

# THE SECRETARY OF HEALTH AND HUMAN SERVICES WASHINGTON, D.C. 20201

MAY - 5 2004

The Honorable J. Dennis Hastert Speaker of the House of Representatives Washington, D.C. 20515

Dear Mr. Speaker:

I am pleased to transmit to Congress the enclosed Report on Access to Information for Performance of Radiation Dose Reconstructions under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), as required by the National Defense Authorization Act for Fiscal Year 2004 (Public Law 108-136).

The report describes the information required to conduct dose reconstructions, and it explains the matters that can adversely affect the ability of the National Institute for Occupational Safety and Health (NIOSH) to obtain the information in a timely, accurate, and complete manner. With the cooperation of the Departments of Labor and Energy, and EEOICPA claimants, and using data from these and other sources, NIOSH continues to complete dose reconstructions while further developing the capacity of its dose reconstruction program.

Your continued support in this critical area of occupational health and safety is greatly appreciated.

Sincerely.

Yommy G. Thompson

Enclosure

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### **Executive Summary**

This report responds to Section 3134(a) of the National Defense Authorization Act for Fiscal Year 2004, which provided for the National Institute for Occupational Safety and Health (NIOSH) to report on its access to information required for radiation dose reconstructions under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). The report describes the information required to conduct such dose reconstructions and explains in detail the matters that can adversely affect the ability of NIOSH to obtain the information in a timely, accurate, and complete manner. The report addresses these matters in Section III of the report with respect to the primary sources of such information, which include the Department of Labor (DOL), the Department of Energy (DOE), sources of information on Atomic Weapons Employers, and claimants. These matters are also addressed in context in Section IV of the report, which describes the dose reconstruction process and the amount of time provided for each component of this process, and identifies when adverse matters can arise and delay the process. The report also provides the following data on performance of the dose reconstruction program in relation to matters addressed in this report, as follows:

### Total Number of Claims Requiring Dose Reconstruction

As of January 15, 2004 NIOSH had received 15,191 cases for dose reconstruction from the DOL. Attachment 2 provides a site-specific breakdown of these cases.

<u>Total Number of Dose Reconstructions Adversely Affected by Matters Addressed in this Report</u>

Almost all of the 15,191 cases received from DOL as of January 15, 2004 have been adversely affected by one or more of the matters addressed in this report, resulting in a delay of the dose reconstruction. As indicated in Section IV of this report, a substantial proportion of cases would have been likely to require more than 150 days for completion without the occurrence of any delay, to provide for the full rights and involvement of claimants and/or the complexity of the particular dose reconstruction.

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#### I. Introduction

The Energy Employees Occupational Illness Compensation Program Act (EEOICPA), 42 U.S.C. §§ 7384-7385, authorized a compensation program to provide a lump sum payment of \$150,000 and prospective medical benefits as compensation to covered employees suffering from designated illnesses incurred as a result of their exposure to radiation, beryllium, or silica while in the performance of duty for the Department of Energy (DOE) and certain of its vendors, contractors and subcontractors. This legislation also provided for payment of compensation for certain survivors of these covered employees. The Department of Labor (DOL) has primary responsibility for administering this compensation program, assisted by the Department of Health and Human Services (DHHS), DOE, and the Department of Justice. DOL began accepting claims for compensation under EEOICPA in July 2001.

EEOICPA required the establishment of a radiation dose reconstruction program to estimate the radiation doses of most cancer claimants. These dose estimates are used by DOL to assess the likelihood that an employee with cancer developed that cancer as a result of exposure to radiation in performing his or her duty at a DOE facility or an Atomic Weapons Employer (AWE) facility. Within DHHS, the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health (NIOSH) conducts the radiation dose reconstructions for cancer claims for which EEOICPA requires dose reconstructions. NIOSH develops these dose reconstructions based on information obtained from DOE, DOL, EEOICPA claimants, and other sources. Once completed, NIOSH transmits the dose reconstruction to DOL for use in making a final decision on the claim.

Section 3134(a) of the National Defense Authorization Act for Fiscal Year 2004 provides as follows:

- a) REPORT ON ACCESS TO INFORMATION FOR PERFORMANCE OF RADIATION DOSE RECONSTRUCTIONS.-(1) Not later than 90 days after the date of the enactment of this Act, the National Institute for Occupational Safety and Health shall submit to Congress a report on the ability of the Institute to obtain, in a timely, accurate, and complete manner, information necessary for the purpose of carrying out radiation dose reconstructions under the Energy Employees Occupational Illness Compensation Program Act of 2000 (42 U.S.C. 7384 et seq.), including information requested from any element of the Department of Energy. (2) The report shall include the following:
- (A) An identification of each matter adversely affecting the ability of the Institute to obtain information described in paragraph (1) in a timely, accurate, and complete
- (B) For each facility with respect to which the Institute is carrying out one or more dose reconstructions described in paragraph (1)-
- (i) a specification of the total number of claims requiring dose reconstruction;
- (ii) a specification of the number of claims for which dose reconstruction has been adversely affected by any matter identified under paragraph (1); and
- (iii) a specification of the number of claims requiring dose reconstruction for which, because of any matter identified under paragraph (1), dose reconstruction has not

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been completed within 150 days after the date on which the Secretary of Labor submitted the claim to the Secretary of Health and Human Services.

