual risk.

Summary

Overall, we find that methods of indirect exposure assessment in DCAS coworker analyses are similar but less refined than those used in published occupational studies. Like dose reconstruction, epidemiologic studies have rarely benefitted from complete exposure information and most have had to rely on exposure proxies to conduct dose-response analyses. Given NIOSH's long standing history in the field of occupational epidemiology, it is not surprising that many of the methods used in its dose reconstruction program are well-grounded in exposure science supporting epidemiologic studies. However, there are some noteworthy differences between indirect exposure assessment in health studies and DCAS dose reconstruction that merit consideration. We found that existing coworker models may benefit from the inclusion of information on other exposure determinants such as job titles

and location, which is a common strategy of JEMs supporting health studies. We also noted that dose reconstruction often lacked internal and external validity testing. Including the results of validity tests or broadening the examination of model limitations would strengthen assurances of credible and claimant-favorable estimates. We recommend that DCAS consider the epidemiologic literature more closely in this regard.

In conclusion, we are mindful that methods suitable for epidemiologic studies are not necessarily translatable to dose reconstruction. For example, qualitative estimates used in some occupational studies lack the precision necessary to adequately assess exposures to a covered individual for EEOICPA purposes. We must also consider that statistical models, which are commonly used to assess the risk to a population under observation, may be poorly suited to estimating individual risk, especially for those in outlying regions of dose distributions. Nevertheless, a more rigorous approach to model development and validity testing may uncover weaknesses in assumptions used and give credence to claims of claimant-favorability.

Other Compensation Programs

Radiation Exposed Veterans

The Radiation-Exposed Veterans Compensation Act was signed into law in 1988, establishing a compensation program for nuclear test veterans. The U.S. Department of Veterans Affairs (VA) administers the program that covers approximately 400,000 military service personnel who: 1) took part in U. S. atmospheric nuclear-weapons testing between 1945 and 1962; 2) were stationed in Hiroshima or Nagasaki, Japan, during the period of occupation (August 6, 1945 through July 1, 1946); or 3) were prisoners of war in Japan at the time of the bombings in 1945 and had exposure potential that was similar to occupation forces. The Defense Threat Reduction Agency (DTRA), formerly the Defense Nuclear Agency (DNA), is responsible for providing dose estimates when necessary for adjudicating claims. The program has a presumptive component (§38 CFR 3.309), which covers 21 select cancers that are compensable if adequate proof of test participation is provided, and a nonpresumptive component (38 CFR 3.311), which covers other radiogenic diseases (e.g., all other cancers). Adjudication of claims for nonpresumptive diseases requires dose reconstruction.

Dose reconstruction is performed under the Nuclear Test Personnel Review (NTPR) Program. Claimant doses are estimated in accordance with policies and procedures described in 32 CFR Part 218 and in a series of standard operating procedures and guidance manuals [DTRA/NPTR 2010a; DTRA/NPTR 2010b; DTRA/NPTR 2010c; DTRA/NPTR 2010d; DTRA/NPTR 2010e; DTRA/NPTR 2010f; DTRA/NPTR 2010g; DTRA/NPTR 2010h; DTRA/NPTR 2010i]. As one of the earliest radiation compensation programs, the NTPR program has been evolving for nearly three decades. Similar to EEOICPA cases, complete exposure histories from personal monitoring are often unavailable for claimants. In fact, less than half of the

estimated 220,000 participants in atmospheric nuclear weapons tests have any film badge data available [§32 CFR 218.1(b)]. Thus, the NTPR program routinely uses exposure information from other sources, in conjunction with proven statistical methods, algorithms or dose reconstruction modeling, to estimate claimant doses. For example, film badges assigned to individuals within a military unit may be used as a surrogate for an individual's dose in the presence of a common relationship in exposure factors [§32 CFR 218.1(d)(2)]. In other instances, doses are assessed using "standard scientific practice" that incorporates information on a particular test site, test series, and job descriptions (such as observer only, maneuver troops, sailors on support ships, boarding parties on target vessels, etc.) to model individual exposures in time and space [§32 CFR 218.1(d)(3)]. In all scenarios, claimant favorable assumptions are used to provide an upper-bound estimate of the total dose, which is then used to determine the probability of causation of a nonpresumptive cancer.

The NPTR methods were recently reviewed by a Committee of the National Research Council [NRC 2003]. Although the Committee made several recommendations for improving the consistency of dose reconstructions, most recommendations were centered on improvement to policies and procedures, rather than technical issues of dose assessment and modeling. Most notably, the Committee was concerned about the credibility of assumed exposure scenarios and issues of quality management, especially documentation of standard operating procedures and individual case files. We note that the Committee raised concerns over whether methods of dose reconstruction and uncertainty analysis provided credible upper bounds (at least upper 95 % credibility limits) of dose in all cases, which is always an important consideration when using inferred dose for evaluating the probability of causation. The Committee was especially critical of NPTR's seemingly underuse of claimant provided information in constructing plausible exposure scenarios. Specifically, the Committee found a pattern of failures in considering claimant's recollections of exposure events and disqualifying such recollections for insufficient reasons. In response to these concerns, an action plan was developed to modify NPTR procedures and improve upon the use of claimant information [Cooper and Klein 2004].

Radiation Exposure Compensation Act

The Radiation Exposure Compensation Act (RECA) was passed by Congress in 1990 and broadened on July 10, 2000 (http://www.justice.gov/civil/torts/const/reca/about.htm). The program is administered by the U.S. Department of Justice (DOJ) and regulations concerning RECA claims are codified under Title 28 CFR Part 79. RECA establishes lump sum compensation awards for individuals who contracted specified diseases, including cancers, in three defined populations: 1) uranium miners, millers, and ore transporters; 2) individuals present at atmospheric nuclear weapons tests; and 3) and individuals who lived downwind of the Nevada Test Site. In general, eligibility criteria include components of disease, exposure, and covered period. However, the compensation scheme includes exposure assessment for uranium miners only and limits this assessment to quantifying cumulative exposure to radon and its

short-lived progeny. Meeting exposure eligibility criteria for other groups in the program is determined by employment histories or place of residence during the covered periods, or combinations thereof.

The RECA program has undergone a number of independent reviews, including a recent review by a committee of the National Research Council [NRC 2005]. The review did not specifically comment on the current methods of exposure assessment used in the compensation program. However, the Committee made a number of recommendations suggesting the inclusion of probability of causation calculations in future compensation decisions. Specifically, the Committee suggested introducing a new process in which probability of causation is used to determine the eligibility of any new claim for compensation for a specified RECA-compensable disease in people who may have been exposed to radiation from fallout from US nuclear-weapons testing.

As previously mentioned, exposure assessment under RECA is limited to uranium miners; whereby to be eligible for compensation, miners must either have been exposed to 40 or more working level months (WLMs) of radiation (i.e., radon) while employed in a uranium mine or worked for at least one year in a uranium mine during the eligibility period (between the years 1942-1971). Personal radon monitoring was rarely, if ever, conducted in most mines. Furthermore, exposure data varied markedly within mines and monitoring coverage is lacking between mines and across time [Lundin et al. 1971]. Therefore, individual exposures are assessed based on employment histories and a hierarchy of available exposure information; whereby exposure data preference is determined by geographical proximity to the miner's location during the period in question [§28 CFR 79.44(g)]. For example, if data are not available for a particular mine during a given time period then information in nearby time periods or from nearby mines is used as a surrogate. If there are no nearby mines (or time periods), then data from regional mines, and then mines within the state are used. Finally, if state level data are unavailable the average radon concentration in Colorado is used. Thus, meeting the RECA eligibility criterion on radon exposure is judged based on estimates derived from exposure algorithms using surrogate data.

RECA exposure assessment methods provide an example of surrogate data use in compensation; however, there are notable program differences relative to EEOICPA. First, the use of surrogate data is explicitly defined under RECA regulations, presumably in acknowledgement of the limitations in available monitoring data that was known from previous epidemiologic studies. Second, risk models for radon exposures among miners were developed from studies using essentially the same data sources and exposure assessment methods described under RECA regulations. Thus, the information used to establish exposure criterion is the same as that used to judge claimant eligibility. Finally, compensation under RECA does not require a calculation of assigned share; therefore, a quantitative assessment of exposure uncertainty is not performed and the exposure assessment can be greatly simplified relative to EEOICPA dose reconstruction.

Quality of Science

The UK Compensation Scheme

The Compensation Scheme for Radiation-Linked Diseases (CSRLD) was established in 1982 as a joint agreement between British Nuclear Fuels (BNFL) and its trades' unions to provide an alternative to litigating radiation-related injury cases under the U.K. Nuclear Installation Act of 1965. (http://www.csrld.org.uk/html/scheme_history.php). Since 1982, the program has expanded to include thirteen employers and nine trade unions. Participation in the CSRLD is completely voluntary and in its 27-year history has processed about 1,500 claims and awarded compensation to 122 U.K nuclear workers. All malignancies are compensable under the program except for chronic lymphocytic leukemia, Hodgkin's lymphoma, melanoma of the skin, and mesothelioma. Similar to the approach used in DCAS dose reconstruction, the CSRLD uses the claimant's exposure information provided by the participating employer to calculate a probability of causation. However, rather than assigning a compensation threshold at 50% PC (as in the case of EEOICPA claims), the CSLD employs a process of proportionate recovery, whereby payment is prorated in four steps beginning at 20% PC until full payment is made at 50% PC. The claimant's dose histories are assessed according to protocols that have been agreed to by both labor and employers. These protocols included several claimant-favorable assumptions including adjustment for measurement uncertainty [Lewis 2002] and provisions of estimating neutron doses when monitoring data are absent [Wakeford et al. 1998]. However, dose reconstruction under CSRLD is greatly simplified in comparison with the methods used in DCAS dose reconstruction [Lewis 2004]. The CSRLD relies principally on the external and internal monitoring results supplied by the employer for individual's seeking compensation. The CSRLD does not consider other source terms (e.g., ambient dose, medical x-ray examinations) and dose estimates are not adjusted for attenuation, exposure geometry, and other factors that are considered in DCAS procedures to estimate tissue dose. The extent to which dose inference is made using indirect methods is uncertain, but it appears that some gaps in the dose record are filled using estimates based on upper values found in contemporaneous records or upper bound estimates from protection standards in place at the time of exposure. However, there is no evidence that CSRLD have developed exposure assessment methods that make use of coworker or surrogate data sources.

Summary

Among the compensation programs reviewed, the NPTR and CSRLD programs are most relevant to the science of dose reconstruction under EEOICPA. However, data on CSRLD dose reconstruction methods were sparse; therefore, only the NPTR program is discussed further. Methods of indirect dose inference used in the NPTR program are generally consistent with those used in EEOICPA dose reconstruction. Personal monitoring information is preferred for estimating doses in both programs. In the absence of personal monitoring data, each program makes use of surrogate exposure information from coworkers or other sources in algorithms or models for estimating dose. Of course, there are differences in the

breadth and depth of exposure assessment when comparing programs because there are considerably fewer exposure scenarios in the NTPR program relative to EEOICPA. These differences tend to magnify concerns over exposure assessment methods that tend to be more complex in situations related to EEOICPA. Nevertheless, the many program similarities suggest that some of the lessons learned from independent review of the NTPR program are relevant to the DCAS dose reconstruction program. In particular, concerns voiced by the NRC over the credibility of assumptions used in NPTR indirect exposure assessment methods, especially in areas related to characterizing uncertainty, should be carefully assessed by DCAS. DCAS indirect exposure assessment methods should provide assurances that assumptions on exposure scenarios are adequate; that is, these methods should assess whether other plausible scenarios could be developed that would result in higher dose estimates. Interestingly, similar complaints on the underuse of claimant supplied information have surfaced in worker outreach activities and public meetings [McKeel D. W. and Ramspott 2007]; Congressional hearings [Hostettler 2006; Kennedy 2007]; and recent correspondence in response to this review [Bennett 2010; McKeel 2010; Ray 2010]. DCAS should consider improving its methods of vetting information from workers. These methods are especially critical when developing credible and bounding exposure scenarios using surrogate data. Thus, a systematic and well documented approach that considers all information provided by workers on their exposures and work conditions may improve the credibility of current models.

Documentation

DCAS technical documents are "controlled" and are managed in a fashion that is similar to Standard Operating Procedures (SOPs) typically found in industries that have adopted high functioning quality management systems. Dose reconstruction documents conform to a layered structure of policies, plans, procedures, implementation guides, technical information bulletins and technical basis documents. Systems are in-place to standardize nomenclature, prescribe document format, and uniquely identify documents. All controlled documents are internally reviewed and require approval prior to issuance. Dose reconstruction methodologies are documented in a technical series, which is comprised mostly of technical basis documents (TBDs) and technical information bulletins (TIBs). A hierarchy is used whereby TBDs address background information and methods rationale, which is refined in one or more TIBs for a specific application. The DCAS dose reconstruction program has incorporated these points in its procedures on document control [ORAU TEAM 2005b].

DCAS guidance on coworker analyses is provided in several TIBs (see Table 1 and Table 2). The TIBs also follow a hierarchy whereby higher tiered TIBs describe the general methodologies for external and internal dose models [ORAU TEAM 2005c; ORAU TEAM 2008c], which are then refined in site-specific documents. Thus, coworker models typically rely on information in multiple TIBs and TBDs linked by site and by model type. For example, the external coworker model for the K25 site in Oak Ridge, Tennessee

Quality of Science

[ORAU TEAM 2006a] uses information on occupational external doses at K25 [ORAU TEAM 2006c], general methods of external dose reconstruction [OCAS 2007], and coworker modeling methodology [ORAU TEAM 2008c].

There are 11 TIBs addressing coworker models for external dose and another 7 TIBs that provide coworker information on internal doses. Current documents and previously approved versions are available as searchable PDFs, which are readily downloaded from a publicly accessible website maintained by DCAS. TIBs used to describe site coworker models contain: 1) a cover sheet, including approvals; 2) a record of revisions; 3) table of contents; 4) body including introduction, purpose and scope, background, approach, applications and limitations, methods (e.g., coworker data used, adjustment for missed dose), and results; and 5) list of citations. The documents are clearly written and well-organized with minimal use of jargon.

General guidelines for the use of surrogate data are presented in OCAS-IG-004, *The Use of Data from Other Facilities in the Completion of Dose Reconstructions under the Energy Employees Occupational Illness Compensation Program Ac* t [OCAS 2008]. The document is brief (11 pages) and is used principally to establish authority under the rule and illustrate minimum expectations in dose reconstruction applications. In practice, surrogate data usage is assessed on a case-by-case basis and appears to be limited to Atomic Weapons Employers (AWEs) who handled uranium and thorium metals. Specific applications of surrogate data in AWE dose reconstructions are described in two technical basis documents: Battelle-TBD-6000, *Site Profiles for Atomic Weapons Employers that Worked Uranium and Thorium Metals* [Battelle 2006b] and Battelle-TBD-6001, *Site Profiles for Atomic Weapons Employers that Refined Uranium and Thorium* [Battelle 2006a]. In each document, information pertaining to specific AWEs is identified in separate appendices. The former contained 16 appendices while the latter had only 5 appendices listed (Table 3). It is important to note that Table 3 does not list all applications of surrogate data. In fact, some of the earlier AWE site profile documents are recognized as the origin of surrogate data use in dose reconstruction. Most notably, the site profile document for Bethlehem Steel uses uranium air sample data from a similar facility (i.e., Simonds Saw, Inc.) to estimate bounding doses to affected workers employed during periods when monitoring data are incomplete. The document was first issued in 2003 and has been revised on two separate occasions. The current revision (July 26, 2007) reflects the resolution of a number of comments raised by SC&A during its review [OCAS 2006a].

Writing style and format were generally consistent among all documents reviewed; however, content varied markedly. Page counts for coworker TIBs ranged between 8 and 21 (median=10.5) for external analyses and between 10 and 55 (median=23) for internal coworker analyses. As expected, the amount of information provided was a correlate of the complexity of the analysis. Thus, internal coworker analyses, which potentially require the synthesis of information on several different radionuclides, were

typically more detailed than external coworker analyses. On average, technical basis documents describing the use of surrogate data were the most comprehensive. For example, each AWE site profile documents was well in excess of 50 pages excluding individual site appendices.

Because many DCAS technical documents share common methods or are linked by an established hierarchy, there is a potential to transfer technical inaccuracies between documents. For example, during our replication analysis of the K25 coworker model (see "Coworker Analysis Replication", page 37) we noted that the K25 coworker model was limited to "Phase I" dose reconstructions, which were defined as cases in which "best and final" dose estimates were not required for claim adjudication [ORAU TEAM 2006a]. However, there was no mention of this caveat in the cited parent document [ORAU TEAM 2008c]. On closer inspection, we realized that the discussion on dose reconstruction "phases" had been removed during a previous revision to ORAUT-OTIB-0020, thus the language expressing the caveat found in ORAUT-OTIB-0026 appeared orphaned. Moreover, this parent-child disconnect was observed in several other external coworker documents [ORAU TEAM 2004b; ORAU TEAM 2006b; ORAU TEAM 2006d; ORAU TEAM 2006e]. Based on subsequent discussions with DCAS staff, the limitation of Phase I dose reconstruction as stated in the site documents is no longer applicable. Thus, documents on site-specific external coworker models should be revised to better align requirements with the parent document, which had previously removed the limitation.

Problems associated with linked or referenced documentation may not be limited to the examples described above. For example, more recent versions of DCAS technical documents were available for all 6 citations listed in the current K25 external coworker model. The extent to which these revisions may have invalidated information used in the coworker model is unknown. Thus, DCAS should institute methods that comprehensively search for all instances of a document citation so that an assessment of the impact to related documents resulting from changes to cited documents can be performed.

