Testimony
Before the Subcommittee on Immigration, Border Security, and Claims
Committee on the Judiciary
United States House of Representatives

Activities of the Department of Health and Human Services under the Energy Employees Occupational Illness Compensation Program Act of 2000

Statement of

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Mr. Chairman and Members of the Subcommittee, my name is John Howard and I am director of the National Institute for Occupational Safety and Health (NIOSH), part of the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS). I am joined today by Mr. Larry Elliott, Director of the NIOSH Office of Compensation Analysis and Support, and Dr. Lewis Wade, Senior Science Advisor at NIOSH. I am pleased to appear before you today to provide testimony on the status of HHS activities under the Energy Employees Occupational Illness Compensation Program Act of 2000 ("the Act").

I will describe and summarize the progress of the HHS responsibilities under the Act, delegated by the President under Executive Order 13179 issued on December 7, 2000:

- Develop scientific guidelines for determining whether a worker's cancer is related to the worker's occupational exposure to radiation ("probability of causation") and methods to estimate worker exposure to radiation ("dose reconstruction"),
- Use the dose reconstruction regulation to develop estimates of radiation dose for workers who apply for compensation,
- Establish a process by which classes of workers can be considered for inclusion in the Special Exposure Cohort, and
- Provide support for the Advisory Board on Radiation and Worker Health

Regulations for Dose Reconstructions and Cancer Causation

HHS was charged with promulgating two regulations. One regulation establishes methods for conducting radiation dose reconstructions for cancer claimants (42 C.F.R. pt. 82). Dose reconstruction is a science-based process for retrospectively estimating the amounts and types of radiation doses incurred by a person. This effort included substantial scientific work by NIOSH to develop specialized analytical methods and tools needed to estimate the occupational radiation doses of nuclear weapons workers.

The second HHS-promulgated regulation establishes guidelines by which the Department of Labor (DOL) determines whether the cancer of an employee is "at least as likely as not' related to the radiation doses estimated for that employee through a dose reconstruction (42 C.F.R. pt. 81). This regulation is for determining the "probability of causation," which is the probability that a person's cancer was related to radiation from employment at the specified facility, required the further development of a scientific tool, the "Interactive RadioEpidemiological Program" (IREP). IREP is a computer program that uses "risk models" for associating radiation doses with risk information on different cancers. IREP estimates the probability of disease causation specific to each employee's unique history of exposures to different types and quantities of radiation during the course of his or her employment. In the final development of this tool, NIOSH collaborated with the National Cancer Institute, which had created the initial

paper version in the 1980s and was in the process of updating it in response to an extensive scientific review by the National Research Council.

In promulgating the two regulations, HHS invited and considered comments of the public and the Presidentially-appointed Advisory Board on Radiation and Worker Health ("the Board"). The Board reviewed and advised HHS on both of these rules during the public comment and supported the final rules, which were finalized on May 2, 2002. The regulations are designed to provide efficiencies in dose reconstruction efforts for purposes of arriving at timely decisions on compensation. The regulations allow for new scientific findings and consensus to be integrated after proper scientific consideration.

An example of this recently occurred when NIOSH published a Federal Register Notice and provided an opportunity for the public to comment on a proposed change in the process for selection of target organs used in dose reconstructions for energy employees with lymphoma cancers. This change was in response to an evaluation by NIOSH of current scientific data on lymphoma, which revealed that the site of the radiation injury can differ from the site of the tumor or cancer origin documented in the medical files of a lymphoma cancer patient. On February 15, 2006, NIOSH finalized the new process (for selecting the dose reconstruction target organs for energy employees with lymphoma cancers). The new process selects the organ that would have received the highest radiation dose from among relevant, possibly irradiated organs, as determined through the

dose reconstruction process, when the identity of the target organ is in question. This change is now being used to complete dose reconstructions for lymphoma cases and may result in DOL calculating a higher probability of causation determinations for select lymphoma cases. NIOSH is also reviewing the dose reconstructions for lymphoma cases that have already been completed and returned to DOL. If the new process will result in DOL calculating a higher probability of causation that will result in approval of a denied case, a new dose reconstruction will be provided to the claimant and to DOL.

Dose Reconstruction Program

The second responsibility of HHS, delegated to NIOSH, is the development and administration of a dose reconstruction program to serve cancer claimants under the Act. This is the largest and most challenging responsibility assigned to HHS. The production scale and scientific complexity of the dose reconstruction program required by the Act are significant compared to other Federal compensation programs requiring dose reconstructions.

NIOSH began developing a dose reconstruction program in the summer of 2001. In accordance with its responsibilities to date, NIOSH established a broad scientific foundation, the cornerstones of which are the radiation dose reconstruction methods and cancer risk models for occupational radiation exposures. The scientific fields and disciplines needed for dose reconstructions include mathematics; health physics; bio-kinetic modeling; statistical treatment,

analyses, and testing; exposure assessment; and nuclear engineering. The development and maintenance of the cancer risk models for this compensation program require epidemiology; statistical treatment, analyses, and testing; medical interpretation; and risk assessment modeling and communication.

To assist in conducting individual dose reconstructions, NIOSH develops different kinds of informational documents and updates them as necessary if more information is obtained.

Site Profile documents provide information on the radiation protection practices of a facility. The six sections of a Site Profile document are called Technical Basis Documents, and each address a specific topic, such as a site description, occupational medical dose, or occupational internal dose. Completion of individual dose reconstructions may require all, none, or only certain sections of a Site Profile document. As each Technical Basis Document is completed, it is used to complete dose reconstructions and assure consistency.