The following report describes the information necessary to perform dose reconstructions, identifies matters that have adversely affected the ability of NIOSH to obtain necessary information in a timely, accurate and complete manner, and provides an overview of the dose reconstruction process to provide a context for understanding the findings of this report. In addition, the report provides requested information, to the extent feasible, on the total number of cases requiring dose reconstruction, the number of cases for which dose reconstruction has been adversely affected by the inability to obtain necessary information in a timely, accurate and complete manner, and a specification of the number of cases requiring dose reconstruction for which dose reconstruction has not been completed within 150 days after the date on which DOL submitted the case to NIOSH.

# II. Information Necessary to Complete Radiation Dose Reconstruction Under EEOICPA

#### Overview on Information Required for Dose Reconstructions

Under EEOICPA and Executive Order 13179, NIOSH conducts dose reconstructions relying primarily on information obtained from DOL, DOE, AWEs, and claimants, while using the science-based knowledge and practices of dose reconstruction. The information obtained from DOE and AWEs includes data such as individual radiation dosimetry records, area radiation monitoring records, and process descriptions of tasks performed. Although individual dosimetry records are the most desirable information for completing dose reconstructions, such information is not required by EEOICPA and is not typically essential scientifically. For example, when individual dosimetry records are not available or are incomplete, dose reconstructions may be completed through the use of area monitoring, process descriptions, and other information summarized in site profiles prepared by NIOSH, together with information on the individual's work history. Dose reconstructions conducted under these circumstances make use of claimant-favorable assumptions to avoid underestimating radiation doses. Consequently, such dose reconstructions typically estimate radiation doses that are substantially higher than those that are likely to have been incurred by the employees.

The type and amount of information necessary to initiate a dose reconstruction is highly dependent on case-specific matters. For example, dose reconstructions for a cancer that has been associated in epidemiological research studies with lower doses of radiation, such as certain types of leukemia, might be completed by summing the original individual monitoring data provided by DOE, without further technical analysis or data collection. This

<sup>&</sup>lt;sup>1</sup> In this report, the term "case" is used instead of "claim" to avoid confusing the count of dose reconstructions, since there are often multiple survivor claimants, each with a claim, when the DOE or AWE employee is deceased. Each DOE or AWE employee whose radiation doses must be reconstructed represents a single case requiring a single dose reconstruction, regardless of the number of claimants seeking compensation for the cancer(s) incurred by the employee.

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simple arithmetic might by itself establish that the employee received sufficiently high radiation doses for DOL to determine that the cancer of the employee was at least as likely as not associated with his radiation dose, and that the claimant should be compensated. Conversely, cancers that might only be associated with very high doses of radiation, such as prostate cancer, may require a full evaluation of all possible sources of exposure, including external, internal, medical and environmental sources, unless very high doses are recorded in the original data provided by DOE.

In cases involving AWEs, NIOSH requests for information are similar. DOE provides information that it maintains and helps NIOSH identify additional sources of information on the radiological exposures of the AWE employees.

The majority of the information required to complete a dose reconstruction is provided by DOL and either DOE, or DOE and other sources of information on the operations of an AWE. Claimants are a third routine source of information. In addition, NIOSH may make use of information from research studies, medical screening, and other sources of information available to characterize the radiological environments of nuclear weapons work.

#### Information Requested from DOL

NIOSH obtains the following information from DOL when DOL refers a case to NIOSH for dose reconstruction:

- 1. <u>Personal information on the covered employee</u> including the employee's name, gender, address, telephone number, birth date, and social security number;
- 2. <u>Identification of each covered facility</u> at which the employee was employed and the period of employment at each facility;
- 3. <u>Identification of the type or types of cancer</u> (defined by International Classification of Disease (ICD-9) codes) of the employee (primary cancers if known, or secondary sites-sites to which the cancer spread- if the primary cancer is unknown);
- 4. Dates of cancer diagnoses;
- 5. <u>Ethnicity of the employee</u>, if the primary cancer is a type of skin cancer;
- 6. Smoking history, if the primary cancer is lung cancer; and
- 7. <u>Personal information on the claimant</u>, if he/she is not the covered employee, including the claimant's name, address, telephone number, relationship to the covered employee, and social security number.