Information on the life-cycle of some technical documents is available using a web-based database referred to as the *Document Control and Tracking Application* (DCTA). The database is used to track documents throughout all stages of development, including status on levels of review and resolution to review findings. Currently the database contains information on 121 documents with a total of 531 documented findings during the review/approval cycle. Given the number and complexity of DCAS technical documents, the DCTA appears to be an invaluable tool and noteworthy feature of the DCAS document management system. Nevertheless, we noted that descriptive statistics on documents in the database did not precisely agree with those recently reported to the Secretary of Health and Human Services (HHS) regarding document status (see discussion in "External review", page 29). There were instances in which reviews and associated findings were not recorded in the database or made available on the web. For example, SC&A reported on their review of Battelle-TBD-6000 in late 2007. However,

the report is still referred to as a "Working Draft" that has not been released to the public [SC&A 2007]. The report discusses 7 findings, 3 of which were considered closed by the working group.

Revision Process

A review of the record of revisions indicated that substantive changes to some documents have been triggered by ABRWH reviews, stakeholder comments, policy changes, or the receipt of new information. However, we note that there is currently no requirement to conduct periodic internal or external reviews and several technical documents have not been reviewed or revised since issuance several years prior. For example, of the 11 external coworker analyses, 4 (36%) were reviewed by the ABRWH and 7 (64%) have been revised at least once. Similarly, 4 of 7 internal coworker analyses (57%) have been reviewed but only 2 (29%) have been revised since issued. Finally, we note that none of the technical documents on surrogate data have been revised, most of which were approved in 2007 (Table 3).

Bethlehem Steel Example

Documents related to the Bethlehem Steel Corporation (BSC) provide an example of the progression of a technical basis in situations using surrogate data in dose reconstruction (Figure 1). BSC facilities in Lackawanna, New York were among several U.S steel rolling mills that participated in uranium fuel rod production between 1949 and 1952 [OCAS 2006a]. The work was conducted under contract with the Atomic Energy Commission (AEC) and managed out of the New York Operations Office (NYOO). Exposure data were sparse, thus an exposure matrix was planned that would combine available monitoring data with employment information. The matrix also used data from similar facilities to offset gaps in exposure information. The *Basis for Development of an Exposure Matrix for Bethlehem Steel Corporation* was initially approved in early 2003 following a three-month period of internal review and comment resolution [ORAU TEAM 2004a]. By late 2003, concerns emerged over the lack of an ingestion pathway in the current matrix and DCAS revised the matrix accordingly in June, 2004 [ORAU TEAM 2004a]. In October, 2004, SC&A completed its review of the matrix and concluded that methods used were "reasonable" but identified several areas for improvement [SC&A 2004]. DCAS responded to the findings in late January, 2005 [OCAS 2005a]. In that same year, DCAS published its assessment of the impact to previously completed claims from adding the ingestion pathway [OCAS 2005b]. A second revision followed in July, 2006 in response to resolving concerns raised in the SC&A review [OCAS 2006a]. DCAS completed its assessment of the impact to claims from the second revision in November, 2006 [OCAS 2006b].

The first of three worker outreach meetings was held on May 4, 2004. Two subsequent meetings were held on July 1, 2004 and June 21, 2006. These meetings were conducted to gather relevant information from former BSC employees. Nevertheless, the fact that DCAS conducted these meetings after first

publishing the site profile document has led to criticism regarding the exclusion of worker input in dose reconstruction methods.

Some of the early concerns raised by affected BSC workers and worker representatives remain unresolved [Bennett 2010; Hostettler 2006; Walker 2006]. Most notably, BSC was one of the first instances of using surrogate data in dose reconstruction, which has sparked public debate on the appropriateness of current DCAS methods [Bennett 2010; Hostettler 2006; Kennedy 2007; Schumer et al. 2009]. However, most criticisms are centered on the legitimacy of surrogate data rather than its scientific validity. A petition to designate a class of BSC employees for inclusion in the Special Exposure Cohort pursuant to 42 CFR 83 is currently under evaluation; thus, many issues related to BSC dose reconstruction, including the use of surrogate data, are being reexamined by DCAS and the ABRWH.

The findings and conclusions expressed in this report are exclusively those of the author(s) and do not necessarily represent the views or position of the National Institute for Occupational Safety and Health (NIOSH), the Centers for Disease Control and Prevention (CDC), or the Department of Health and Human Services (HHS). This document is only one of many inputs that the NIOSH Director may consider in the ten-year review of NIOSH's performance under the Energy Employees Occupational Illness Compensation Program.

Quality of Science

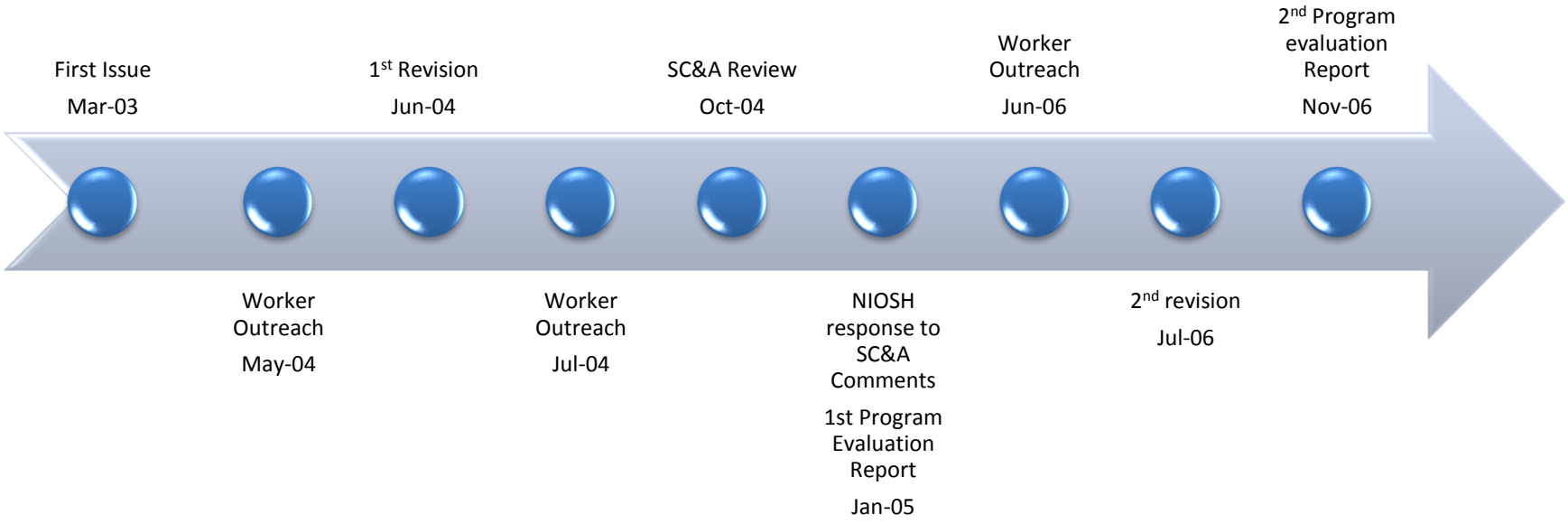


Figure 1. Evolution of the Bethlehem Steel Corporation exposure matrix

Quality of Science

Summary

DCAS has adopted an approach to technical documentation that is similar to standard operating procedures (SOPs) used in current industrial settings. Technical documents are considered "controlled" such that formal approval and publication is required [ORAU TEAM 2005b]. In general, controlled documents:

- Must be legible and readily identifiable;
- Must contain text that is clear, concise, and relevant to the points of use;
- Must be approved for adequacy prior to issue; and
- Must be reviewed and updated as necessary.

Ideally, a document control system should prevent the unintended use of obsolete documents. We found that the DCAS system of documents generally meets this expectation. The technical documents reviewed were identifiable, well written, followed a consistent format, and used a graded-approach to presentation. Processes were in-place for internal review and approval. Publication is accomplished by providing unrestricted access to technical documents through the DCAS dose reconstruction website: http://www.cdc.gov/niosh/ocas/. However, DCAS documents contain guidelines rather than firm requirements, thus strict compliance is not mandated nor routinely assessed. For example, periodic internal reviews, which are common for compulsory SOPs, are not routinely performed in DCAS dose reconstruction.

In review of the BSC documents, we found that many of the early issues may have been avoided had worker input been available prior to document development. In the case of the BSCS technical documents, concerns voiced by some workers following the publication of the site profile document may have been avoided had DCAS sought and incorporated worker input prior to document approval (see "Peer Review", page 29, for more information).

DCAS considers its dose reconstruction documents to be "general working documents", thus revisions were anticipated as new information developed. However, many of the documents we reviewed have not been revised since first issued. The deliberate manner in which science issues are typically resolved between the ABRWH and DCAS can greatly impact the timeliness of revisions (see "External review", page 29). We also acknowledge that, in addition to the quality of science, revisions require careful consideration of program impact in other areas. Nonetheless, continuous improvement in technical documentation cannot transpire without first improving methods for carrying out revisions. For example a document revision process whereby relatively minor inaccuracies are readily identified and removed would greatly enhance the quality of current documents and improve the stakeholder perception of the work conducted in the dose reconstruction program.

Quality of Science

We noted that several external coworker documents (e.g., ORAUT-OTIB-0021, -0026, -0030, -0031) contained information that had become outdated following revision to a higher tiered document (ORAUT-OTIB-0020). Similarly, we found that the issuance of site specific documents on surrogate data preceded approval of the implementation guide (OCAS-IG-0004). To maintain the appropriate hierarchy, Battelle-TBD-6000 and -6001 and any other documents that specify surrogate data use should be reviewed and revised, as needed, to remove any inconsistencies with OCAS-IG-004. Although there are a number of advantages to sharing information between documents, it should be understood that cross-referencing or establishing a hierarchy can be problematic unless provisions are in-place to comprehensively search across documents for inconsistencies. 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 and improve the quality of the controlled document system related to linked documents.

The findings and conclusions expressed in this report are exclusively those of the author(s) and do not necessarily represent the views or position of the National Institute for Occupational Safety and Health (NIOSH), the Centers for Disease Control and Prevention (CDC), or the Department of Health and Human Services (HHS). This document is only one of many inputs that the NIOSH Director may consider in the ten-year review of NIOSH's performance under the Energy Employees Occupational Illness Compensation Program.

Quality of Science

Table 1. List of Coworker Technical Information Bulletins

ID	Description	First issue Date	Effective Date	Revisions	Data Source[1]	Extent (# of pages)	Reviewed by ABRWH[2]
ORAUT-OTIB-0020	Use of Coworker Data for External Dose Assignment	12/29/2004	12/04/2008	2	NA	9	Yes
ORAUT-OTIB-0021	Technical Information Bulletin – External Coworker Dosimetry Data for the X-10 Site	12/29/2004	12/29/2004	0	CEDR and CER	8	Yes
ORAUT-OTIB-0026	External Coworker Dosimetry Data for the K-25 Site	05/31/2005	11/15/2006	2	CEDR	11	Yes
ORAUT-OTIB-0030	External Coworker Dosimetry Data for the Hanford Site	03/23/2005	11/07/2006	1	CEDR	10	Yes
ORAUT-OTIB-0031	External Coworker Dosimetry Data for the Paducah gaseous Diffusion Plant	05/19/2005	11/07/2006	2	DOR	12	No
ORAUT-OTIB-0032	External Coworker Dosimetry Data for the Savannah River Site	05/31/2005	11/07/2006	1	DOR	10	No
ORAUT-OTIB-0040	External Coworker Dosimetry Data for the Portsmouth Gaseous Diffusion Plant	07/29/2005	11/07/2006	1	DOR	10	No
ORAUT-OTIB-0064	Coworker External Dosimetry for the Y12 National Security Complex	08/03/2009	12/18/2009	1	CER	21	No
ORAUT-OTIB-0072	External Coworker Dosimetry Data for the Sandia National Laboratory, New Mexico	09/26/2008	09/26/2008	1	DOR	12	No
ORAUT-OTIB-0073	External Coworker Dosimetry Data for the Fernald Environmental Management Project	09/22/2008	09/22/2008	0	DOR	12	No
ORAUT-OTIB-0077	External Coworker Dosimetry Data for Area IV of the Santa Susana Field Laboratory, the Canoga Avenue Facility [Vanowen Building and the De Soto Avenue Facility (sometimes referred to as Energy Technology Engineering Center [ETEC] or Atomics International)]	08/03/2009	08/03/2009	0	The Rocketdyne Study data	10	No

Quality of Science

1. CEDR - Comprehensive Epidemiologic Data Resource; CER -Oak Ridge Associated Universities Center for Epidemiologic Research ; DOR - facility Dose of Record; NA - Not Applicable
2. Based on our review of available records, we determined whether or not a review by or on behalf of the Advisory Board on Radiation Worker Health had been conducted.

Quality of Science

Table 2. List of Coworker Technical Information Bulletins for Internal dose estimates.

ID	Description	Period Covered	First issue Date	Effective Date	Revisions	Data Source[1]	Extent (# of pages)	Reviewed by ABRWH[2]
ORAUT-OTIB-0019	Analysis of Coworker Bioassay Data for Internal Dose Assignment	NA	12/29/2004	10/07/2005	1	NA	10	Yes
ORAUT-OTIB-0065	Internal Dosimetry Coworker Data for Lawrence Livermore National Laboratory	1958-1996	02/17/2007	02/16/2007	0	DOR	23	No
ORAUT-OTIB-0037	Internal Dosimetry Coworker Data for Paducah Gaseous Diffusion Plant	1952-1988	09/20/2005	09/20/2005	0	DOR	15	Yes
ORAUT-OTIB-0036	Internal Dosimetry Coworker Data for Portsmouth Gaseous Diffusion Plant	1954-1988	07/29/2005	07/29/2005	0	DOR	16	No
ORAUT-OTIB-0039	Internal Dosimetry Coworker Data for the Hanford Site	1944-1988	10/28/2005	10/01/2007	3	DOR	55	Yes
ORAUT-OTIB-0061	Internal Dosimetry Coworker Data for the Mound Site	1944-1990	06/22/2007	06/22/2007	0	DOR	30	No
ORAUT-OTIB-0034	Internal Dosimetry Coworker Data for X-10	1951-1988	12/13/2005	12/13/2005	0	CER	29	Yes

1. CEDR - Comprehensive Epidemiologic Data Resource; CER -Oak Ridge Associated Universities Center for Epidemiologic Research ; DOR - facility Dose of Record; NA - Not Applicable.
2. Based on our review of available records, we determined whether or not a review by or on behalf of the Advisory Board on Radiation Worker Health had been conducted.

The findings and conclusions expressed in this report are exclusively those of the author(s) and do not necessarily represent the views or position of the National Institute for Occupational Safety and Health (NIOSH), the Centers for Disease Control and Prevention (CDC), or the Department of Health and Human Services (HHS). This document is only one of many inputs that the NIOSH Director may consider in the ten-year review of NIOSH's performance under the Energy Employees Occupational Illness Compensation Program.

Quality of Science

Table 3. Technical documents related to the use of surrogate data in DCAS dose reconstruction.

ID	Description	Effective Date	Extent (# of pages)	Reviewed by ABRWH[1]
OCAS-IG-0004	The Use of Data from Other Facilities in the Completion of Dose Reconstructions Under the Energy Employees Occupational Illness Compensation Program Act	08/21/2008	11	Yes
Battelle-TBD-6000	Site Profiles for Atomic Weapons Employers that Worked Uranium and Thorium Metals	12/13/2006	57	Yes
Appendix AS	Copperweld Steel Co.	07/16/2007	8	No
Appendix B	Birdsboro Steel & Foundry Company	09/14/2007	9	No
Appendix BB	General Steel Industries	06/25/2007	12	Yes
Appendix BD	Heald Machine Company	07/16/2007	8	No
Appendix BL	Jessop Steel Co.	05/25/2007	10	No
Appendix BO	LaPointe Machine & Tool Co.	05/25/2007	9	No
Appendix BP	Landis Machine Tool Co.	07/31/2007	9	No
Appendix C	Dow Chemical Co. (Madison Site)	09/28/2008	13	Yes
Appendix CD	Seymour Specialty Wire Co.	07/16/2007	20	No
Appendix CO	U.S. Steel, National Tube Division	06/15/2007	10	No
Appendix CU	Mitts & Merrel Co.	07/31/2007	9	No
Appendix G	Anaconda Co.	04/30/2007	7	No
Appendix Q	Allegheny-Ludlum Steel Company	04/30/2007	16	No
Appendix R	Aluminum Company of America – Pennsylvania (Alcoa 1)	04/30/2007	10	No
Appendix S	Aluminum Company of America (Alcoa 2) – New Jersey	04/30/2007	7	No
Appendix V	American Chain and Cable Company	07/16/2007	8	No
Battelle-TBD-6001	Site Profiles for Atomic Weapons Employers that Refined Uranium and Thorium	12/13/2006	66	No
Appendix AA	Hooker Electrochemical Company	06/15/2007	10	No
Appendix B	DuPont Deepwater Works	01/03/2008	10	No
Appendix C	Electro Metallurgical Company	12/21/2007	8	No
Appendix D	United Nuclear Corp.	03/14/2008	7	No
Appendix P	Baker-Perkins– Michigan	09/14/2007	7	No

Quality of Science

Based on our review of available records, we determined whether or not a review by or on behalf of the Advisory Board on Radiation Worker Health had been conducted.

Quality of Science

Peer Review

Internal review

DCAS dose reconstruction documents, including coworker model TIBs, undergo an internal review process prior to final approval by the DCAS Associate Director of Science (ADS). The review includes both informal and formal reviews that are managed by the Document Owner. The informal review is performed by the authors, subject matter experts (SMEs) not directly involved with the task, and technical staff support staff (e.g., technical editors). The formal review is conducted, at a minimum, by the assigned SMEs, Document Owner, and DCAS staff. Once all comments are reconciled, document approval is obtained from the Document Owner and at least one other responsible person associated with the assigned task. Final approval for use is reserved for the DCAS ADS.

External review

External scientific peer review or stakeholder review is not required for the technical documents used in dose reconstruction. However, these documents are subject to review by the Advisory Board on Radiation Worker Health (ABRWH); or contract staff working on behalf of the ABRWH. ABRWH membership requires presidential appointment and is comprised of leading scientists in epidemiology, health physics, and nuclear engineering, medical professionals, and affected workers and worker representatives.

The ABRWH is charged with advising the Secretary of HHS on the validity and quality of dose reconstruction. To carry out this charge, the ABRWH seeks the assistance of SC&A in providing scientific review and consult on DCAS program documents related to dose reconstruction. Findings from these reviews are documented and tracked to provide a record of resolution. Findings are closed with approval by the ABRWH. There are currently 121 documents listed in the DCAS document tracking database. As of January 29, 2010, the ABRWH reported that it has reviewed a total of 105 documents, resulting in 538 individual findings. DCAS staff has satisfactorily addressed 254 (47%) of these findings [Ziemer 2010]. Specifically regarding coworker analyses, reviews were conducted for 8 of 17 related TIBs, resulting in 32 findings. Of these findings, 25 (78%) remain open at this time. Likewise, SC&A has completed reviews of OCAS-IG-004 (7 findings); Battelle-TBD-6000, main document (7 findings), Appendix BB (13 findings), and Appendix C (5 findings); and Battelle-TBD-6001 (6 findings). Of the 38 findings listed, 7(004=2, 6000=3 closed, BB=0, C=2) are now considered to be closed or have been recommended to be closed.

The processing of findings from reviews by SC&A provides an example of the scientific rigor applied to reviews on dose reconstruction methods. Although typically released to the public without redaction, all reviews by SC&A are pre-decisional and are meant solely as informational sources for the ABRWH. Thus,

the public is kept abreast of issues in-kind. The ABRWH considers the merits of the findings in subcommittees or working groups that specialize in the particular area addressed in the report. Findings are tracked by the working group throughout the resolution process or until transferred to another working group. Often issues are complex and require considerable efforts by working group members, SC&A staff, DCAS, and others to reach suitable resolution. The resolution process may require substantial reanalysis, new analysis, independent scientific opinion, and extensive open debate prior to reaching consensus. As a consequence, an array of supporting documents may be developed (e.g., calculations, research papers, and model results) as tools for aiding deliberations. During this process, findings can remain open, be transferred to another working group, or held in abeyance until a final revision to the technical document is approved.

Although there are several examples of a deliberate scientific process for peer comment resolution, we found it difficult to determine the resolution status of specific issues addressed in reviews. As previously mentioned, the results of the reviews are not centrally tracked. Furthermore, SC&A reviews and issue matrices are intended as tools for the working groups and decisions on public availability appear arbitrary. The process of handling concerns from reviews is not formalized and varies markedly between working groups. Some reviews were followed with detailed reports on comment resolution that are readily accessible [OCAS 2005a; SC&A 2010], while information on other reviews was sparse (e.g., SC&A review of Battelle-TBD-6000). Issues and concerns are prioritized by work group members based on a number of variables (e.g., relevance, programmatic impact, complexity, relation with other issues, stakeholder opinion). DCAS responds to concerns at the request of the working group; therefore, some concerns, and perhaps the results of entire reviews, have not been thoroughly investigated because the interworking of the work group and its prioritization of activities has not aligned with the review findings.

Additional Information on Transparency

All ABRWH activities must comply with the requirements of the Federal Advisory Committee Act (U.S. Congress 1972). Thus, meeting agendas are made available for public comment and all meetings are open to the public. ABRWH meetings are transcribed and the transcriptions are made available by web link. Therefore, ABRWH activities associated with review and approval of coworker analyses can be monitored. Details concerning access to ABRWH documents are documented *in NIOSH Procedures for Providing Public Access to Records or Documents of the Advisory Board on Radiation and Worker Health* http://www.cdc.gov/niosh/ocas/pdfs/abrwh/2009/bddocp110909.pdf. In addition, special working groups of ABRWH members have been assembled to review certain technical documents including Battelle-TBD-6000 and Battelle-TBD-6001. As with the full board, meeting times are announced and transcripts of past meetings have been made accessible to the public by web link.

Quality of Science

Transparency is further enhanced by maintaining current and previous versions of technical documents on the NIOSH internet site, which also includes a mechanism for public comment. Public comments on EEOICPA regulation are also available by docket http://www.cdc.gov/niosh/ocas/ocasdoci.html. Finally, DCAS has established a Worker Outreach Program to provide workers, scientists, and other stakeholders, with opportunities to participate in developing technical documents used in dose reconstruction. Worker Outreach Meetings are periodically held at locations near affected sites and solicit attendance from current and former DOE and AWE employees.

The degree to which transparency has affected work processes is difficult to assess. We did not observe a systematic process for incorporating worker and public comment in DCAS technical documents. When documentation of comments is available; the actions taken by DCAS are not responsive in some cases. For example; DCAS received written comments from worker advocates at an Advisory Board meeting held on July 17-19, 2007 [ABRWH 2007; McKeel D. W. and Ramspott 2007]. These comments addressed concerns regarding a then recently (i.e., two weeks prior) released appendix to Battelle-TBD-6000 that provided information on General Steel Industries. Their comments pointed out several inconsistencies in facility, process, and equipment descriptions and suggested revision to the appendix was needed. In August, 2007, DCAS followed with a detailed letter acknowledging that some points raised by the advocates needed attention but none of the issues resulted in a change to bounding calculations [Elliott 2007]. On April 21, 2008, SC&A released its review of Appendix BB in which SC&A scientists independently replicated exposure models incorporating information from workers collected during scheduled interviews. In all, SC&A reported 13 findings that collectively suggested substantive errors in the DCAS technical document. SC&A reviewed the previous comments made by the worker advocates and recommended that "…in the interest of a more comprehensive report", DCAS should address the workers' concerns in a future revision. DCAS has not yet revised the affected document.

In part, changes to documents are slowed by the deliberate manner in which science issues are resolved between the ABRWH and DCAS (see "External review", page 29). Issues are documented, rigorously analyzed, and scientifically debated prior to resolution; a process which has taken years to complete in some cases (e.g., exposure matrix for BSC). Another possible explanation for delays is that revisions can trigger a reevaluation of individual dose reconstructions. In the worst-case, small changes to a document that have no bearing on adjudication could place an unnecessary burden on the claims process if the Department of Labor, who can act without input from DCAS, decides to reopen cases because of a newly revised technical document. As a precaution, NIOSH has delayed document revisions, to the extent practical, until all issues are resolved to the satisfaction of the ABRWH and a formal assessment of the potential impact to claimants is complete. A potential disadvantage of this deliberate process of document revision is a resulting perception of carelessness. Revisions that require little scientific deliberation, such as inaccuracies in site descriptions, should not be allowed to linger. A graded

approach to conducting future revisions for improving document quality should be considered. More timely revision would not only buttress claims of "living documents" that serve the dynamic needs of the program, but may lead to an improved sense of responsiveness that is currently lacking, as evidenced by recent complaints.

Summary

DCAS technical documents require internal review prior to issuance but do not require external scientific peer review or review by stakeholders. We found that some of the documents under our review could have benefited from external peer review before approval. We acknowledge that in early years of program development peer review may have been deferred for expediency in meeting the needs of claimants. However, many of the technical documents now in use arguably contain a science component that can benefit from rigorous scientific peer review. Moreover, peer review of approved documents could now be conducted without hindering the program. DCAS should consider seeking external review on those documents that have not been reviewed by ABRWH or its subcontractor. DCAS should also 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.

Post-hoc scientific peer review of technical documents is conducted at the request of the ABRWH on a case-by-case basis. These reviews are frequently triggered by stakeholder concerns. There are several examples where reviews of indirect exposure assessment methods have resulted in significant deliberations between the ABRWH and DCAS to reach a suitable resolution of comments. However, not all documents have been similarly reviewed and not all reviews have led to actions to resolve comments. A centralized system to document and track concerns raised by the ABRWH or its subcontractor in review of its technical documents is not in place. Currently, activities between SC&A, the ABRWH, and DCAS staff on particular technical documents are coordinated by the respective working groups; a compartmentalized practice that leads to inconsistencies in the handling of concerns. Processes to provide a comprehensive status on its technical documents and associated reviews would improve the quality of the technical documentation and may better demonstrate responsiveness to concerns raised by the ABRWH and stakeholders, alike.

External Radiation Coworker Analyses

The use of coworker data for reconstructing doses from external sources is described in ORAUT-OTIB-0020, *Use of Coworker Dosimetry Data for External Radiation* [ORAU TEAM 2008c]. Other Technical Information Bulletins (TIBs), used in conjunction with ORAUT-OTIB-0020, provide site-specific guidance for coworker assignments. These documents are listed in Table 1.

Quality of Science

In concept, doses to workers with incomplete monitoring within a monitoring period can be reasonably estimated from monitoring data that is available for coworkers during the same period. In practice, the typical coworker analysis for external exposures has involved three basic steps:

1. **Data Selection:** Identify and collect facility monitoring data for all available years and validate these data by comparison with a sample of claim-specific data;
2. **Adjust the Data:** Evaluate and adjust annual dose distributions to account for biases that may be present, such as (but not limited to), biases from measurement sensitivity (i.e., "missed dose") and incomplete monitoring.
3. **Analyze and Estimate:** Using the adjusted annual dose distributions, calculate the 50^{th}- and 95^{th}-percentile annual doses. When reported doses are not available, use these values in dose reconstruction as reasonable approximations of reported doses for the unmonitored period. According to current DCAS procedures, the 50^{th}-percentile dose is used if the claimant's exposure was likely to be intermittent and the 95^{th}-percentile dose is used when routine exposure is expected.

In all cases, coworker estimates are intended to represent the results of unmonitored individuals had they been monitored. Thus, estimates are used in conjunction with other modifying factors (e.g., factors that address energy dependence, angular dependence, and exposure geometry in relation to the target organ) to calculate a tissue dose used in assessing the probability of causation [OCAS 2007].

Data selection:

The premise of any indirect method of exposure estimation is the ability to link individuals without measurement data to representative measured values. In developing coworker models, one must determine: 1) if the source data are sufficient to characterize dose distributions; 2) the extent to which these distributions are representative of doses to unmonitored workers; and 3) the appropriate linkage between covered workers and source data to reasonably infer dose. In the special case of dose reconstruction, assurances of data sufficiency to estimate plausible outlying doses must be obtained to prevent underestimation of unmonitored exposures. Therefore, the quality and quantity of the source data and the limitations imposed by the lack thereof are essential elements of all coworker analyses. Coworker analyses should: 1) address source data quantity, reliability, and validity; and 2) describe the coverage and limitations (i.e., generalizability) in using coworker models developed from these data.

The data sources used in DCAS external coworker models are listed in Table 1. Some analyses relied on dosimetry information gathered directly from site databases [ORAU TEAM 2006e; ORAU TEAM 2006f; ORAU TEAM 2008a; ORAU TEAM 2008b]. These data represent the dose of record (DOR) for all or most individuals who were ever monitored and are expected to exactly correspond to data provided by DOE

in response of EEOICPA request made on behalf of covered individuals. Other analyses used data previously reported to the Center for Epidemiologic Research (CER) in support of its past mission of conducting health and mortality studies for DOE and its predecessor agencies [ORAU TEAM 2004b; ORAU TEAM 2009b]. In large part, these data are anticipated to be identical to DOR values maintained at individual sites although some minor differences are possible due to data cleaning employed at CER. Still other analyses used exposure information maintained by the Comprehensive Epidemiologic Data Resource (CEDR) [ORAU TEAM 2004b; ORAU TEAM 2006a; ORAU TEAM 2006d]. This system of records is a Department of Energy (DOE) public-use repository of data primarily from health studies of workers at DOE facilities. Exposure information abstracted from CEDR may be specific to the cohort criteria established by the epidemiologic study design, including any adjustments that researchers deemed appropriate to reduce exposure misclassification in dose-response analyses. Thus, there may be notable differences in cohort characteristics and dose distributions when comparing CEDR and DOR data systems. Finally, we note that one coworker study used data that were collected for a retrospective cohort mortality study [ORAU TEAM 2009a]. In that epidemiologic study, Boice et al. [2006a; 2006b] attempted to assess all occupational ionizing radiation exposures to study participants and expanded their search for exposure information to employment outside of the study facility. A positive bias in coworker analysis may result given that nearly 32% of the study participants had exposure data from employment elsewhere.

Information on the characteristics of the data used for coworker analyses varied markedly among facilities. In many cases, descriptive statistics were not available in sufficient detail to illustrate the breadth and depth of the available data. For example, only two coworker models provided information on the number of person-years of external monitoring data used to develop annual estimates [ORAU TEAM 2009a; ORAU TEAM 2009b]. Although models present percentiles from the data, it is unclear whether data were sufficient for using these percentiles to characterize dose distributions for all years, especially in distribution tails.

Information on data validation methods also varied widely in coworker models examined. For example, the coworker model for Y12 external doses contained detailed information on multiple data validation methods [ORAU TEAM 2009b]. In contrast, data validation was completely absent from discussion in a recently approved coworker TIB [ORAU TEAM 2009a]. In most models, validation appears limited to comparisons made between the selected data and a small random sample of claimant information [ORAU TEAM 2004b; ORAU TEAM 2006a; ORAU TEAM 2006d; ORAU TEAM 2008a]. These comparisons generally included information on the sample size and total person-years sampled; however, there was little offered on the representativeness of the sample. For example, the coworker mode for the Savannah River Site states that data validity was "confirmed" by a comparison of exposure data for two claimants [ORAU TEAM 2006b]. No additional information on sample size or statistical methods was

provided; however, it is unlikely that any suitable comparison would require only two observations. We also note that reasonable agreement between cohort level data and claimant data is expected during later years of exposure or when both datasets originate from the same source (e.g., printouts of annual external dose summaries from site dosimetry databases). Perhaps more meaningful comparisons may occur between the electronic data and original exposure records (e.g., weekly film meter record cards). Moreover, in conducting these comparisons we note that data validation lacked information on sampling methods (e.g., statistical power, inclusion criteria) tests performed, and criteria for data acceptance.

Overall, we found that the information on the quality, quantity, and generalizability of data used in coworker analyses could be improved to buttress claims of sufficiency in characterizing external dose distributions for coworker analyses, especially in the high dose range. Facility data should be preferred to other sources of information in lieu of evidence of systematic errors in the DOR. There should be careful consideration given to using data that was collected for an epidemiologic study in coworker models intended to estimate the DOR. Although there are advantages to using publicly available data (e.g., data from CEDR), there are concerns that study data may significantly differ from the DOR. Nonetheless, most TIBs were not informative on the reasons for dataset choice or what limitations result from using the selected data. Analyses relying on CEDR data should at a minimum: 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 in lieu of the DOR. Finally, we note that CEDR datasets do not contain personal identifiers and are intended for statistical purposes only (e.g., replication of epidemiologic analyses). As such, primary users are prohibited from linking the data from CEDR with any other sources of information that may lead to the identification of an individual. Therefore, it is unclear how data validations were accomplished by comparison with claimant dosimetry data as stated in current coworker analyses using CEDR data.

Adjust Data:

DCAS uses substitution methods to adjust left-censored data. The essence of substitution is to replace non-detects with values derived as a function of the recorded detection limit [Helsel 2004]. In this case, DCAS uses one-half of the recording threshold as a substitution value, which has been a common assumption in similar settings [Hewett and Ganser 2007; NRC 1989; Nehls and Akland 1973]. The recording threshold is the minimum positive integer recorded for the monitoring interval and is not necessarily the laboratory limit of detection. This threshold may vary, thus DCAS selected the threshold that is consistently most conservative.

Quality of Science

Several studies have suggested that substitution methods of censored data analysis (CDA) lack a sound statistical basis and are likely to bias results [Daniels and Yiin ; Gilliom and Helsel 1986; Gleit 1985; Helsel 2004; Helsel 2006; Helsel 1990; Hornung and Reed 1990; Lubin et al. 2004]. Researchers have criticized the use of substitution methods given that more precise and accurate methods are readily available [Helsel 2010; Helsel 2006]. The directionality and magnitude of the bias is dependent on the characteristics of the underlying distribution, in particular, the true geometric standard deviation, true percent censoring and the sample size [Hewett and Ganser 2007]. To our knowledge, the tendencies of this bias have received little attention in settings that are specific to radiation exposure data. Nevertheless, there is evidence that the directionality of the bias is likely to be away from the null (i.e., claimant favorable) in largely censored and highly right-skewed data [Antweiler and Taylor 2008; Daniels and Yiin ; Hornung and Reed 1990].

To elucidate the conservatism of the coworker model, DCAS performed a comparison between K-25 external coworker modeling results to doses calculated using maximum likelihood [ORAU TEAM 2008c]. We found that this comparison lacks sufficient information to conclude that the statistical methods used were appropriate. For example, the analysis does not specify the number of observations used in the regression for each year. For each model, the degree to which data censoring occurred is not indicated. The robustness of parameter estimates was not examined. All of these factors may greatly influence model fit; however, fit statistics or graphical representations of goodness of fit were not provided. The authors cited methods previously developed for examining dose distribution in a similar facility [ORAU TEAM 2005a]. However, that analysis was conducted in a facility with relatively higher doses, which were provided in quarterly intervals. Both of these factors are likely to reduce left-censoring relative to K-25 exposure data. Finally, only maximum likelihood methods were used for comparison; in most CDAs, comparisons are made using multiple methods, including both parametric and non-parametric approaches.