#### Information Requested from DOE and/or an AWE Source of Data

DHHS and DOE established a Memorandum of Understanding (MOU) to coordinate the Departments' interdependent activities for the implementation of EEOICPA. The MOU is facilitating the efforts of DOE and NIOSH to accomplish our work in the most timely and efficient way possible. With respect to dose reconstruction, the MOU specifies authorities, responsibilities, and procedures for NIOSH to request information for dose reconstructions, for DOE to respond to such requests, and for NIOSH to provide DOE with final dose

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reconstruction reports. The MOU also addresses important issues that can relate to these exchanges of information, such as ensuring the protection of individuals' privacy under the Privacy Act, processing security clearances for NIOSH dose reconstruction personnel, and managing classified information.

#### Case-specific Data Requests

Under the MOU between DOE and DHHS, NIOSH requests the following information from DOE upon receiving a case from DOL:

- 1. <u>Individual monitoring data,</u> including individual readings from any personal radiation dosimeters the employee wore and individual results from bioassay samples (biological samples used to measure personal radiation exposure, such as urine samples) and whole-body monitoring of the employee (a method of measuring radioactive materials inhaled, ingested, or taken in through the skin or lesions).
- 2. Records of any diagnostic x-rays that the employee may have been required to receive, as a condition of employment, in the course of routine medical examinations; alternatively, the individual DOE sites may provide facility-wide information on the administration of x-ray examinations over the operating history.
- 3. <u>Incident investigation records</u> for any radiological incidents in which the energy employee was involved.

#### Batch Data Requests

NIOSH also obtains individual monitoring data in batches (e.g., pertaining to all the employees of an entire facility or site) from DOE and/or from an AWE source of data. This is often necessary when obtaining records from an AWE source, which would typically lack the resources to provide records on a case-by-case, as needed, basis.

#### Site Profile Data Requests

NIOSH requests site and facility information from DOE and/or from an AWE source of data that is used to interpret and supplement individual employee radiation monitoring data and to substitute for such data as necessary. DOE and/or the AWE source of data are requested to provide detailed descriptions of the radiation control practices of the facility throughout the period of operations. This information includes dosimetry program information such as the types and accuracy of radiation dosimeters, the frequency with which the dosimeters were read, and bioassay techniques employed. It also includes information on facility operations and radiological conditions. Such information includes the amount, types and chemical forms of the radioisotopes present at the facility, area radiological monitoring results, and environmental radiation levels in and around the facility. All of this information is used to develop site profiles, which are site-specific guidance documents used in support of dose reconstructions.

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### <u>Information Requested from Claimants</u>

NIOSH obtains the following information from claimants:

- 1. <u>Claimants are interviewed to assist NIOSH</u> in interpreting and supplementing information provided by DOE, DOL and other sources, including information on work performed by the employee, the employee's involvement in radiological incidents and radiation protection practices in place during the employee's employment;
- 2. <u>NIOSH provides every claimant the opportunity to review and comment on the NIOSH interview report</u> to ensure that NIOSH accurately captures information provided by the claimant;
- 3. After the draft dose reconstruction report is completed, NIOSH provides every claimant the opportunity to review and comment on the draft dose reconstruction report to ensure that any information provided by the claimant and subsequently used in the dose reconstruction is accurate and to help the claimant understand the information, methods, and results of the dose reconstruction;
- 4. NIOSH asks every claimant to review and sign the "Statement by the Claimant Closing the Record on a NIOSH Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act" (the "OCAS-1 form"). This statement verifies that the claimant has completed providing information to NIOSH for the dose reconstruction. After receiving the signed statement from the claimant, NIOSH will forward the completed dose reconstruction report to DOL and the claimant.

# III. Identification of Matters Adversely Affecting the Ability of NIOSH to Obtain Information in a Timely, Accurate, and Complete Manner

Many matters have affected NIOSH's ability to obtain information in a timely, accurate, or complete manner, for completing an individual dose reconstruction or for being able to complete a group of individual dose reconstructions associated with a particular nuclear weapons facility or site. These factors are described in detail below and within the context of the dose reconstruction process under section IV of this report.

It should be understood that, in this report, obtaining information in an accurate and complete manner means obtaining information that NIOSH has requested, sufficient to conduct a dose reconstruction. It is not typical for individual dosimetry data to be accurate or complete, particularly data that are decades old, because the technology and practices of radiation monitoring have improved over time, and because these practices have been designed to prevent exposures above regulatory limits, rather than to track radiation doses accurately. However, it is not necessary for such data to be accurate and complete in order to complete a dose reconstruction. Dose reconstruction is a practice specifically intended to estimate doses when monitoring information is missing, incomplete, or inaccurate. In this process of estimation, one type of information, such as information on dosimetry practices or work processes, is used to correct or substitute for another type of information, such as individual monitoring or area monitoring records. Uncertainties in information are identified when

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present and taken into account when they could substantially affect the result of the dose reconstruction.