We generally agree that the methods used in DCAS dose reconstruction are likely to overestimate the "missed dose" from exposures below measurement thresholds that indicate left-censoring. However, the current comparison between substitution and maximum likelihood methods used to quantify missed dose lacks the scientific rigor necessary to support the assertion of claimant-favorability in all applications of coworker models. Future research aimed to better characterize the degree of claimant-favorability that is afforded by methods for adjusting doses for measurement biases, including the bias from exposures below detection, would aide in validating dose estimates.

Analyze and Estimate:

As previously discussed, DCAS coworker models limit examination to doses stratified by time only (see "Epidemiologic Studies", page 8). Therefore, information on dose distributions in other strata, such as

work location or job assignment, is not available. A question remains whether cohort dose distributions used in current analyses are sufficient to infer doses to select groups of workers given that between-job exposures may vary widely (e.g., secretary versus chemical operator) and within- job exposures may be correlated [Johnston et al. 1986].

Furthermore, current coworker analyses provide little information on criteria used to judge whether the covered individual's exposure should be considered intermittent or routine. Rather, this decision is left to the responsible analyst to render a case-specific opinion on the matter, which is presumably based on work activities discussed in claimant files. However, analyses stratified by task or work location could markedly improve consistency in decisions regarding which percentile to use for dose assignment. For these reasons, DCAS should consider using work history information to improve existing coworker models.

Coworker Analysis Replication

To examine the reliability of estimates from coworker analyses, we replicated the coworker model for external doses at the Oak Ridge Gaseous Diffusion Plant (ORGDP) using information from a previous epidemiologic study [Yiin et al. 2009] and methods outlined in the associated DCAS TIBs [ORAU TEAM 2006a; ORAU TEAM 2008c]. Our primary aim was to determine if similar results could be obtained using another data source as input to the model. We also wished to examine the validity of modeling assumptions by comparing estimates of cumulative doses to the DOR for monitored individuals.

Background

In February, 1945, the Oak Ridge Gaseous Diffusion Plant (ORGDP) began operations to separate U-235 for the weapons production program. Uranium enrichment continued at ORGDP with relatively few changes in processes until production ceased in 1987. During production activities, routine external radiation monitoring was assigned to workers based on their potential to exceed permissible dose limits. [Watkins et al. 1997] Therefore, coworker models are needed for reconstructing doses to unmonitored workers during the earlier periods of plant operations. ORGDP workers have participated in a number of previous epidemiologic studies that required the collection and assessment of work history and exposure information including some studies conducted by DCAS researchers. Thus, sufficient information from these studies is available to replicate coworker analyses.

The ORGDP coworker model used for dose reconstruction is described in ORAUT-OTIB-0026, *External Coworker Dosimetry Data for the K-25 Site* [ORAU TEAM 2006a]. The model used annual summaries of penetrating and shallow "doses" calculated from individual doses reported in CEDR for K-25 workers. CEDR data were deemed sufficient for developing an exposure model covering the period between 1945 and 1985. During this time, doses were reported yearly between 1945 and 1975 and quarterly

thereafter. Dose values were adjusted for measurement bias. Adjusted data were used to estimate annual median and 95th-percentile doses. The former value serves as the annual dose estimate for those unmonitored individuals who are likely to be exposed intermittently to low levels of external radiation. The latter value is used to estimate the dose to workers who are routinely exposed.

Methods:

All statistical analyses were conducted using SAS Version 9.2 [2007]. Exposure information collected from ORGDP for a previous epidemiologic study was used to replicate the co-worker analysis. The dataset originated from the facility database file "Y-12/K-25/PGDP TLD Data" and was received by DCAS in 1996. These data are referred to as the unadjusted dose values used in our replication study. Descriptive statistics for annual and cumulative doses were presented. The data were also examined for outliers and to elucidate patterns of monitoring coverage. The 95th-percentile doses were examined from rank order of *n* observations using the observation closest to (*n*+1)*p* where p=0.95 (i.e., PCTLDEF=2, in SAS). Dose statistics utilized reported exposure values for penetrating radiation. We further assume that reported values are reasonable approximations of equivalent dose to the whole body.

To make comparisons with values reported in the coworker model, annual doses between 1945 and 1985 and excluding 1977 were adjusted for a potential negative bias from measurement sensitivity (i.e., missed dose adjustment) using essentially the same methods prescribed in ORAUT-OTIB-0026. For null values, the annual missed dose contribution was set to one-half of the maximum annual missed dose (MAMD) reported in Table 1 of ORAUT-OTIB-0026 , which was estimated as the product of the number of monitoring events expected within the year multiplied by the minimum measurement sensitivity. A measurement sensitivity of 0.3 mSv was assumed for all years prior to 1988. Monitoring was assumed to be at weekly intervals in years prior to 1975 and quarterly intervals thereafter. Comparisons were made between adjusted cumulative doses and cumulative doses calculated from the annual 95th-percentile dose values in Table 2 of ORAUT-OTIB-0026 (i.e., "routine" coworker model data). Potential outliers were defined as workers whose adjusted cumulative penetrating dose exceeded the 95th-percentile of the distribution of cumulative doses calculated using routine coworker data.

Employment histories were used to determine annual employment frequencies. Hard copy records were reviewed to determine actual dosimeter processing cycles and to examine the extent of recorded results. The NOCTS database was searched for information on claimants with previous ORGDP employment to determine coworker monitoring coverage. Similar to the methods use in ORAUT-OTIB-0026, the study data were compared to the data from a random sample of claimants that was provided by DOE in response to DCAS requests. However, we limited our comparison to the years when incomplete monitoring was most likely (i.e., prior to 1975).

Results:

Unadjusted doses

The exposure data are comprised of 156,761 records for ORGDP workers (n=12,440) exposed between the years 1945 and 1988 resulting in a collective dose of 18.5 person-Sv. Exposures were recorded as annual whole-body dose summaries (n=19,479) through 1975 and quarterly thereafter (n=137,282). Of 78,613 annual dose values, only 1,133 (1.4%) were above the MAMD. When compared to one-half the MAMD, there were 6,181 (7.9%) annual doses above the threshold. Both annual and cumulative dose distributions were highly skewed, with outlying cumulative doses in excess of 100 mSv for three workers.

Quality of Science

Table 4. Statistics for unadjusted K25 external exposure data (penetrating doses).

Statistic	Penetrating Doses	
	Annual	cumulative
N	78,163	12,440
Average (mSv)	0.23	1.49
Median (mSv)	0.0	0.60
Standard deviation (mSv)	1.31	4.95
Minimum (mSv)	0.0	0.00
95th-percentile (mSv)	1.04	4.40
Maximum (mSv)	89.20	180.49

Inspection of the data revealed patterns of incomplete workforce monitoring until 1975 (Figure 2). Monitoring information was available for only two of the 20,000+ workers employed in 1945. About 10% of the workforce was monitored between 1946 and 1974. The number of annual doses between 1946 and 1962 ranged between 54 and 1,295 (average = 804 ± 394). Fewer individuals were monitored between 1962 and 1974, with yearly numbers between 114 and 155 (average=129 ± 12).

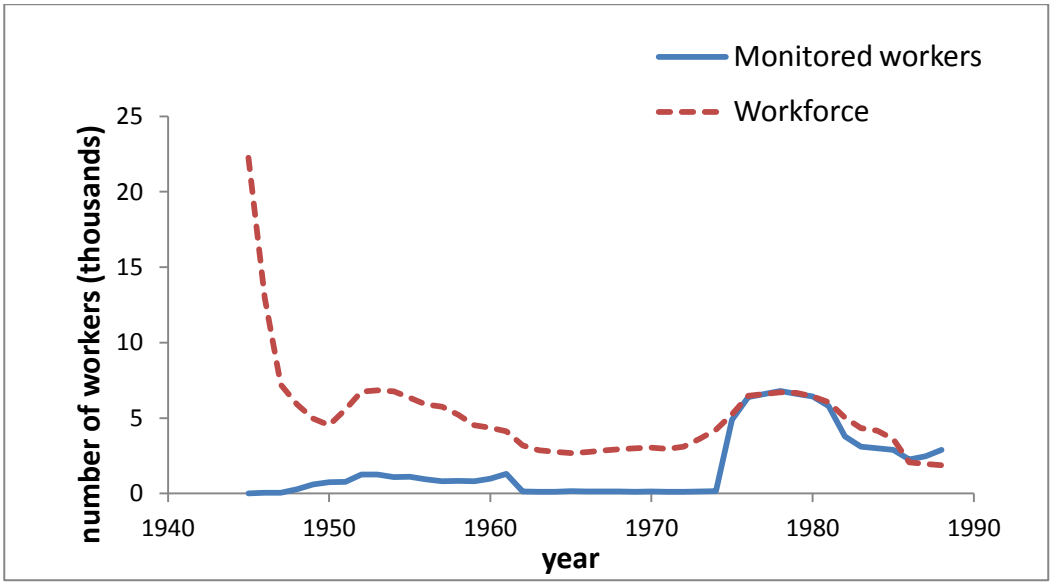


Figure 2. ORGDP external monitoring over time.

We observed a nominal assignment of 1.04 mSv for the third quarter of 1977 for 3,565 workers (56.3%). Inspection of the hard copy records revealed that this assignment was the highest recorded dose value

for that period and was used as a surrogate for a number of film badges that were inadvertently de-identified during processing.

The available hard copy records indicated that film badge monitoring was initially conducted weekly for those workers whose quarterly doses could exceed 10% of the allowable dose. The periodicity was later extended to bi-weekly by 1957, monthly in the first quarter of 1959, and quarterly for exposed plant personnel beginning in the 4th quarter of 1964. To examine potential exposures to remaining workers, films from the "take-home" security badges were processed for a random sample of about 300 workers each quarter. Sufficient records characterizing these samples were available for all quarters between 1962 and 1971. During this time, about 11% of the "unmonitored" population was sampled at least once. Positive results were obtained in approximately 3.5% of the badges processed. Approximately 73% of all positive penetrating doses were less than or equal to 0.30 mSv with an overall average dose of 0.17 mSv. Quarterly maximum dose ranged between 0.15 mSv and 2.16 mSv. There was no evidence that the results from these random samples were ever assigned to the workers dose of record.

Comparing adjusted doses to coworker model values

Adjusted annual doses between 1945 and 1985 were available for 9,270 subjects. The 95th-percentile doses were in reasonable agreement with the corresponding coworker model values (Figure 3). Nevertheless, the results from paired comparisons were significantly different from the null (difference=0.03 mSv, p=0.037) and indicated that adjusted annual doses in our model were slightly lower than the values reported in ORAUT-OTBID-0026.

Quality of Science

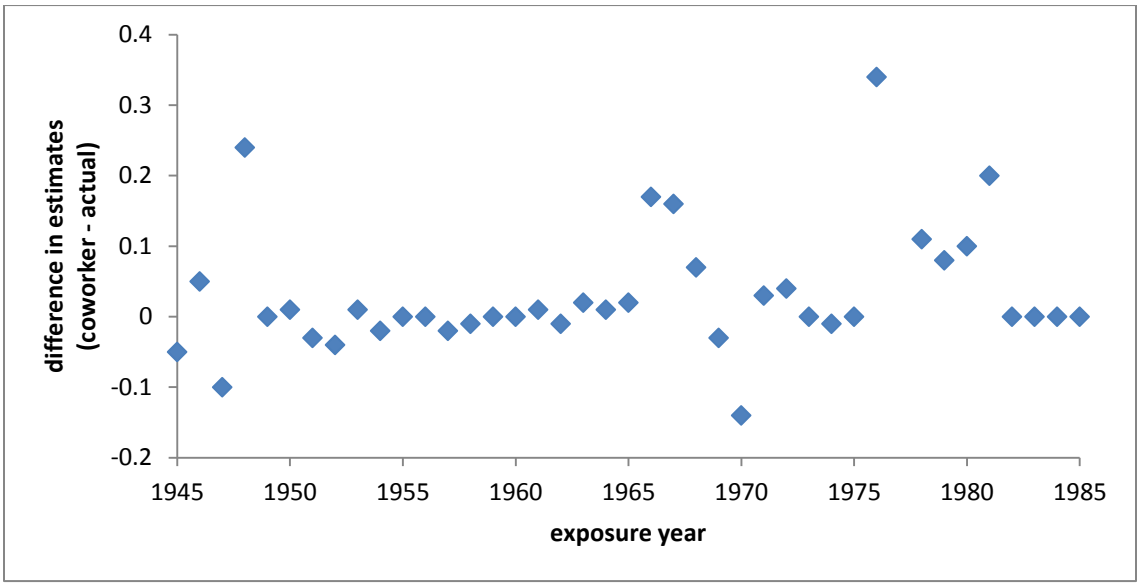


Figure 3. Comparison of annual doses between measurements and reported coworker values. The 95th-percentile values for penetrating radiation were used.

The mean and median adjusted cumulative doses from our data were 14.61 mSv and 4.02 mSv, respectively. The 95th-percentile cumulative dose was 66.85 mSv. In comparison, the mean and median coworker cumulative dose values, calculated by summing the annual 95th-percentile coworker exposures for years of reported exposure, were 18.52 mSv and 7.14 mSv, respectively. There were 242 (2.6%) workers who had reported cumulative doses in excess of cumulative doses calculated from the DCAS coworker model. Of these, there were 5 workers whose cumulative dose exceeded the 95th-percentile of the coworker cumulative doses (81.85 mSv). These workers had 62 person-years of exposure, which included 37 person-years in which the adjusted annual dose exceeded the coworker modeled dose and 17 person-years in which coworker values underestimated reported doses (Figure 4). Two of the workers had remarkably similar outlying doses in 1980. Inspection of the dosimetry file revealed evidence of damaged dosimetry in the second quarter of 1980 for these two workers. Furthermore, there were 144 subjects with similarly flagged results during this period. Unfortunately, the available information was not informative as to the cause of the damage or to the extent dose values shown were estimated based on other information. Nevertheless, the average dose (9.8 mSv) for these 144 workers was elevated compared to the average dose to others (n=6,030) in the same period (0.1 mSv).

Work histories for the 5 workers ranged between 8.9 and 33.2 years with mean and median employment of 16 years and 13.2 years, respectively. Jobs did not vary markedly within each worker's total employment period whereby all employment person-years were attributed to operators (n=3

workers, 58.5 person-years), laborer/operator (n=1 worker, 9.3 person years), and engineers (n=1 worker, 13.1 person-years). Employment periods overlapped exposure periods whereby approximately 15 person-years of employment was without associated monitoring data.

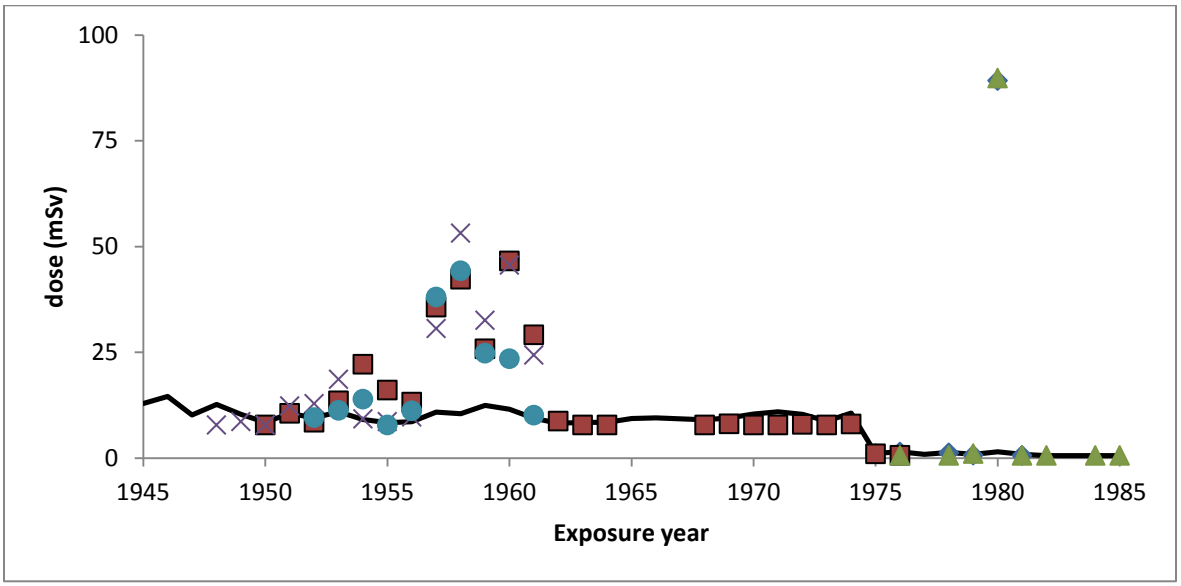


Figure 4. Annual doses for workers (n=5) with outlying cumulative doses relative to the coworker model. Solid line indicates coworker 95th-percentile values from Table 1 of ORAUT-OTIB-0026.

Examination of claimant data

There were 2,517 claimants identified with ORGDP employment. Of these workers, 811 (32%) had exposure information in the study dataset. Of the 811 workers, there were 129 (16%) identified with external exposures occurring exclusively prior to 1975. Dosimetry information was abstracted from the files of a random sample (n=10) of claimants drawn from the 129 who were exposed prior to 1975. This information was in perfect agreement with the information in the source file for 9 of 10 subjects in our sample. One subject was found without external dosimetry information in the claimant files, although there were 9 exposure-years recorded in the electronic database (6.45 mSv). The near perfect agreement between claimant records and our electronic dataset was not surprising because the DOE-provided claimant records are merely printouts of computerized annual summaries from the same database used in our replication study. In fact, early film badge monitoring records (excluding annual summaries) were not found in any of the claimant files. However, photocopies of film badge records for certain years are available in records previously collected by NIOSH, thus comparisons could be made to examine the validity of doses reported in the database. As a test case, we selected one claimant and compared the weekly film badge records from 1951 to the values reported in our dataset and in the

claimant's file for the same year. Of 52 weekly badge readings for that year, the test subject had positive values for 12 "shielded" and 34 "open-window" results. The sums of these results were in perfect agreement with the other data sources examined.

Discussion

The exposure data used in our analysis were presumed to be the information source for the CEDR file referenced in ORAUT-OTIB-0026; however, direct comparisons between the two datasets could not be made because the necessary identifiers have been removed from the CEDR file. Moreover, ORAUT-OTIB-0026 does not specify the CEDR file used for analysis or describe data characteristics in sufficient detail to ensure the appropriate file is selected for comparison. The unadjusted exposure information confirmed that patterns of poor monitoring coverage existed prior to 1975. Additionally, our review findings generally supported the DCAS description of the monitoring practices at K25 with one notable exception. Our examination revealed that film processing was conducted weekly until 1957, then biweekly 1957-1959, monthly 1969-1965, and quarterly thereafter. However, the current DCAS assumption of processing film at weekly intervals prior to 1975 is claimant favorable.

In general, doses were low among the monitored population whose average recorded cumulative dose while employed at K25 was about 1.5 mSv. The review of dosimetry data from the random samples conducted by K25 dosimetrists between 1962 and 1971 suggest that a small percentage of the unmonitored workforce may have had comparable exposures to monitored workers. However, these data generally support the conclusion that a coworker model based on existing measurements tend to overestimate exposures to unmonitored workers in a situation in which monitoring was conducted as a condition of exposure.

Validation was conducted by comparing the 95th-percentile annual adjusted doses from our model to the corresponding values reported in ORAUT-OTIB-006. We also examined model validity by comparing adjusted cumulative doses to model results using DCAS coworker values. Coworker doses from our replicate model were in reasonable agreement with the values specified in Table 2 of ORAUT-OTIB-0026, suggesting both models are comparable. We also observed that the mean of cumulative doses calculated using DCAS coworker values was elevated relative to the mean of worker cumulative doses from the exposure data, suggesting that, on average, the DCAS coworker model is bounding. Nevertheless, worker cumulative doses exceeded corresponding estimates from the coworker model in approximately 3% of the population under observation. The larger reported cumulative doses were a consequence of individual dose histories that included: outlying annual doses; correlations in annual doses; or a combination of both. Moreover, we noted similarities in jobs assigned among five individuals identified with the highest differences in cumulative doses. In all, these observations suggest that underlying dose distributions may markedly differ between groups of workers and within certain

workers. Therefore, the current coworker model, although conservative when examining doses in aggregate, may poorly characterize the bounding dose for some workers.

Conclusion

We replicated the coworker model described in ORAUT-OTIB-0026 to test modeling methods and to gain some insight into model validity. Overall, we found that the model was reproducible using data from another source, which suggests modeling methods are reliable. For validity testing, we compared the cumulative doses of monitored workers to cumulative doses calculated using the coworker model (i.e., assuming the worker was not monitored). Although this comparison does not consider the bias from preferential monitoring, we believe it is a reasonable approach in lieu of a better gold-standard. Our results raised questions on the robustness of the model for estimating bounding doses and we believe that some additional emphasis in this area would substantially improve the DCAS model.

Public Comment

In February, 2010, NIOSH established Docket 194 to facilitate public comment on its Ten-Year Review of the NIOSH Radiation Dose Reconstruction Program. We reviewed these comments for applicability to concerns on the quality of science. We found that most science concerns could be placed into four broad categories:

- **The validity of surrogate data use:** This category includes comments on the legitimacy of surrogate data as well as the appropriateness of scientific methods in which these data are used. Commenters were wary of differences in facilities (known and suspected) that could have significantly impacted exposures based on the assumptions for surrogate data.

- **Use of incomplete or erroneous information:** These comments mainly described a perceived underutilization of workers' knowledge in the development of dose reconstruction methods. Commenters point out that most technical documents were developed and approved without review or input from affected workers. Commenters urged better use of CATI interviews and worker outreach programs. Some expressed that NIOSH has been unresponsive to concerns that developed from reviews and worker input, as evidenced by a lack of timely revision in documents containing known errors.

- **Lack of quality control:** This concern stems from comments addressing technical inaccuracies and inadequate detail found in some NIOSH documents. Commenters mentioned that DCAS documents varied substantially in terms of scientific rigor.

- **Complexity:** Some commenters expressed concerns the dose reconstruction is a complicated process that is difficult to understand. As such, claimants are wary that the process is arbitrary and may potentially bias adjudication in a claimant-adverse manner.

We have attempted to address these concerns during our review. For example, we similarly found the need for improved methods for addressing worker and public comments on dose reconstruction methods. Moreover, we generally agree that DCAS products could greatly benefit from improved transparency through reviews by scientific peers and affected workers provided that methods for revising technical documents are improved in tandem. Issues on the complexity of dose reconstruction are difficult to address. The program, as defined under law, is inherently complicated and demands a great deal of scientific expertise to carry out its responsibilities. We are also mindful that expert judgment is inevitable in retrospective exposure assessment; therefore, methods are always subject to differing scientific opinion. Indirect exposure assessment methods can be especially prone to inappropriate assumptions which can bias results. Thus, these analyses require rigorous validation to strengthen assertions that estimates are claimant-favorable. Our review suggested that there are opportunities for improvement in this area.

Summary of Findings and Recommendations

The NIOSH dose reconstruction program has succeeded greatly in ten years of operation. The program is responsible for several advancements in methods of retrospective exposure assessment and has gathered a wealth of information on the U.S. atomic weapons program. To date, nearly 24,000 dose reconstructions have been completed. To carry out its mission, the program requires over 100 technical documents and has collected nearly 100,000 historical documents from over 350 facilities. Although a great deal has been accomplished, there is much yet to be done. NIOSH is committed to continuous program improvement, as evidenced by the recent initiation of this ten-year program review.

In our review of the quality of science, we found that epidemiologic research has provided the scientific foundation for the use of coworker models and other surrogate information in NIOSH dose reconstruction. DCAS has applied these methods using a graded-approach, in efforts to balance precision and accuracy with fairness and efficiency. Therefore, the scientific rigor applied in dose reconstruction, in some cases, is understandably less than that typically encountered in epidemiology or other settings of exposure science. The development and application of methods to assess the reliability and validity of dose reconstruction may greatly enhance confidence in the program. Additionally, incorporation of lessons learned from documentation and review practices may improve the overall quality of science. Thus, most of our recommendations emphasize program improvements in areas of documentation, peer review, and validation of exposure assessment methods.

Quality of Science

Improved Documentation

DCAS technical documentation is similar to standard operating procedures (SOPs) commonly found in quality management systems. The documentation system appears to be highly functional in ensuring documents are legible, identifiable, and consistently developed. In general, we found technical documents were clear, concise, and relevant to the points of use. However, we found that improvement to control of cross-referenced or layered documents was needed. We also recommend that DCAS consider changes to its document system that address the timeliness of revisions and responsiveness to concerns introduced in reviews.

1. We found that many of the technical documents used in dose reconstruction were interrelated. Although we generally agree that sharing information between sources is beneficial for reducing needless redundancy, cross-referencing and hierarchal approaches also increase the likelihood of transferring technical inaccuracies between documents, as evidenced by inconsistencies we found in documents related to indirect exposure methods.

   Recommendation: 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. Revisions to DCAS technical documents were anticipated as new information developed. However, many of the documents we reviewed have not been revised since first issued. We found that delay in document revision is partly explained by the deliberate manner in which science issues are typically resolved between the ABRWH and DCAS. We also observed a general reluctance in revising documents because of the potential for misinterpretation of the impact to existing claims. In some cases, minor technical inaccuracies have lingered in documents, resulting in a perception of carelessness in carrying out dose reconstruction.

   Recommendation: 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.

Quality of Science

Expanded Peer and Stakeholder Review

External scientific peer review or stakeholder review is not required for the technical documents used in dose reconstruction. However, these documents are subject to review by the ABRWH or contract staff working on behalf of the ABRWH. Although generally effective in assuring high quality scientific documentation, these reviews encompass only a small percentage of DCAS technical documents. Review findings are prioritized by work group members based on a number of variables (e.g., relevance, programmatic impact, complexity, relation with other issues, stakeholder opinion). DCAS responds to concerns at the request of the working group; therefore, some concerns, and perhaps the results of entire reviews, have not been thoroughly investigated because of the interworking of the work group and its prioritization of activities.

We also found that efforts to solicit information from stakeholders generally follow document approval and publication. This policy has resulted in mistrust by some affected workers, caused by the notion that DCAS is unwilling to include input from those who are most knowledgeable of the working conditions. Subsequent public comment and worker outreach activities have identified technical inaccuracies (perceived or real) in the newly approved document that may have been better addressed prior to approval. Dose reconstruction could greatly benefit from additional reviews conducted by scientific peers and affected workers provided that provisions for revising technical documents are improved in tandem.

1. Documents related to indirect exposure assessment methods contain a science component that could benefit from rigorous peer review.

   Recommendation: 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.

2. DCAS has not implemented a centralized system to address concerns raised by the ABRWH. Currently, science issues are typically coordinated by the respective working groups; a compartmentalized practice that leads to inconsistencies in the handling of concerns.

   Recommendation: 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.

Improved Validation of Indirect Exposure Assessment methods

As in dose reconstruction, epidemiologic studies rarely benefit from complete exposure information and most have had to rely on exposure proxies. Thus, many of the methods used in its dose reconstruction program are well-grounded in exposure science supporting epidemiologic studies. Nevertheless, epidemiologic studies are designed to examine aggregate risk, whereas dose reconstruction is conducted to assess the probability of causation for *the individual.* We are mindful that small biases in dose estimates that are unlikely to adversely affect population risk estimates may play a large role in a particular individual's compensation decision. Therefore, in addition to validating exposure methods suitable for defining central estimates, dose reconstruction must also validate bounding doses found in outlying regions of dose distributions where standard statistical assumptions are less robust. We offer a number of recommendations aimed to achieve improvements in validation methods.

1. We feel that a general improvement in methods that assess the reliability and validity of dose reconstruction may greatly improve confidence in the program.

   Recommendation: 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.

2. DCAS external coworker models assess annual exposure distributions at the facility level; therefore, the underlying assumption is that the average exposure for every person under observation is the same within that year. Similar analyses supporting epidemiologic studies typically include strata to represent spatial variance, such as job and location variables as a means to account for exposure heterogeneity. Some studies suggest that within-worker correlation in doses may persist for several years, suggesting that some workers may be dose-prone. The question remains whether the annual dose distribution for a population under observation is sufficient to infer doses to select groups of workers given that between-job exposures may vary widely (e.g., secretary versus chemical operator) and within- job exposures may be correlated (i.e., dose-prone individuals).

   Recommendation: DCAS should consider methods to examine between- and within-worker variance components in current coworker models.

3. Current coworker models provide little information on criteria used to judge whether the covered individual's exposure should be considered intermittent or routine (i.e., should the individual be assigned the 50th- or 95th- percentile dose?). Analyses stratified by task or work location could markedly improve consistency in decisions regarding which percentile to use for dose assignment.

   Recommendation: 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.

4. Data sources varied among the models examined whereby some models used facility data, others used data from epidemiologic studies, and still others relied on a combination of both sources. Data validation appears limited to comparisons made between the selected data and a small sample of claimant information. Information necessary to determine the reasonableness of these comparisons is not provided. Overall, information on the quality, quantity, and generalizability of data used in coworker analyses could be improved to support claims of sufficiency in characterizing external dose distributions for coworker analyses, especially in the high dose range.

   Recommendation: 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.

   Recommendation: 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.

5. DCAS technical documents address many dose uncertainties in a manner that tends to be generous towards claimants. For example, DCAS dose reconstruction methods are likely to overestimate the contribution of "missed dose" that is likely in most left-censored external dose distributions. Nonetheless, we found that DCAS technical documents may not adequately support claimant-favorability in all applications of indirect exposure assessment.

   Recommendation: 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.

Reference List

ABRWH [2007]. Transcript of the 48th Meeting of the Advisory Board on Radiation Worker Health, July 17-19. Richland, WA: NIOSH (47 pgs).

ABRWH [2010]. Transcript of the 67th Meeting of the Advisory Board on Radiation Worker Health, February 9-11. Manhattan Beach, CA: NIOSH.

Antweiler RC, Taylor HE [2008]. Evaluation of statistical treatments of left-censored environmental data using coincident uncensored data sets: I. Summary statistics. Environ Sci Technol 42: (10), 3732-3738.

Armstrong TW, Pearlman ED, Schnatter AR, Bowes SM 3rd, Murray N, Nicolich MJ [1996]. Retrospective benzene and total hydrocarbon exposure assessment for a petroleum marketing and distribution worker epidemiology study. Am Ind Hyg Assoc J 57: (4), 333-343.

Battelle [2006a]. Site profiles for Atomic Weapons Employers that refined uranium and thorium. Richland, WA: Battelle, Pacific Northwest Division: Battelle-TBD-6001 (75 pgs).

Battelle [2006b]. Site profiles for Atomic Weapons Employers that worked with uranium and thorium metals. Richland, WA: Battelle, Pacific Northwest Division: Battelle-TBD-6000 (57 pgs).

Benke G, Sim M, Fritschi L, Aldred G [2000]. Beyond the job exposure matrix (JEM): the task exposure matrix (TEM). Ann Occup Hyg 44: (6), 475-482.

Bennett TR [2010]. Memorandum of April 11, 2010 from Bennett TR, Bethlehem Steel Action Group, to NIOSH Docket Office. Amarillo, TX.

Blair A, Stewart P, O'Berg M, Gaffey W, Walrath J, Ward J, Bales R, Kaplan S, Cubit D [1986]. Mortality among industrial workers exposed to formaldehyde. J Natl Cancer Inst 76: (6), 1071-1084.

Boice JD, Cohen SS, Mumma MT, Dupree Ellis E, Eckerman KF, Leggett RW, Boecker BB, Brill AB, Henderson BE [2006a]. Mortality among radiation workers at Rocketdyne (Atomics International), 1948-1999. Radiat Res 166: (1 Pt 1), 98-115.

Boice JD Jr, Leggett RW, Ellis ED, Wallace PW, Mumma M, Cohen SS, Brill AB, Chadda B, Boecker BB, Yoder RC, Eckerman KF [2006b]. A comprehensive dose reconstruction methodology for former Rocketdyne/atomics international radiation workers. Health Phys 90: (5), 409-430.

Brown SC, Schonbeck MF, McClure D, Baron AE, Navidi WC, Byers T, Ruttenber AJ [2004]. Lung cancer and internal lung doses among plutonium workers at the Rocky Flats Plant: a case-control study. Am J Epidemiol 160: (2), 163-172.

Quality of Science

Burstyn I, Kromhout H, Kauppinen T, Heikkila P, Boffetta P [2000]. Statistical modelling of the determinants of historical exposure to bitumen and polycyclic aromatic hydrocarbons among paving workers. Ann Occup Hyg 44: (1), 43-56.

Burstyn I, Boffetta P, Burr GA, Cenni A, Knecht U, Sciarra G, Kromhout H [2002]. Validity of empirical models of exposure in asphalt paving. Occup Environ Med 59: (9), 620-624.

Checkoway H, Eisen EA [1998]. Developments in occupational cohort studies. Epidemiol Rev 20: (1), 100-111.

Checkoway H, Pearce N, Kriebel D [2004]. Research Methods in Occupational Epidemiology, Second Edition. New York, NY: Oxford University Press (372 pgs).

Cooper DL, Klein D [2004]. Radiation dose reconstruction program of the Department of Defense (DOD) report to Congress. Washington, DC: Defense Threat Reduction Agency (48 pgs).

Daniels RD, Yiin J [2006]. A comparison of statistical methods for estimation of less than detectable ionising radiation exposures. Radiat Prot Dosimetry; 121(3):240-251.

DTRA/NPTR [2010a]. Internal RDA Interviews. Standard Operating Procedure (SOP), Defense Threat Reduction Agency (DTRA) Nuclear Test Personnel Review Program (NTPR). Fort Belvoir, VA: DTRA/NPTR: RA04 (13 pgs).

DTRA/NPTR [2010b]. Radiation Dose Assessment for Cases Requiring Detailed Analysis. Standard Operating Procedure (SOP), Defense Threat Reduction Agency (DTRA) Nuclear Test Personnel Review Program (NTPR). Fort Belvoir, VA: DTRA/NPTR: RA01 (15 pgs).

DTRA/NPTR [2010c]. Film Badge Dose Assessment. Standard Method, Defense Threat Reduction Agency (DTRA) Nuclear Test Personnel Review Program (NTPR). Fort Belvoir, VA: DTRA/NPTR: ED01 (15 pgs).

DTRA/NPTR [2010d]. Whole Body External Dose - Reconstruction. Standard Method, Defense Threat Reduction Agency (DTRA) Nuclear Test Personnel Review Program (NTPR). Fort Belvoir, VA: DTRA/NPTR: ED02 (26 pgs).

DTRA/NPTR [2010e]. Skin Dose from External Sources. Standard Method, Defense Threat Reduction Agency (DTRA) Nuclear Test Personnel Review Program (NTPR). Fort Belvoir, VA: DTRA/NPTR: ED03 (51 pgs).

DTRA/NPTR [2010f]. Skin Dose from Dermal Contamination. Standard Method, Defense Threat Reduction Agency (DTRA) Nuclear Test Personnel Review Program (NTPR). Fort Belvoir, VA: DTRA/NPTR: ED04 924 pgs).

DTRA/NPTR [2010g]. Lens of the Eye Dose. Standard Method, Defense Threat Reduction Agency (DTRA)

Nuclear Test Personnel Review Program (NTPR). Fort Belvoir, VA: DTRA/NPTR: ED04 (19 pgs).