When NIOSH does not receive information it has requested, this delays NIOSH in conducting the dose reconstruction or group of dose reconstructions related to the information request. As is discussed below, however, dose reconstructions have also been delayed by the development of the infrastructure needed for the dose reconstruction program, and the collection and analysis of data to establish site profiles.

#### Matters Concerning Information from DOL

The following matters concern information supplied by DOL:

- 1. <u>Information provided by the Department of Labor (DOL) is occasionally inaccurate or incomplete</u>: This information, as described above, includes contact information, employment history, cancer diagnosis, and when applicable, smoking history or ethnicity. Deficiencies in this information have typically involved either incomplete employment or cancer diagnosis information, and often occur when the sources of information upon which DOL relies are inaccurate or incomplete. These situations are typically identified through the dose reconstruction process, which involves NIOSH interviewing the claimants and reviewing more extensive employment-related records than are germane to DOL processes for determining that an employee is eligible to be considered for compensation. NIOSH then asks DOL to supplement the record to reflect this new information, since DOL has the responsibility for verifying employment and medical conditions.
- 2. <u>Additional cancer diagnosed during case processing:</u> Some energy employees have been diagnosed with an additional cancer after the initial case file was submitted to NIOSH by DOL. Since radiation doses are estimated for the specific cancer site or sites relevant to the case, NIOSH must revise the dose reconstruction to include dose estimates for the new cancer site.

# Matters Concerning information from DOE or Sources of AWE Data

The following matters concern information supplied by DOE or sources of data for cases involving AWEs:

1. <u>Data does not exist in a readily retrievable format:</u> Several DOE facilities have maintained data in filing systems that were not designed for the efficient collection of data relating to individual employees. For example, some sites filed data by time period (month, quarter or year) rather than by any individual identifier such as name, social security number, badge number etc. In these circumstances, extensive sets of files have to be searched to fulfill each individual request for dosimetry data. DOE is working to convert such filing systems to support more efficient retrieval of data for individuals.

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2. <u>Individual exposure records cannot be located:</u> In some cases, some or all records of work and/or exposure for an individual cannot be located. In such cases, as specifically allowed by EEOICPA, NIOSH requires co-worker exposure data and/or other data to characterize the potential exposures of the energy employee. The development of substitute information is time-consuming.

- 3. DOE was providing dosimetry data from some of its sites in summary form:
  NIOSH requests dosimetry data in the form of individual measurements from radiation monitors and bioassays, rather than summaries of this information that are more frequently used by DOE for other purposes. The individual measurements are much more readily usable in dose reconstructions and are more precise information. DOE sites are now consistently providing data in the requested form, when it is available. When it is not available, NIOSH has to substitute other types of information and analytic work.
- 4. <u>Limitations concerning AWEs:</u> DOE often does not have detailed information concerning radiological exposures at AWEs, and some AWEs are no longer in business or may have little incentive to promptly search and provide their records. DOE helps NIOSH to identify additional sources of information and to obtain the information available. These operations are time-consuming. In addition, the records available for AWEs are likely to be less extensive than are generally available for DOE facilities because many AWEs operated during the first years of the U.S. nuclear weapons program, when radiological monitoring and protection programs were relatively unsophisticated.
- 5. <u>Administrative matters affecting the provision of information by DOE</u>: In addition to the matters described above, DOE previously has reported that resource limitations and other administrative matters have affected the provision of information requested for dose reconstruction. DOE has worked to effectively resolve these administrative matters when they arise.

### Matters Concerning Information from Claimants

The following matters concern information provided by claimants:

1. Claimants may not know or cannot recall information that might be useful or may inadvertently provide inaccurate information: Many claimants are survivors and the majority of survivors were not well informed of the employee's work experience (most employees kept many details of their work experiences confidential for the protection of national security). In addition, some employees were not informed or well informed about their radiation exposures and other relevant information, and many of these employees are elderly and may have difficulty remembering correctly the details of their work experiences. While the claimant interviews are voluntary and dose reconstructions can rely on other sources of information, the limitations concerning the knowledge of claimants can delay the progress of the dose reconstruction. In particular, NIOSH may have to interview co-workers or seek additional records to establish the work history of the employee or may have to conduct additional analyses to take into account uncertainties about the work history.

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2. <u>Claimants may provide additional information after the dose reconstruction is drafted:</u> After receiving NIOSH's draft dose reconstruction report, claimants sometimes provide additional information. NIOSH considers the relevance of this information to the dose reconstruction and revises the dose reconstruction if necessary. The late provision of this information delays the completion of the dose reconstruction.