DTRA/NPTR [2010h]. Doses to Organs from Intakes of Radioactive Materials. Standard Method, Defense Threat Reduction Agency (DTRA) Nuclear Test Personnel Review Program (NTPR). Fort Belvoir, VA: DTRA/NPTR: ID01 (45 pgs).

DTRA/NPTR [2010i]. Standardized Radiation Dose Assessment Reports and Dose Calculation Worksheets. Standard Operating Procedure (SOP), Defense Threat Reduction Agency (DTRA) Nuclear Test Personnel Review Program (NTPR).Fort Belvoir, VA: DTRA/NPTR: RA03 (29 pgs).

Dement JM, Harris RL Jr, Symons MJ, Shy CM [1983]. Exposures and mortality among chrysotile asbestos workers. Part I: exposure estimates. Am J Ind Med 4: (3), 399-419.

Dupree EA, Watkins JP, Ingle JN, Wallace PW, West CM, Tankersley WG [1995]. Uranium dust exposure and lung cancer risk in four uranium processing operations. Epidemiology 6: (4), 370-375.

Eheman CR, Tolbert PE [1999]. Estimating occupational radiation doses when individual dosimetry information is not available: a job exposure matrix. Am J Ind Med 36: (3), 348-359.

Eisen EA, Smith TJ, Wegman DH, Louis TA, Froines J [1984]. Estimation of long term dust exposures in the Vermont granite sheds. Am Ind Hyg Assoc J 45: (2), 89-94.

Elliott, LJ [2007]. Memorandum of August 24, 2007 from Elliott, LJ, Director, Office of Compensations, Analysis, and Support. Cincinnati, OH (13 pgs).

Ford DP, Schwartz BS, Powell S, Nelson T, Keller L, Sides S, Agnew J, Bolla K, Bleecker M [1991]. A quantitative approach to the characterization of cumulative and average solvent exposure in paint manufacturing plants. Am Ind Hyg Assoc J 52: (6), 226-234.

Friesen MC, Davies HW, Teschke K, Marion S, Demers PA [2005]. Predicting historical dust and wood dust exposure in sawmills: model development and validation. J Occup Environ Hyg 2: (12), 650-658.

GAO [2010]. Energy Employees Compensation: Additional independent oversight and transparency would improve program's credibility. Washington, DC: United States Government Accountability Office (GAO): GAO-10-302 (63 pgs).

Gardner MJ, Winter PD, Pannett B, Powell CA [1986]. Follow up study of workers manufacturing chrysotile asbestos cement products. Br J Ind Med 43: (11), 726-732.

Gilliom RJ, Helsel DR [1986]. Estimation of distributional parameters for censored trace level water quality data; estimation techniques. Water Resource Res 22: (2), 135-146.

Glass DC, Adams GG, Manuell RW, Bisby JA [2000]. Retrospective exposure assessment for benzene in

the Australian petroleum industry. Ann Occup Hyg 44: (4), 301-320.

Gleit A [1985]. Estimation for small normal data sets with detection limits. Environ. Sci. Technol. 19, 1206-1213.

Goldberg M, Kromhout H, Guenel P, Fletcher AC, Gerin M, Glass DC, Heederik D, Kauppinen T, Ponti A [1993]. Job exposure matrices in industry. Int J Epidemiol 22 Suppl 2, S10-15.

Grimson RC, Kammerman LA, Soukup J [1983]. Statistical procedures for assignments of upper bounds for radiation doses to an unbadged individual in a group for which some individuals are badged. Health Phys 45: (3), 723-729.

Hallock MF, Smith TJ, Woskie SR, Hammond SK [1994]. Estimation of historical exposures to machining fluids in the automotive industry. Am J Ind Med 26: (5), 621-634.

Hamra G, Nylander-French LA, Richardson D [2008]. Dose reconstruction for an occupational cohort at the Savannah River nuclear facility: evaluation of a hybrid method. Radiat Prot Dosimetry 131: (2), 188-197.

Helsel D [2010]. Much ado about next to nothing: incorporating nondetects in science. Ann Occup Hyg 54: (3), 257-262.

Helsel DR [2004]. Nondetects and Data Analysis: Statistics for Censored Environmental Data, Hoboken, NJ: Wiley-Interscience (268 pgs).

Helsel DR [2006]. Fabricating data: how substituting values for nondetects can ruin results, and what can be done about it. Chemosphere 65: (11), 2434-2439.

Helsel DR [1990]. Statistical treatment of data below the detection limit. Environ. Sci. Technol 24: (12), 1766-1774.

Hewett P, Ganser GH [2007]. A comparison of several methods for analyzing censored data. Ann Occup Hyg 51: (7), 611-632.

Hoar S [1983]. Job exposure matrix methodology. J Toxicol Clin Toxicol 21: (1-2), 9-26.

Hoar SK, Morrison AS, Cole P, Silverman DT [1980]. An occupation and exposure linkage system for the study of occupational carcinogenesis. J Occup Med 22: (11), 722-726.

Hornung RW, Reed LD [1990]. Estimation of average concentration in the presence of nondetectable values. App. Occup. Environ. Hyg. 5, 46-51.

Hornung RW, Greife AL, Stayner LT, Steenland NK, Herrick RF, Elliott LJ, Ringenburg VL, Morawetz J

[1994]. Statistical model for prediction of retrospective exposure to ethylene oxide in an occupational mortality study. Am J Ind Med 25: (6), 825-836.

Hostettler JN [2006]. Chairman. Energy Employees Occupational Illness Compensation Program: Are We Fulfilling the Promise We Made to these Cold War Veterans When We Created this Program? (Part IV). Committee on the Judiciary: Subcommittee on Immigration, Border Security, and Claims; Serial No. 109-157 (612 pgs).

Johnston PD, Brenot J, Kendall GM [1986]. A study of worker dose distributions with respect to ICRP dose limitation recommendations. Health Phys 51: (5), 579-599.

Kauppinen TP [1994]. Assessment of exposure in occupational epidemiology. Scand J Work Environ Health 20 Spec No, 19-29.

Kennedy EM [2007]. Chairman. EEOICPA: Is the Program Claimant-Friendly to our Cold War Heroes. Hearing of the Committee on Health, Education, Labor and Pensions. United states Senate 110th Congress First Session on Examining the Efficacy of the Energy Employees Compensation Program (EEOICPA) focusing on our Cold War Heroes; S. HRG. 110-737 (96 pgs).

Kromhout H, Symanski E, Rappaport SM [1993]. A comprehensive evaluation of within- and between-worker components of occupational exposure to chemical agents. Ann Occup Hyg 37: (3), 253-270.

Kubale T, Hiratzka S, Henn S, Markey A, Daniels R, Utterback D, Waters K, Silver S, Robinson C, Macievic G, Lodwick J [2008]. A cohort mortality study of chemical laboratory workers at Department of Energy Nuclear Plants. Am J Ind Med 51: (9), 656-667.

Lewis M. The UK compensation scheme for radiation linked diseases. In: Occupational radiation protection: Protection workers against exposures to ionizing radiation. Geneva, Switzerland: International Atomic Energy Agency; 2002.

Lewis M [2004]. A comparison of outcomes between the Compensation Scheme and the U.S. Department of Energy Employees Occupational Illness Compensation Program. United Kingdom: Compensation Scheme for Radiation Linked Diseases: CSRLD/TWP (04) P2 (38 pgs).

Lewis SJ, Bell GM, Cordingley N, Pearlman ED, Rushton L [1997]. Retrospective estimation of exposure to benzene in a leukaemia case-control study of petroleum marketing and distribution workers in the United Kingdom. Occup Environ Med 54: (3), 167-175.

Lubin JH, Colt JS, Camann D, Davis S, Cerhan JR, Severson RK, Bernstein L, Hartge P [2004]. Epidemiologic evaluation of measurement data in the presence of detection limits. Environ. Health Perspect. 112: (17), 1691-1696.

Lundin FE, Wagoner JK, Archer VE [1971]. Radon daughter and respiratory cancer quantitative and

temporal aspects. Springfield, VA: U. S. Department of Health, Education, and Welfare Public Health Service: Joint Monograph No. 1 (176 pgs).

Lyles RH, Zhang F, Drews-Botsch C [2007]. Combining internal and external validation data to correct for exposure misclassification: a case study. Epidemiology 18: (3), 321-328.

McKeel DW and Ramspott J [2007]. Memorandum of July 13, 2007, Southern Illinois Nuclear Workers, St Louis, MO.

McKeel DW [2010]. Memorandum of March 5, 2010 from McKeel DW, Southern Illinois Nuclear Workers, to NIOSH Docket Office. Van Buren, MO.

NRC [1989]. Film Badge Dosimetry in Atmospheric Nuclear Tests. Committee on Film Badge Dosimetry in Atmospheric Nuclear Tests, Energy Engineering board, Commission on Engineering and Technical Systems, National Research Council (NRC). Washington, DC: National Academy Press (225 pgs).

NRC [2003]. A Review of the Dose Reconstruction Program of the Defense Threat Reduction Agency. Committee to Review the Dose Reconstruction Program of the Defense Threat Reduction Agency, Board on Radiation Effects Research, Division on Earth and Life Studies, National Research Council (NRC) Washington DC: The National Academies Press (399 pgs).

NRC [2005]. Assessment of the Scientific Information for the Radiation Exposure Screening and Education Program. Committee to Assess the Scientific Information for the Radiation Exposure Screening and Education Program, Board on Radiation Effects Research, Division on Earth and Life Studies National Research Council (NRC). Washington DC: The National Academies Press (430 pgs).

Nehls GJ, Akland GG [1973]. Procedures for handling aerometric data. J. Air Pollut. Assoc. 23: (3), 180-184.

DOL [2009]. 2009 Annual Report of the Ombudsman for the Energy Employee Occupational Illness Compensation Program of the U.S. Department of Labor. Washington, DC: U.S. Department of Labor (56 pgs).

Nylander-French LA, Kupper LL, Rappaport SM [1999]. An investigation of factors contributing to styrene and styrene-7,8-oxide exposures in the reinforced-plastics industry. Ann Occup Hyg 43: (2), 99-105.

OCAS [2005a]. NIOSH Comments on the SC&A Review of the Bethlehem Steel Site Profile Specific Responses to Findings, Observations and Procedural Non-conformances. Cincinnati, OH: Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH) (14 pgs).

OCAS [2005b]. Evaluation of the Effect of Adding Ingestion Intakes to Bethlehem Steel Cases. Cincinnati, OH: Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health

(NIOSH), OCAS-PER-0003 (3 pgs).

OCAS [2006a]. Technical Basis Document: Basis for Development of an Exposure Matrix for Bethlehem Steel Corporation, Lackawanna, New York; Period of Operation: 1949-1952. Cincinnati, OH: Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), OCAS-TKBS-0003 (34 pgs).

OCAS [2006b]. Evaluation of the Effect of Revision 2 of the Site Profile on Previously Completed Bethlehem Steel Cases. Cincinnati, OH: Cincinnati, OH: Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), OCAS-PER-0007 (7 pgs).

OCAS [2007]. External Dose Reconstruction Implementation Guide. Cincinnati, OH: Cincinnati, OH: Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), OCAS-IG-001 (77 pgs).

OCAS [2008]. The use of data from other facilities in the completion of dose reconstructions under the Energy Employees Occupational Illness Compensation Program Act. Cincinnati, OH: Cincinnati, OH: Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), OCAS-IG-004 (11 pgs).

ORAU TEAM [2004a]. Technical Basis Document: Basis for Development of an Exposure Matrix for Bethlehem Steel Corporation, Lackawanna, New York; Period of Operation: 1949-1952. Oak Ridge, TN: Oak Ridge Associated Universities, ORAUT-TKBS-0001 (13 pgs).

ORAU TEAM [2004b]. Technical Information Bulletin External Coworker Dosimetry Data for the X-10 Site. Oak Ridge, TN: Oak Ridge Associated Universities, ORAUT-OTIB-0021 (8 pgs).

ORAU TEAM [2005a]. Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee. Oak Ridge, TN: Oak Ridge Associated Universities: ORAUT-RPRT-0032 (138 pgs).

ORAU TEAM [2005b]. Document Control. Oak Ridge, TN: Oak Ridge Associated Universities: ORAUT-PROC-0001 (53 pgs).

ORAU TEAM [2005c]. Analysis of Coworker Bioassay Data for Internal Dose Assignment. Oak Ridge, TN: Oak Ridge Associated Universities: ORAUT-OTIB-0019 (10 pgs).

ORAU TEAM [2006a]. External Coworker Dosimetry Data for the K-25 Site. Oak Ridge, TN: Oak Ridge Associated Universities: ORAUT-OTIB-0026 (11 pgs).

ORAU TEAM [2006b]. External Coworker Dosimetry Data for the Savannah River Site. Oak Ridge, TN: Oak Ridge Associated Universities, ORAUT-OTIB-0032 (10 pgs).

ORAU TEAM [2006c]. Technical Basis for the K25 Site - Occupational External Dose. Oak Ridge, TN: Oak

Ridge Associated Universities, ORAUT-TKBS-0009-6 (24 pgs).

ORAU TEAM [2006d]. External Coworker Dosimetry Data for the Hanford Site. Oak Ridge, TN: Oak Ridge Associated Universities, ORAUT-OTIB-0030 (10 pgs).

ORAU TEAM [2006e]. External Coworker Dosimetry Data for the Paducah gaseous Diffusion Plant. Oak Ridge, TN: Oak Ridge Associated Universities, ORAUT-OTIB-0031 (12 pgs).

ORAU TEAM [2006f]. External Coworker Dosimetry Data for the Portsmouth Gaseous Diffusion Plant. Oak Ridge, TN: Oak Ridge Associated Universities, ORAUT-OTIB-0040 (10 pgs).

ORAU TEAM [2008a]. External Coworker Dosimetry Data for the Fernald Environmental Management Project. Oak Ridge, TN: Oak Ridge Associated Universities, ORAUT-OTIB-0073 (12 pgs).

ORAU TEAM [2008b]. External Coworker Dosimetry Data for the Sandia National Laboratory, New Mexico. Oak Ridge, TN: Oak Ridge Associated Universities, ORAUT-OTIB-0072 (12 pgs).

ORAU TEAM [2008c]. Use of Coworker Dosimetry Data for External Dose Assignment. Oak Ridge, TN: Oak Ridge Associated Universities, ORAUT-OTIB-0020 (9 pgs).

ORAU TEAM [2009a]. External Coworker Dosimetry Data for Area IV of the Santa Susana Field Laboratory, the Canoga Avenue Facility [Vanowen Building and the De Soto Avenue Facility (sometimes referred to as Energy Technology Engineering Center [ETEC] or Atomics International)]. Oak Ridge, TN: Oak Ridge Associated Universities, ORAUT-OTIB-0077 (10 pgs).

ORAU TEAM [2009b]. Coworker External Dosimetry for the Y12 National Security Complex. Oak Ridge, TN: Oak Ridge Associated Universities, ORAUT-OTIB-0064 (21 pgs).

Panko JM, Gaffney SH, Burns AM, Unice KM, Kreider ML, Booher LE, Gelatt RH, Marshall JR, Paustenbach DJ [2009]. Occupational exposure to benzene at the ExxonMobil refinery at Baton Rouge, Louisiana (1977-2005). J Occup Environ Hyg 6: (9), 517-529.

Peretz C, Goren A, Smid T, Kromhout H [2002]. Application of mixed-effects models for exposure assessment. Ann Occup Hyg 46: (1), 69-77.

Rappaport SM, Kromhout H, Symanski E [1993]. Variation of exposure between workers in homogeneous exposure groups. Am Ind Hyg Assoc J 54: (11), 654-662.

Rappaport SM, Lyles RH, Kupper LL [1995]. An exposure-assessments strategy accounting for within- and between-worker sources of variability. Ann Occup Hyg 39: (4), 469-495.

Rappaport SM, Weaver M, Taylor D, Kupper L, Susi P [1999]. Application of mixed models to assess exposures monitored by construction workers during hot processes. Ann Occup Hyg 43: (7), 457-469.

Ray, SD [2010]. Memorandum of March 9, 2010 from Ray SD, Alliance of Nuclear Worker Advocacy Groups, to NIOSH Docket Office. Amarillo, TX.

Rice C, Harris RL Jr, Lumsden JC, Symons MJ [1984]. Reconstruction of silica exposure in the North Carolina dusty trades. Am Ind Hyg Assoc J 45: (10), 689-696.

Richardson D, Wing S, Watson J, Wolf S [1999]. Missing annual external radiation dosimetry data among Hanford workers. J. Expo. Anal. Environ. Epidemiol. 9: (6), 575-585.

Richardson DB, Wing S, Wolf S [2007]. Mortality among workers at the Savannah River Site. Am J Ind Med. 2007 Dec; 50(12):881-891.

Rinsky RA, Smith AB, Hornung R, Filloon TG, Young RJ, Okun AH, Landrigan PJ [1987]. Benzene and leukemia. An epidemiologic risk assessment. N Engl J Med 316: (17), 1044-1050.

SAS [2007]. SAS Software, Version 9.1.3, Copyright (2002-2003), SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.

SC&A [2004]. Review of NIOSH Site Profile for Bethlehem Steel Plant, Lackawanna, NY. McLean, VA: S. Cohen and Associates, SCA-TR-TASK1-0001 (87 pgs).

SC&A [2007]. Draft review of Battelle-TBD-6000, Site Profiles for Atomic Weapons Employers That Worked Uranium and Thorium Metals. McLean, VA: S. Cohen and Associates (39 pgs).

SC&A [2010]. Resolutions of SC&A Findings on Appendix C (Dow Madison) of Battelle-TBD-6000. Vienna, VA: S. Cohen and Associates (5 pgs).