3. Claimants may not return the OCAS-1 form within 60 days: A claimant has 60 days to sign and return the OCAS-1 form indicating that the claimant has no additional information to provide for the dose reconstruction. After sixty days, NIOSH sends two reminder letters (the first at 60 days and another at 74 days) to the claimant notifying the claimant that the dose reconstruction and case may be administratively closed if the claimant does not sign and return the OCAS-1 form. The sooner the claimant signs and returns the OCAS-1 form, the sooner NIOSH forwards the case to DOL for a decision. Sometimes this step is delayed for cases involving multiple claimants (survivors) associated with a particular case, because, in general, a case is not forwarded to DOL until an OCAS-1 form has been received from each claimant. NIOSH will, however, forward a case to DOL after all of these steps have been completed, provided that NIOSH has received at least one signed OCAS-1 form from among a group of multiple claimants.

# Matters Concerning the Development of a Dose Reconstruction Program by NIOSH

In addition to issues related to obtaining information in a timely, complete and accurate manner, NIOSH has had to develop the infrastructure, analyses, and protocols required to process and apply this information efficiently in dose reconstructions. The progress of this developmental work has been the single most important matter affecting the pace of dose reconstructions. The following is the status of this developmental work:

- 1. The infrastructure needed to complete dose reconstructions has been developed. EEOICPA was enacted October 30, 2000, and Executive Order 13179, which assigned DHHS its responsibilities under EEOICPA, was issued on December 7, 2000. NIOSH developed the data management systems, basic procedures for dose reconstructions, and published final rules concerning methods for dose reconstruction and probability of causation determinations, in 2001 and 2002. NIOSH completed the development of internal facilities and the recruitment of staff in 2003.
  - NIOSH awarded a large support contract in September of 2002 to obtain the majority of the resources required to handle the high volume of cases referred by DOL for dose reconstruction. The contractor completed hiring and training its staff and developing its facilities and primary systems in 2003.
- 2. The development of site profiles is underway. NIOSH is in the process of producing site profiles, which summarize the operational history, radiation control procedures, dosimetry practices, and other general information related to radiation exposures, for all major DOE and AWE sites. These site profiles provide the health physicists who conduct dose reconstructions with consistent general information to support their

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completion of individual dose reconstructions. NIOSH is developing first the profiles for sites for which NIOSH has the largest number of dose reconstruction cases. The pace at which NIOSH can complete these site profiles is limited, however, by the limited expert resources available to conduct this exceptionally specialized work, the complexity of the history and variety of operations at particular sites, and other factors.

As of January 31, 2004, NIOSH had completed site profiles for two major DOE sites and four AWEs. Site profiles are underway or scheduled for completion in 2004 for other DOE sites and AWEs.

#### IV. Overview of Dose Reconstruction Process

The following overview of the dose reconstruction process explains how NIOSH processes EEOICPA cases and identifies the points at which matters that adversely affect the work, as identified under Section III of this report, can occur. This context is important for understanding the normal operation of the NIOSH dose reconstruction program at this point in time, as well as for understanding how the given matters affect the accurate, complete, and timely acquisition of information needed for dose reconstructions. A time line illustrating this process is included as Attachment 1, "Dose Reconstruction Processing Time Line Goals." The "T=" notations below signify the time in days after receipt from DOL, during which each action is expected to take place when there are no delaying circumstances.

- 1. <u>Case is received from the DOL (T=0):</u> The starting point of NIOSH's dose reconstruction process is when NIOSH receives the case from DOL. NIOSH then assigns the case an identification number and enters it into the NIOSH Tracking Database.
- Request Data from DOE (T=1): A NIOSH request for data from DOE is 2. automatically generated and sent to the appropriate DOE facility point of contact. In cases where the employee worked at more than one facility, multiple dose information requests must be made. DOE is requested to provide a response within 60 calendar days. This response depends on the availability of the data and may include: 1) the data requested; 2) an indication that no data was found; or 3) an indication that the search is continuing. In some circumstances, typically involving AWE facilities, NIOSH, with the assistance of DOE, has to identify a point of contact (a source for records), which delays the process of requesting records. It may take considerable investigation to identify the repository or repositories of data, particularly for operations that were discontinued decades ago and for employers no longer in business. In other circumstances, NIOSH does not obtain data for cases individually, either because the data is being obtained through a facility-wide data capture effort or because NIOSH has been informed that personal dosimetry data is not available.

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3. Receive DOE Data (T=61): When NIOSH receives the records from DOE, it scans the images into a tracking database and reviews the data for quality. A period of seven calendar days is allotted for this initial quality review (quality issues may also be addressed at the time a health physicist conducts the dose reconstruction). If inadequacies are identified, such as when individual exposure records are not located or are not of the type requested, NIOSH sends an additional request for information to DOE. The additional request can cause substantial delay at this step, particularly if the inadequacy of the initial response from DOE relates to a systemic limitation on data retrieval of the type previously described in this report. Also, an important cause of delay at this step had been the initial lack of an infrastructure at NIOSH to review the adequacy of records received from DOE and the resulting backlog of cases that has accrued during this infrastructure development. The infrastructure was put into place in 2003 through contract support and this review work is proceeding, as discussed later in this report. Similarly, DOE also had to develop capacity to respond to NIOSH requests for DOE data or to identify other sources of data on AWEs.

- 4. Send initial interview letter to claimant (T=68): NIOSH attempts to interview all claimants to obtain any information they might have that would supplement or correct information available from other sources that might be used in the dose reconstruction. NIOSH sends a letter informing the claimant that someone will be contacting them to conduct an interview and provides a list of the questions that will be asked during the course of the interview. The claimant normally is provided 14 calendar days (from the date of mailing) to review the questions. An incorrect mailing address (due to a change of address) is presently the principal cause of delays relating to this step, requiring NIOSH to relocate the claimant through DOL or other sources. Previously, the development of the infrastructure required to conduct a high volume of interviews was the principal cause of delay at this step.
- 5. Schedule claimant interview (T=68-82): During the claimant's review of the interview questions, NIOSH contacts the claimant by telephone to schedule the interview. This call can be delayed when the claimant has a change of phone number and when the claimant is unavailable. If the claimant cannot be contacted by phone, NIOSH sends a follow-up letter, at least 14 days after the initial interview letter, explaining that attempts to contact the claimant by phone were unsuccessful and that the case will be forwarded for dose reconstruction, unless the claimant contacts NIOSH at the number provided to schedule the interview.
- 6. <u>Conduct Claimant Interview (T= 83-90):</u> NIOSH attempts to schedule interviews of claimants during the third week after the initial interview letter was mailed. After the interview is completed, NIOSH summarizes the interview in a written report, which is sent to the claimant for review within seven days. NIOSH requests the claimants to provide comments if the report omits important information or is inaccurate. Delays at this step usually result from the claimant

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- being unavailable at the scheduled interview time or as a result of iterative interactions with claimants who supplement the interview record.
- 7. Send Dose Reconstruction Introduction Letter to Claimants (T=91): After the interview has been completed and documented, and sufficient data is believed to exist to begin a dose reconstruction, NIOSH sends a letter to the claimant providing a list of health physicists who may be assigned to perform the dose reconstruction. This letter includes a brief description of the health physicists who may be assigned to the case and the facilities where the health physicists have worked. NIOSH asks whether the claimant would view any of the proposed health physicists as having a conflict of interest in conducting the dose reconstruction. Claimants have 14 calendar days to respond to this query. If no response is received, NIOSH assumes the claimant does not view any of the proposed health physicists as having a conflict of interest. NIOSH has not experienced significant delays associated with this step, but has experienced significant delays in initiating this step since most dose reconstructions require the use of a site profile.
- 8. Conduct dose reconstruction (T = 105-165) NIOSH assigns the case to a health physicist, and the dose reconstruction is started. Once drafted, the dose reconstruction undergoes multiple levels of quality review by health physicists with the contractor and at NIOSH. Delays in completing a draft dose reconstruction can result from newly identified inaccuracies or omissions in information concerning exposures, cancer diagnosis, employment periods, and demographic information, and the identification of new cancers diagnosed since the claim was submitted. Delays also can arise from quality reviews and as individual dose reconstructions broach new technical issues requiring procedural determinations by senior health physicists. Finally, dose reconstructions that require highly specialized expertise have been delayed while the relevant experts have developed methods that can be applied by their colleagues.
- 9. Obtain any additional relevant information from the claimant prior to completing the dose reconstruction (T=166-226) NIOSH sends the completed draft dose reconstruction report to the claimant, together with an OCAS-1 form, which enables the claimant to certify that he/she has provided all relevant information so that the dose reconstruction can be finalized and the case referred back to DOL. NIOSH conducts a closing interview with the claimant to explain the dose reconstruction methods and results and obtain any additional information the claimant might provide. If the claimant does not provide additional information relevant to the dose reconstruction, the claimant has 60 days to sign and return the OCAS-1 form to NIOSH. Delays at this step result when the claimant does not return the OCAS-1 form to NIOSH within 60 days, is not available to conduct a closing interview, makes alterations to the OCAS-1 form that require follow-up, or provides additional information that might be relevant to the dose reconstruction.