Schubauer-Berigan MK, Daniels RD, Fleming DA, Markey AM, Couch JR, Ahrenholz SH, Burphy JS, Anderson JL, Tseng CY [2007]. Risk of chronic myeloid and acute leukemia mortality after exposure to ionizing radiation among workers at four U.S. nuclear weapons facilities and a nuclear naval shipyard. Radiat Res 167: (2), 222-232.

Schumer, CE, Gillibrand, K, Higgins, B, Slaughter, LM, Massa, E, and Lee, C [2009]. Memorandum of June 4, 2009 from Schumer, CE, Gillibrand, K, Higgins, B, Slaughter, LM, Massa, E, and Lee, C, U.S. Congress, to P. Ziemer. Washington, DC.

Seixas NS, Checkoway H [1995]. Exposure assessment in industry specific retrospective occupational epidemiology studies. Occup Environ Med 52: (10), 625-633.

Simon SL, Weinstock RM, Doody MM, Neton J, Wenzl T, Stewart P, Mohan AK, Yoder RC, Hauptmann M, Freedman DM, Cardarelli J, Feng HA, Bouville A, Linet M [2006]. Estimating historical radiation doses to a cohort of U.S. radiologic technologists. Radiat Res 166: (1 Pt 2), 174-192.

Stewart PA, Dosemeci M [1994]. A bibliography for occupational exposure assessment for epidemiologic studies. Am Ind Hyg Assoc J 55: (12), 1178-1187.

Stewart PA, Lees PS, Francis M [1996]. Quantification of historical exposures in occupational cohort studies. Scand J Work Environ Health 22: (6), 405-414.

Strom DJ [1983]. A strategy for assessing occupational monitoring data from many facilities for use in epidemiologic studies. Chapel Hill: University of North Carolina (544 pgs).

Symanski E, Kupper LL, Kromhout H, Rappaport SM [1996]. An investigation of systematic changes in occupational exposure. Am Ind Hyg Assoc J 57: (8), 724-735.

Tielemans E, Marquart H, De Cock J, Groenewold M, Van Hemmen J [2002]. A proposal for evaluation of exposure data. Ann Occup Hyg 46: (3), 287-297.

U.S. Congress [2000]. Energy Employees Occupational Illness Compensation Program Act of 2000. U.S.C. 7384 et seq. (as amended): Public Law 106-398.

Wakeford R, Antell BA, Leigh WJ [1998]. A review of probability of causation and its use in a compensation scheme for nuclear industry workers in the United Kingdom. Health Phys 74: (1), 1-9.

Walker, E [2006]. Memorandum of June, 2006 from Walker E, Bethlehem Steel Action Group, to L. Elliott, NIOSH.

Watkins JP, Cragle DL, Frome EL, Reagan JL, West CM, Crawford-Brown D, Tankersley WG [1997]. Collection validation, and treatment of data for a mortality study of nuclear workers. Appl. Occup. Environ. Hyg 12: (3), 195-205.

Watson JE Jr, Wood JL, Tankersley WG, West CM [1994]. Estimation of radiation doses for workers without monitoring data for retrospective epidemiologic studies. Health Phys 67: (4), 402-405.

Wong O [1987]. An industry wide mortality study of chemical workers occupationally exposed to benzene. II. Dose response analyses. Br J Ind Med 44: (6), 382-395.

Woskie SR, Smith TJ, Hammond SK, Schenker MB, Garshick E, Speizer FE [1988]. Estimation of the diesel exhaust exposures of railroad workers: I. Current exposures. Am J Ind Med 13: (3), 381-394.

Yiin JH, Anderson JL, Daniels RD, Seel EA, Fleming DA, Waters KM, Chen PH [2009]. A nested case-control study of multiple myeloma risk and uranium exposure among workers at the Oak Ridge Gaseous Diffusion Plant. Radiat Res 171: (6), 637-645.

Ziemer, PL [2010]. Memorandum of January 29, 2010 from Ziemer PL, Chairman Advisory Board on Radiation and Worker Health, to K. Sebelius. Cincinnati, OH.

Appendix A: Surrogate Data Use

Quality of Science

Introduction

The Division of Compensation Analysis and Support (DCAS)[1] has developed a wide range of excellent technical documents and comprehensive procedures to retrospectively estimate occupational exposure encountered at the DOE[2] and AWE[3] facilities over time and to calculate dose to workers, all with the purpose of determining probability of causation for the individual worker. This review has focused on specific factors involved in assessing the quality of the dose reconstruction process, vis-à-vis use of surrogate data, that could impact the validity of the predicted dose for an individual worker whenever information to estimate occupational radiation exposure may not be available, is incomplete, or of questionable quality. Use of surrogate data in the process of retrospective dose reconstruction is one of several options used in the process of estimating occupational radiation exposure especially for workers employed in the early history of the DOE and AWE facilities for whom monitoring data may be unavailable or incomplete (42CFR82). During this early period procedures, instruments, and technology available to monitor workers for exposure to radiation and radioactive materials were evolving as detectors and methods to measure radiation were being developed. Thus, information retrieved from historical records describing occupational exposure from the 1940s and early 1950s is likely to contain data that may not have the sensitivity or specificity as that found in more contemporary files. In addition, the relationship between radiation exposure and risk was also evolving from its infancy as recognized by the reduction in occupational radiation exposure limits that, initially, were not as protective as currently recognized. Since DCAS has the responsibility to reconstruct dose to individual workers, even if specific monitoring data is less than adequate or unavailable, it may be necessary to rely upon other sources of information to develop an estimate of exposure for an individual to determine probability of causation (OCAS-IG-004).

Background

Contemporary methods for evaluating occupational radiation exposure involve use of a combination of personnel monitoring data, area monitoring, and source term characterization in order to comply with regulations for occupational and environmental protection (10CFR20; 10CFR835). However, during the early history of the U. S. atomic weapons programs, requirements and methods for monitoring occupational radiation exposure were less rigorous than contemporary practices, which is reflected by the voids found in some of the historical records that contain results of occupational radiation exposure measurements from the 1940s and early 1950s. DCAS has been provided with guidance in estimating dose for workers who were unmonitored, inadequately monitored, or for whom records of exposure

[1] Formerly known as the NIOSH Office of Compensation Analysis and Support (OCAS).
[2] The use of the acronym DOE refers to the U. S. Department of Energy and all of its predecessor agencies.
[3] AWE refers to a contractor for the DOE that hires Atomic Weapons Employees

were lost or missing (42CFR82) and has developed an extensive collection of documented procedures and guidelines for fulfilling their mission.

Surrogate Data

A common practice in exposure assessment is to use a well characterized set of monitoring data collected at one (primary) site to predict occupational exposure at other (secondary) sites where workers are performing similar tasks under similar conditions with materials that are predicted to generate similar concentrations of the contaminant in air. DCAS is authorized to adopt this practice if occupational exposure was unmonitored or if data is missing or highly uncertain (42CFR82). The USEPA also uses validated surrogate measurements in evaluating risk whenever direct measurements are not available (USEPA 1997), so the practice of using surrogate data is not unique to DCAS. If the tasks, exposure conditions, and/or source materials at the secondary location differ from those at the primary location, then predictions of occupational exposure for workers at the secondary location, based upon data from the primary location (as the surrogate), may be problematic (Seixas and Checkoway 1995). Surrogates for exposure measurements have limitations in their use especially when the metric for exposure has a distribution that is skewed. Furthermore, the industrial environment is highly variable with regards to ventilation, equipment, maintenance, and housekeeping within a facility and between different facilities. Therefore, identical operations conducted in different facilities may yield vastly different occupational exposures. Differences in worker training or experience may also affect occupational exposure. The use of surrogate data obtained from historical records relating to the early history of the DOE and AWE programs may be based upon methods and instruments that have insufficient sensitivity and reliability for developing a reliable estimate of exposure for workers who were unmonitored or inadequately monitored. Therefore, retrospective exposure assessment involving use of surrogate exposure data for workers at a facility that involves conditions or uses materials that differ from the surrogate facility is destined to be fraught with uncertainty and may produce results for workers at the secondary facility that are no better than a guess.

The representativeness of the surrogate data should be documented before it is used to estimate risk to one or more workers who were unmonitored or inadequately monitored (USEPA 1997). That is, surrogate measurements are validated when (1) the *population* of surrogate workers should adequately represent the *population* of unmonitored or inadequately workers, (2) *individual* monitored workers should adequately represent individual workers for whom exposure data is inadequate or missing, and (3) the spatial and temporal characteristics of the surrogate exposure data should be similar to that of the unmonitored or inadequately monitored facility.

DCAS procedures include a well-described hierarchical process that allows use of surrogate data to predict exposure to individuals whenever data is missing or incomplete (OCAS-IG-004). Although explicit criteria for the use of surrogate data is provided by DCAS, no guidance is given to determine appropriateness of the surrogate data, whether it is of sufficient quality, and whether source term, facility, and process data from the surrogate facility are adequately representative of conditions leading

to occupational exposure at the secondary facility. The document makes the assumption that surrogate data accurately characterizes the exposure environment. Whether occupational exposure data at one facility is transportable to another facility should be thoroughly evaluated to determine if parameters describing the distribution of measured exposure at the surrogate facility are similar to exposure predicted to occur at the secondary facility. The assumption of transportability is strengthened only if the exposure distributions are similar (Spiegelman 2010). On the other hand, lacking data on exposure for individual workers, DCAS may establish a bounding value on exposure based upon measurements obtained from a more adequately monitored facility or process. This highly conservative practice is adequate for compensation given that the bounding value is plausible and that the assumptions used in the dose assessment are "fair, consistent, and well grounded in the best available science" (42CFR82). DCAS recognizes that tests for reasonableness and plausibility are required when establishing bounding exposure models for estimating exposure to unmonitored or inadequately monitored workers. DCAS draws upon technical basis documents, technical information bulletins, and guidance issued by the Advisory Board on Radiation and Worker Health to substantiate decisions on the use of surrogate data.

Use of radiation monitoring information collected at one facility to predict occupational exposure at another facility during the early period at the atomic weapons facilities may be an unreliable practice, especially for AWE facilities where exposure monitoring data is likely to be inadequate, unavailable, or mismeasured. Unlike contemporary radiation monitoring programs, where methods and procedures have been adopted to comply with a rigid set of regulations, radiation monitoring practices during the early history of the Manhattan Project were undergoing rapid development in response to a burgeoning collection of guidance documents and research findings that initially adopted limits on occupational exposure that were less restrictive than current practice. Many workers in the early history of the atomic weapons facilities were unmonitored, so it is difficult to establish a reliable estimate of occupational radiation exposure for an individual worker whenever monitoring data is missing or unavailable. Thus, DCAS may be required to use data from a surrogate facility or process to reconstruct a dose.

Health and Radiation Monitoring Data

Beginning with the discovery of radioactivity and x-rays up through the 1940s, proclamations on the level of radiation exposure considered safe were consistently being reduced over time as new findings about health risks associated with radiation exposure became available (Kathren 1978). In the early history of the nuclear program in the United States, workers were exposed to a wide range of radiation sources and radioactive materials that retrospectively were determined to increase their risk of incurring radiation-related health effects. Routine medical monitoring programs were established for atomic weapons workers in the 1940s in response to knowledge gained from radiation exposure and

health risks encountered by workers using radium (NBS 1938). For example, extensive medical monitoring programs were established at Hanford and Oak Ridge that involved pre-employment and routine physical exams, especially for those workers exposed to radiation. Parker (1947) described how evaluation of the early clinical observations made by Health Division program at Hanford and Oak Ridge helped to confirm the practical concept of thresholds of exposure, below which workers would be protected, as a means to protect workers from the then-recognized deleterious effects of radiation exposure.

Historical records from these early health monitoring programs contain x-ray films, results of routine blood and urine chemical analyses, physical examinations, and other findings and conclusions from routine and accidental exposures that can reveal the health status of individual workers. Limited results of personal radiation exposure monitoring, such as urinalysis, nasal smears, and collection of sputum, are found in medical records. Other historical site records contain results of workplace monitoring that have been used in epidemiologic studies and by DCAS to estimate exposure from direct external radiation and to determine the gross concentration of airborne radioactive particles which can be used to estimate intake. Although methods adopted in these medical monitoring programs included performing routine complete blood counts for radiation workers every 3 months, it was likely that an acute exposure of 25 rem (0.25 sievert) would not be detected using prevalent blood chemistry in the 1940s (NBS 1949).

Detection of isotopes exhibiting low specific activity (e.g., uranium, plutonium, and thorium) in urine as metric to monitor occupational radiation exposure is challenging, especially during the early history of the weapons program since the sensitivity of instruments and the selectivity of analytical methods was significantly less than that available later in time. Resources to conduct a comprehensive bioassay monitoring program were unavailable during the early history of the weapons program. Furthermore, biokinetic models that relate the quantity of activity excreted and occupational exposure were relatively crude which would result in dose estimates with high uncertainty. On the other hand, urinalysis monitoring for isotopes with a high specific activity, e.g., polonium, were monitored very effectively (Meyers 1993) and provide a reasonable basis for retrospective dose assessment.

The National Committee of Radiation Protection (NCRP) recommended that a large facility employing 25 or more radiation workers should have full time personnel qualified in radiation protection that are responsible for the radiological safety of radiation workers (NBS 1949). Historical records demonstrate that all DOE (and predecessor) facilities employed full time professionals with responsibilities for monitoring occupational and environmental radiation exposure. However, small AWE contractor facilities were rarely provided with resources to support a professional or technical staff solely with the responsibility to conduct a radiation monitoring program, which explains why records of occupational

exposure at these locations are unavailable or incomplete. Contract workers at DOE and AWE facilities were even less likely to be monitored, a practice that continued well into the 1980s.

Historical records indicate that many, but not all, radiation workers at DOE facilities in early years were provided with pocket ionization chambers to monitor and record daily direct radiation exposure and a film dosimeter to monitor cumulative weekly exposure as recommended by the National Committee on Radiation Protection (NCRP) (NBS 1949). Parker (1948) reported that pocket chamber measurements were quite variable producing results that were accurate only to within 25 mR (milliroentgen) per week. Whole body exposure to gamma radiation was limited to 300 mR/week, which was "...believed to be a safe as far as any bodily injury...[4]" was concerned. This permissible exposure rate would result in an annual permissible dose limit of 15 rem[5]. Other practices, such as area monitoring for surface and airborne alpha and beta contamination, were established by the NCRP (NBS 1949; NBS 1953) to limit possible inhalation and ingestion of radioactive materials to quantities that would prevent exposure above prescribed recommended limits. Unfortunately, in the early period of the weapons program, these airborne and contamination limits were close to the limits of detection (Parker 1948). Thus, due to a lack of sensitivity, records of occupational radiation exposure for this early history are of limited value as a resource for predicting exposure for unmonitored or inadequately monitored workers.

Following recommendations adopted at the Chalk River (Canada) conference in 1949, the NCRP adopted maximum permissible levels of internal and direct external radiation exposure to limit the annual dose to 12 rem, a limit that the NCRP deemed safe according to available information (NBS 1954, Dummer 1958). As new information became available about the health risk associated with radiation exposure, permissible levels of exposure were further reduced, which required development of improved, more sensitive methods for monitoring occupational radiation exposure. Thus, historical health and exposure monitoring records at DOE and AWE facilities must be interpreted with a keen knowledge of the evolution of monitoring requirements, methods, instruments, and regulations with time in order to develop a reasonable estimate of exposure for an individual worker.

Like most industrial hygiene monitoring during this period, exposure monitoring was performed to insure that the workplace was safe according to best practices and current knowledge and not necessarily to estimate dose to individual workers. Thus, retrospective dose assessment for workers being monitored during the early history of the atomic weapons program necessarily include data that was collected to demonstrate compliance with an upper bound exposure limit rather than to determine dose (risk) for an individual worker. Retrospectively estimating exposure for an individual worker

[4] National Bureau of Standards Handbook 42, Safe handling of radioactive isotopes. 1949.
[5] For comparison, the current annual limit for occupational radiation exposure in the U. S. is 5 rem. (10CFR20; 10CFR835) whereas the International Commission on Radiological Protection suggests 2 rem. (ICRP 2001).

involved in a one-of-the kind process having little, if any, reliable radiological monitoring data will lead to a highly uncertain result. Although epidemiologic studies have used data from these records to predict the likelihood of radiation-related health outcomes with dose for groups of workers, it is another matter to reconstruct the dose to an individual worker when the data is sparse or incomplete since the resulting dose will be highly uncertain (NEA 1988). Uncertainty could be reduced if the missing data could be imputed using information from workers performing similar tasks or from process operations involving similar materials and equipment. However, imputing data to estimate exposure for workers using materials and processes during the early history of the atomic weapons facilities is challenging since these processes and operations were new, unique and involved radioactive materials and exposures that were difficult to measure reliably using equipment available at the time. Furthermore, great differences existed in radiation safety and monitoring practices at facilities operated by the Atomic Energy Commission or its contractor facilities. It was not unlikely that the AWE contractor had no personnel radiation monitoring program. Any exposure monitoring was likely limited to large, high volume area samplers.

Methods of dose reconstruction for former workers at atomic weapons facilities require use of historical measurements of occupational radiation exposure to calculate dose. Although measurements of occupational radiation exposure have improved remarkably since the beginning of the weapons program, measurements obtained during the early years of these facilities (when the health risk related to radiation exposure was less understood) were performed less frequently and with less sensitive equipment than today. These early, historical measurement results exhibit high variability and relatively poor sensitivity since methods and instrumentation for monitoring radiation exposure were under development along with growth of the weapons program (Dummer 1958, NBS 1952). The general methods for controlling radiation exposure involved rotating work schedules to limit the duration of exposure, using procedures to maintain some distance between the worker and the source of radiation, and shielding the worker from direct exposure. Work practices were implemented that provided shielding from direct radiation and exhaust ventilation to reduce airborne contamination. Nonetheless, during the early years of the atomic weapons facilities, workers received more radiation exposure than would be permitted according to contemporary regulations and practices. For many jobs, if the likelihood was small that the worker would exceed the permissible limit of exposure, the worker was not monitored. Thus, retrospective dose assessment for this worker is challenging.