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10. Complete the dose reconstruction and refer the case back to DOL (T=227-228)
Once a signed OCAS-1 form is returned by the claimant or claimants for a case, the NIOSH analysis record for the dose reconstruction is closed and a final dose reconstruction report is sent to DOL, DOE, and the claimant. This final step is normally completed within two days of receiving the signed OCAS-1 form. Delays at this step can occur when a signed OCAS-1 form is returned prior to the closing interview.

### V. Data Quality Review

NIOSH has reviewed the quality of the DOE responses for dosimetry data on a site-by-site basis, in accordance with the order in which site profiles are being developed. NIOSH has reviewed the majority of case-specific data received from DOE for those sites for which site profiles have been issued or are expected to be issued soon. Alternatively, NIOSH has reviewed a representative sample of the data received from DOE for those sites for which site profiles are expected to be completed later in 2004.

The data associated with each case is thoroughly reviewed prior to being forwarded on for dose reconstruction. This review is performed to determine if the information provided is adequate to perform a dose reconstruction. The information associated with a case will be considered adequate if any one of the following criteria is met:

- 1. The data requested is provided and is sufficiently detailed to perform a dose reconstruction for compensation purposes.
- 2. If personal dosimetry information (regarding the employee and/or coworkers at the facility) is not available, NIOSH has approved a site profile applicable to the covered employee's place(s) of employment and particular cancer.
- 3. Limited available dosimetry information results in a dose estimate sufficiently high to produce a probability of causation of 50% or greater.

Sites Providing Adequate Responses to Data Requests for Dose Reconstruction (determined by a review of almost all cases)

As of January 15, 2004, NIOSH had reviewed 96% of the 8,198 DOE submittals from the sites listed below and had determined that all of the DOE submittals reviewed are adequate for the initiation of the dose reconstruction. About 4,600 cases associated with these sites are awaiting the completion of site profiles. Approximately 400 cases are awaiting additional information from sources other than DOE, such as cancer diagnosis information that would come from DOL. The number of cases associated with each site is indicated in Attachment 2.

- Savannah River
- Hanford
- Y-12 Plant
- Oak Ridge National Laboratory (X-10)
- Rocky Flats Plant

- Oak Ridge Gaseous Diffusion Plant (K-25)
- Pacific Northwest National Laboratory

# Sites Providing Adequate Responses to Data Requests for Dose Reconstruction (determined by a review of a random sample of cases)

As of November 30, 2003, NIOSH had reviewed a random sample of 1,598 (36%) of 4,450 DOE submittals, stratified across sites listed below, to evaluate the adequacy of the DOE submittals for dose reconstruction. NIOSH determined that the data from these sites should be adequate for the initiation of dose reconstruction for a large majority of claims. At least 1,416 of the submittals reviewed (89%) appear to be adequate. (Adequacy cannot be fully evaluated until the site profiles for these sites are completed.) The number of cases associated with each site is indicated in Attachment 2.

- Idaho National Engineering Laboratory
- Nevada Testing Site
- Feed Materials Production Center (FMPC)
- Mound Plant
- Paducah Gaseous Diffusion Plant
- Portsmouth Gaseous Diffusion Plant
- Kansas City Plant Energy Technology Engineering Center
- Lawrence Livermore National Laboratory
- Argonne National Laboratory East
- Pinellas Plant
- Sandia National Laboratory
- Clarksville Facility
- Argonne National Laboratory West
- Sandia National Laboratory Livermore
- Pacific Proving Ground
- Median Facility
- Grand Junction Operations Office
- West Valley Demonstration Project
- Albuquerque Operations Office
- Oak Ridge Institute for Science and Education
- Oak Ridge Thermal Diffusion Plant (S-50)
- Lawrence Berkeley National Laboratory
- Ames Laboratory
- Sandia Laboratory Salton Sea Base
- Lovelace Respiratory Research Institute
- Fermi National Accelerator Laboratory
- Environmental Measurements Laboratory
- Yucca Mountain Site Characterization Project

### Sites with Special Consideration

The following represent sites where monitoring data was obtained through sources other than DOE, as identified below. NIOSH has reviewed records on 684 individuals and found 674 (99%) of these to be adequate to initiate dose reconstructions.

- Mallinckrodt (data source: Environmental Measurements Laboratory)
- Iowa Ordinance Plant (data sources: University of Iowa, the Department of Defense, Oak Ridge Associated Universities)
- Shippingport Atomic Power Plant (data source: Atlanta National Archives)

### Sites Not Providing Data Requested for Dose Reconstruction

There is one site, the Trinity Nuclear Explosion Site, with 1 request for information, for which no DOE submittals have been received.