Progress reports and other technical documents in the historical files demonstrate that the health of workers was being monitored for a range of chemical and physical agents, including radioactive contamination and radiation exposure. However, measurement of direct exposure to radiation and inhalation of radioactive materials was a new responsibility for plant managers at the beginning of the Manhattan Project. Although safety programs were established to prevent deterministic effects

associated with acute radiation exposure, the safety programs needed more maturity to develop and implement features to protect workers from stochastic effects since, at the time, this factor was not well understood. Methods for protecting workers from health risks due to occupational radiation exposure were based upon establishing maximum permissible limits as recommended by various technical committees (NBS 1949) and were consistent with industrial hygiene practices that consider workers are safe if the airborne concentrations of most chemical or physical agents are below designated threshold levels. Therefore, methods and instrumentation were developed to demonstrate compliance with the permissible exposure levels rather than estimate the individual radiation dose to a worker.

Pocket ionization chambers were the first devices used to monitor personal radiation exposure during the very early years of the Manhattan Project at Chicago and later at Oak Ridge. The chamber was worn, usually in pairs, in the pocket of the worker (hence the term "pocket chamber"). Cumulative radiation exposure, determined by the discharge of a quartz fiber capacitor in the chamber, was read-out daily after being worn by the worker. The pocket chamber was the primary device for monitoring exposure until 1944 when the film dosimeter became the official record of dose (Meyer 1993; Mitchell et al. 1993). However, pocket chambers continued to be used to monitor external penetrating radiation on a daily basis. Job assignments would be adjusted whenever pocket meters worn by a worker suggested that an exposure limit was being jeopardized. Although useful in controlling exposure and identifying incidents of an overexposure, pocket chambers were relatively insensitive and highly susceptible to physical discharge which results in an overestimate of exposure. On the other hand, the pocket meter results are useful in establishing an upper bound to the exposure received by a worker that can justifiably be extended to other unmonitored or inadequately monitored workers performing a similar job under similar exposure conditions.

Packets of dental film were also carried in the pocket for personal monitoring. Initially, darkening of the film was qualitatively related to exposure. Following the development of the photophotometer, film dosimeters could provide a reliable, quantitative measurement of occupational radiation exposure for workers who were provided with dosimeters. Initially, film dosimeters were exchanged on a weekly basis and provided a reliable measure of cumulative exposure, but were less useful in controlling worker exposure to penetrating ionization since dose was reported long after exposure was received. Dosimeter films exhibited a sensitivity of approximately 0.30 mSv. After the mid 1950s, dosimeter films were exchanged on a monthly basis to improve measurement sensitivity by effectively reducing the quantity of undetected cumulative dose.

Analogous Compensation Programs – Uranium Miners

The Radiation Exposure Compensation Program (RECA) was established by Congress for certain members of the military and workers who mined, milled, or transported uranium (42USC2210). Uranium miners represent an exposed group not unlike DOE or AWE employees who received occupational exposure to a much broader range of sources and types of radiation. The RECA program compensates uranium miners who incur certain medical conditions (e.g., lung cancer) if they worked at a uranium mine during the period from 1942 through 1971 for at least one year or if they cumulated exposure to radon progeny of at least 40 working level months. Unlike the Energy Employee's Occupational Illness compensation Program Act (EEOICPA), causation is not considered for uranium miner compensation.

There is a well described relationship between health effects and inhalation of elevated concentrations of radon that is based upon results of many epidemiologic studies of underground uranium miners (NAS 1999). Because most of underground uranium mines worked during the 1940s and early 1950s had little or no ventilation, miners received significant cumulative inhalation exposure to radon during this period (Holaday 1967). Unfortunately, records of occupational exposure are relatively incomplete or missing for these workers. Occupational exposures received by these miners have been estimated using very incomplete information, values often inaccurate and imprecise, obtained using *ad hoc* procedures and anecdotal evidence to fill missing data. Thus, cumulative exposure for uranium miners are necessarily based on various estimates rather than measurements for a particular mine where a worker was exposed. Furthermore, records of employment (work histories) are known to be inaccurate, especially for early mining years (NAS 1999; Holaday 1967). Uncertainty in work history and cumulative exposure introduces considerable uncertainty in the dose-response model. This situation is not unlike that for DOE and AWE workers during the 1940s and early 1950s, except that the primary source of exposure in a uranium mine is essentially limited to inhalation of radon and its progeny.

Deficiencies in evaluating exposure for uranium miners were replaced by various pragmatically determined strategies that draw upon measurements performed for regulatory compliance and research to fill in gaps (NAS 1999). On the other hand, the elevated incidence of respiratory disease observed in uranium miners is irrefutable. Uranium miners are at excess risk for lung-cancer.

Similar to the exposure records for DOE and AWE workers, measurement records for uranium miners are most complete and accurate during later years when exposures were generally lowest. Radon measurements performed in mines were typically obtained at one location at one time for control or regulatory compliance rather than monitoring all work areas with equal frequency to develop a distribution of exposure conditions for all workers in the mine. This situation appears to be analogous to the radiological compliance monitoring performed during the early history of atomic weapons facilities

and AWE sites where occupational exposure (not dose) was controlled by establishing tolerance or permissible levels of airborne or surface contamination or direct exposure.

Discussion

Procedures developed by DCAS insure that covered employees under EEOICPA receive a fair and reasonable estimate of their radiation dose, determined expeditiously, using all available dosimetry and workplace monitoring data. A detailed exposure assessment may involve an inordinate amount of time to produce an accurate dose, especially when dosimetry and workplace monitoring data is incomplete, lacking or unavailable. Therefore, DCAS developed well documented methods and procedures to expedite dose assessments suitable for deciding upon compensation for covered employees under EEOIPA when exposure metrics are available (e.g., TIB 18; TIB 33).

One option in determining occupational exposure for workers for whom exposure monitoring data is incomplete, lacking, or unavailable is establishing a *plausible* upper limit of exposure that someone actually present at the workplace could receive. For example, site profile information contained in TBD-6000 represents a technically sound set of data for establishing plausible limits of exposure for workers performing various operations with natural uranium metals. However, the exposure adopted as a plausible upper limit should be a value that could reasonably be received by a worker performing a job at the workplace that realistically reflects the actual source material and the prevalent conditions surrounding the job being performed. Exposure information gleaned from similar jobs performed at other facilities or locations represents a sound technical basis from which to establish a plausible upper limit of exposure for workers at another facility if adjustments are made to account for differences in the scale (size) of the facility, source material, and working environment (e.g., ventilation) affecting workers at the facility being studied. Decisions on compensation based upon plausible upper bounds of exposure have greater credibility than other estimates derived from models or distributions that may be more difficult for claimants to interpret or understand. DCAS has not established criteria for evaluating whether upper bounds of exposure based upon surrogate data are plausible. Instead, DCAS applies "reasonableness tests" to determine whether upper bounds predicted using surrogate data can be adopted (OCAS 2008). An upper bound is considered reasonable if the related occupational exposure is devoid of acute deterministic effects (e.g., asphyxiation, acute radiation sickness). It is highly unlikely that an upper bound based upon this DCAS reasonableness criterion is plausible and will be difficult to defend. DCAS needs to substitute the existing reasonableness criteria with a more logical, practical basis for adopting upper bounds of exposure that are truly plausible.

The US EPA has a structured data protocol to impute a surrogate value according to a specific hierarchy of assumptions (EPA 2001). Perhaps DCAS could review the EPA methodology and consider developing a

hierarchy of assumptions for establishing guidelines to determine when it is acceptable to use surrogate data. Devoid of such DCAS guidelines, decisions on the use of surrogate data will necessarily be delegated to others with a concomitant delay in estimating exposure for unmonitored or inadequately monitored workers. For example, review of the use of surrogate data for workers at Bethlehem Steel involved several years before a decision was made to designate a special exposure cohort.

The US Environmental Protection Agency (EPA) uses probabilistic methods similar to those used by DCAS to characterize uncertainty and variability when assessing risk. The EPA requires that adequate supporting data and *credible* assumptions be established whenever probabilistic methods are used. If exposure data is lacking (e.g., missing data, non-detect results), the EPA has surrogate protocols to address data gaps so that risk assessments can be performed. For example, the EPA accepts the use of surrogate data for structurally-related chemicals if uncertainties for other parameters of the exposure scenario are well documented for the unmonitored or inadequately monitored population (EPA 1997). Likewise, credible assumptions regarding exposure have been adopted for underground uranium miners, whose exposure records are minimal at best, but who were similarly exposed to uranium ore and radon with its short-lived progeny (albeit at different concentrations and durations). An exposure value is assigned to an underground uranium miner for a work period in a mine based upon a single point estimate. Why not do the same for DOE and AWE workers using plausible upper bounds rather than attempting to make highly uncertain predictions of occupational exposures based upon meager monitoring data? On the other hand, use of surrogate data from Simonds Saw to predict occupational exposure at Bethlehem Steel is fraught with uncertainty because procedures, facilities, and physical conditions were different at these AWE sites even though the source material was similar.

A recent subcommittee report found that the EPA surrogate protocols were conservative relative to protecting human health and the environment (EPA 2002). The EPA clearly distinguishes between risk estimates based upon actual exposure data and that based upon surrogate data. This distinction is made repeatedly within the body, tables, and appendices of EPA reports on risk so that readers, who have a range of technical expertise, can recognize that the methods used to determine risk were reasonable and intuitive. Such explicit designations aid in establishing credibility with workers and the public.

All documents, procedures, and decisions adopted by DCAS are likely to receive detailed analysis by the Advisory Board on Radiation and Worker Health. The Advisory Board may request additional review of DCAS documents from its support contractor, S. Cohen and Associates, and may create technical working groups to evaluate special exposure scenarios. These technical reviews are comprehensive, thorough and are especially important in substantiating the use of surrogate data when evaluating exposure to unmonitored or inadequately monitored workers. However, the time required to perform these reviews may be lengthy in order to resolve details associated with technical questions which may

delay decisions on compensation. For example, decisions on exposure evaluation for workers at Bethlehem Steel have required several years (2005 – 2010) to resolve with the Advisory Board recently reversing their position by recommending that workers at Bethlehem Steel be considered a special exposure cohort because exposure data from Simonds Saw & Steel could not be considered an appropriate surrogate for activities at Bethlehem Steel for the period from 1949 through 1950. This delay has the potential to instill a lack of confidence in applicants. It is likely that if DCAS would develop a surrogate data protocol similar to that adopted by the EPA, decisions on the use of surrogate data would be less contentious and would certainly be accepted in a more expeditious time frame. The EPA surrogate data protocol allows for a risk assessment to be conducted when data inputs are incomplete and provides a consistent procedure for selecting surrogate values. The use of the surrogate data protocol appears to have a conservative bias in the perspective of protecting human health, when compared to risk assessments performed solely on survey data (EPA 2001).

Conclusions

The use of surrogate data to estimate occupational radiation exposure for workers who were unmonitored or inadequately monitored is a conventional practice that is successfully used by governmental agencies and in epidemiological studies to determine risk to humans. Typically a model is constructed using exposure monitoring data from a well-monitored cohort to predict exposure to another group for whom monitoring data is lacking or incomplete. A technical challenge arises if the surrogate model is used to predict exposure to a specific individual in the unmonitored group, especially if the exposure environment is different from the surrogate environment. DCAS addresses this challenge by preparing detailed site profiles for each DOE and AWE facility that describe source materials, working conditions, and worker activities in order to accommodate any unique exposure conditions so that the surrogate model can reasonably be applied. Technical basis documents are also available that describe processes and exposure conditions prevalent for each of the facilities. For example, OCAS-TKBS-0003 describes the basis for an exposure matrix for Bethlehem Steel Corporation and ORAUT-TKBS-0032 is a document describing the site profile for Simonds Saw and Steel. However, even with a strong technical basis of information, the decision on the use of surrogate data to estimate exposure to unmonitored or inadequately monitored workers cannot be based solely on factual information if there are outstanding questions on the equivalency (i.e., transferability) of the surrogate data with the secondary facility. The recent decision of the Advisory Board to make Bethlehem Steel a Special Exposure Cohort even though the application of Simonds Saw and Steel data to supplement the Bethlehem Steel data was reviewed and found to be an acceptable technical approach, is an example of how decisions on compensation involve more than a technical basis of fact. Alternatively, DCAS can address some of the outstanding questions by adopting plausible upper bounds on exposure that can be used in determining compensation. The question then arises on deciding upon what exposure is plausible. Here, DCAS can

draw upon the wealth of information from site profiles which list measurement results to develop a plausible upper exposure limit upon which risk to individual workers can be determined.

Recommendations

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.

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.

References

10CFR20. Standards for Protection against Radiation. Code of Federal Regulations, Title 10, Part 20. U. S. Nuclear Regulatory Commission.

10CFR835. Occupational Radiation Protection. Code of Federal Regulations, Title 10, Part 835. U. S. Department of Energy.

42CFR82. Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Final Rule. Code of Federal Regulations, Title 42, Part 82. U. S. Department of Health and Human Services.

J. Dummer. Los Alamos Handbook of Radiation Monitoring. Los Alamos Scientific Laboratory, LA-1835, 1958.

D. Holaday, D. Rushing, R. Coleman, P. Wookrich, H. Kusnetz, W. Bale. Control of radon and daughters in uranium mines and calculations of biologic effects. U. S. Public Health Service Publication #494. U. S. Public Health Service, Washington, DC.; 1967.

International Commission on Radiological Protection. The 2007 Recommendations of the International commission on Radiological Protection. ICRP Publication 103.

R. Kathren. Historical development of radiation measurement and protection. Pp 13-51 in *Handbook of Radiation Measurements and Protection*. (A. Brodsky, ed.). CRC, West Palm Beach, FL; 1978.

H. Meyer. History of the Mound Bioassay Programs, MLM-MV-93-003. EG&GG Mound Applied Technologies. 1992.

H. Meyer. Historic overview of external monitoring methods. In: NIOSH Research Issues Workshop: Epidemiologic use of nondetectable values in radiation exposure measurements. pp. 10-18; Cincinnati, OH. 9-10 September, 1993.

T. Mitchell, G. Ostrouchov, E. Frome, G. Kerr. A method for estimating occupational radiation dose to individuals using weekly dosimetry data. ORNL Report #7668; Oak Ridge National Laboratory, Mathematical Sciences Section, Oak Ridge, TN. 1993.

G. Morgan. Surveying and monitoring of radiation from radioisotopes. Nucleonics 4(3): 24-37; 1949.

National Bureau of Standards (NBS), Radium Protection. NBS Report # 23. National Bureau of Standards, Washington, DC. 1938.

Quality of Science

National Research Council. Health Effect of Exposure to Radon, Biological Effects of Ionizing Radiation VI. National Academy of Science, National Academy Press; Washington, DC.; 1999.

National Bureau of Standards (NBS), Safe handling of radioactive isotopes. NBS Report # 42. National Bureau of Standards, Washington, DC. 1949.

National Bureau of Standards (NBS), Control and removal of radioactive contamination in laboratories. NBS Report # 48. National Bureau of Standards, Washington, DC. 1952.

National Bureau of Standards (NBS), Radiological monitoring methods and instruments. NBS Report # 51. National Bureau of Standards, Washington, DC. 1952.

National Bureau of Standards (NBS), Maximum permissible amounts of radioisotopes in the human body and maximum permissible concentrations in air and water. NBS Report # 52. National Bureau of Standards, Washington, DC. 1953

National Bureau of Standards (NBS), Permissible dose from external sources of ionizing radiation. NBS Report # 59. National Bureau of Standards, Washington, DC. 1954.

Nuclear Energy Agency (NEA). Epidemiology and radiation protections. Nuclear Energy Agency, Organization for Economic Co-operation and Development. Workshop Proceedings on Epidemiology and Radiation Protection: 151; Paris, 1988.

OCAS-IG-004. The use of data from other facilities in the completion of dose reconstructions under the Energy Employees Occupational Illness Compensation Program Act. OCAS-ID-004; August 21, 2008.

H. Parker. Health Physics, Instrumentation, and Radiation Protection. Health Phys 38(6): 226-282; 1948.

SCA. NIOSH site profile surrogate data survey. S. Cohen & Associates, Vienna, VA. 2007.

N. Seixas, H. Checkoway. Exposure assessment in industry specific retrospective occupational epidemiology studies. Occup. Environ. Med. 52: 625-633; 1995.

D. Spiegelman. Approaches to uncertainty in exposure assessment in environmental epidemiology. Ann. Rev. Public Health. 31: 149-163; 2010.

TBD 6000. Site Profiles for Atomic Weapons Employers that worked with Uranium and Thorium Metals. Battelle-TBD-6000; 2006.

TIB 18. Internal Dose Overestimates for Facilities with Air Sampling Programs; ORAUT-OTIB-0018; 2005.

TIB 33. Application of Internal Doses Based on Claimant-Favorable Assumptions for Processing as Best Estimates; ORAUT-OTIB-0033; 2005.

USEPA. Exposure Factors Handbook. Office of Research and Development, National Center for Environmental Assessment. EPA/600/P-95/002Ba. 1997.

USEPA. Industrial Surface Impoundments in the United States. U. S. Environmental Protection Agency, Office of Solid Waste; report # EPA530-R-01-005; March 2001.

USEPA. Review of the Office of Solid Waste's Study, *Industrial Surface Impoundments in the United States*: An EPA Science Advisory Board Report EPA-SAB-EEC-03-001, 25 October 2002.