# Sites Not Consistently Providing Adequate Responses to Data Requests for Dose Reconstruction

(determined by a review of a random sample of cases)

The sites listed below are not providing the data requested for dose reconstruction for a substantial proportion of cases. NIOSH has reviewed a random sample of 364 (42%) of the 876 DOE submittals from these sites, as well as the submittals responding to a total of three requests to Los Alamos Medical Center. Of the sample of submittals reviewed, 259 (71%) appear to be adequate for the initiation of dose reconstruction. The number of cases associated with each site is indicated in Attachment 2.

- Los Alamos National Laboratory
- Los Alamos Medical Center
- Pantex Plant
- Brookhaven National Laboratory
- Stanford Linear Accelerator Facility
- Oak Ridge Hospital

Some of the specific deficiencies of the data provided by these sites that could result in delays in dose reconstructions are as follows:

- Los Alamos National Laboratory has not submitted individual bioassay data, nor detailed external dosimetry data. The submittals consist of derived dose quantities, which cannot readily be used in dose reconstructions because they use a different methodology than NIOSH uses for dose reconstructions.
- Los Alamos Medical Center has submitted derived dose quantities instead of individual bioassay data and detailed external dosimetry data for one of three cases for which it received requests.
- Pantex Plant has submitted inconsistent data. For a substantial number of cases, monitoring data provided in summary form are inconsistent with detailed data.

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- Brookhaven National Laboratory has not submitted raw bioassay data, nor detailed external dosimetry data. The submittals have consisted of summary data, which cannot be readily used in dose reconstructions.
- Stanford Linear Accelerator Facility has provided only summary data.
- Oak Ridge Hospital has provided only summary data.

### DOE Support of the Development of Site Profiles

Throughout 2003, NIOSH worked on the development of 14 profiles for DOE sites. As discussed in Sections II and III, these site profiles provide a summary and compilation of basic dosimetry and related information used to assist health physicists in conducting individual dose reconstructions for employees at the sites. DOE has been supportive in assisting NIOSH to locate and obtain the site characterization information. There have been delays in this process, however, to comply with procedures for assuring national security when information requested is in classified documents.

# VI. Data Requested on the Performance of the NIOSH Dose Reconstruction Program

# Total Number of Claims Requiring Dose Reconstruction

As of January 15, 2004 NIOSH had received 15,191 cases for dose reconstruction from the DOL. Attachment 2 provides a site specific breakdown of these cases.

# <u>Total Number of Dose Reconstructions Adversely Affected by Matters Addressed in this</u> Report

Almost all of the 15,191 cases received from DOL as of January 15, 2004 have been adversely affected by one or more of the matters addressed in this report, resulting in a delay of the dose reconstruction process outlined in Section IV of this report. It is not possible, however, to specify further the number of cases at each facility that were affected specifically by any particular matter. More than one of the matters identified in Section III of this report can affect a single claim and many of these matters are not tracked. For example, most of the claims referred to NIOSH by DOL have been delayed while NIOSH has developed the infrastructure and site profiles required to conduct the dose reconstructions.

As indicated in Section IV of this report, a substantial proportion of cases would have been likely to require more than 150 days for completion without the occurrence of any delay, to provide for the full rights and involvement of claimants and/or the complexity of the particular dose reconstruction. Also, as indicated in Section III of this report, there are a number of factors that caused delays in obtaining information in a timely, complete and accurate manner, and NIOSH has had to develop the infrastructure, analyses, and protocols required to process and apply this information efficiently in dose reconstructions. By continuing to address these issues, NIOSH has greatly improved the completion rate for dose reconstructions. While it took NIOSH a little more than two years from when it received its first referral from DOL to complete the first 1000 dose reconstructions, NIOSH completed the second 1000 dose reconstructions in less than four months. NIOSH is hopeful that these

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improvements throughout the program will result in future dose reconstructions being completed as expeditiously as possible.

#### VII. Conclusion

NIOSH, with the cooperation of DOL, DOE, EEOICPA claimants, and other sources of data, is completing more dose reconstructions while continuing to develop the capacity of the dose reconstruction program authorized under EEOICPA. The progress of this endeavor, however, has not been as rapid as planned. Although NIOSH foresaw substantial challenges in creating a dose reconstruction program of this unprecedented scale at the time EEOICPA was enacted, far more extensive developmental work than anticipated has proven necessary. Specifically, NIOSH has found that it must complete the development of a site profile, as discussed in Section II of this report, prior to completing most dose reconstructions for employees who worked at the site addressed by the site profile. NIOSH is working to complete site profiles as quickly as possible.

NIOSH is also making every effort to continue to expedite the completion of dose reconstructions for which site profiles are completed or other sources of information are sufficient. NIOSH is dedicated to providing the best possible scientific and technical service to the EEOICPA program and its claimants.