We also develop Technical Information Bulletins, which provide clarification on how a specific method can be used to complete a dose reconstruction, on how the information in a Technical Basis Document or Site Profile can be used to meet a specific need in the dose reconstruction process, or on how to provide

specific technical information that supports or justifies the tables or information included in a Technical Basis Document or Site Profile.

NIOSH also developed and implemented procedures for performing dose reconstructions; developed a records and data management system; and initiated numerous records retrieval efforts. NIOSH established and coordinated efforts with DOL, the Department of Energy (DOE), and the Defense Threat Reduction Agency in the Department of Defense.

NIOSH has two contractors to assist with the development of site profile information and completion of dose reconstructions. The first contract was awarded on October 12, 2003, to Oak Ridge Associated Universities (ORAU). The contract involves personal interviews with the claimants, retrieval and validation of individual monitoring data, reconstruction of exposure conditions at various DOE and DOE contractor facilities (site profile development), and the completion of individual dose reconstructions. The second contract was awarded on October 12, 2005, to Battelle Science and Technology International (Battelle). The contract involves the reconstruction of exposure conditions at various Atomic Weapons Employer facilities and the completion of individual dose reconstructions.

Following are the status and accomplishments of the dose reconstruction program:

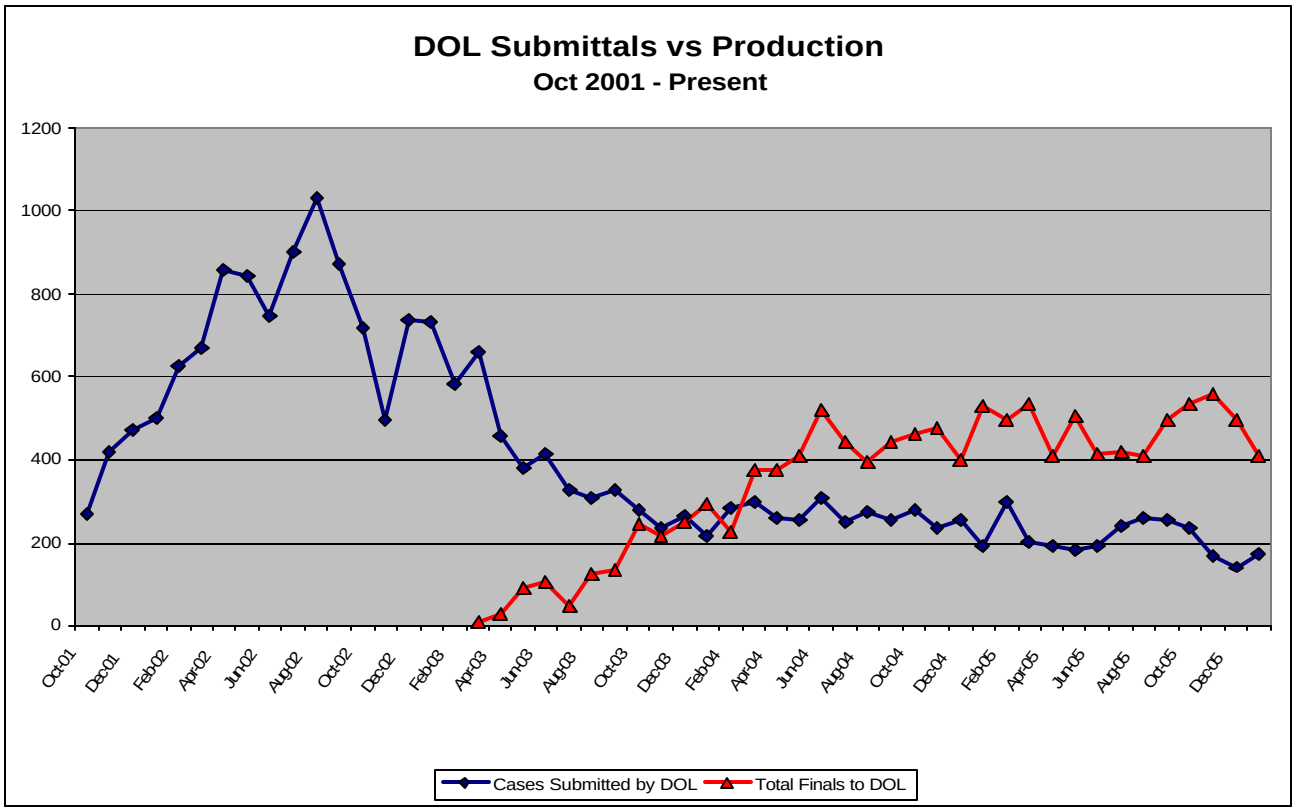
General Claim Information

- EEOICPA encompasses 362 covered sites. NIOSH has received claims from 195 of those sites, over 100 of which have five or fewer claims.
- Of the 362 covered sites, approximately 40 are DOE sites and represent the majority of claims; more than 300 sites are Atomic Weapons Employer sites (sites which processed or produced material that emitted radiation and was used in the production of atomic weapons, excluding uranium mining and milling).

Dose Reconstructions

- Cases sent to NIOSH by DOL for dose reconstruction: 21,092
- Cases returned to DOL: 13,742 (65% of total 21,092)

The chart below illustrates NIOSH progress in monthly caseloads:



Documents

- Developed 129 Technical Basis Documents, 40 Technical Information Bulletins
- Developed 63 implementation procedures (45 ORAU procedures and 18 OCAS procedures)

Special Exposure Cohort

The next responsibilities of HHS are directly related to the dose reconstruction program: defining the requirements for adding classes of employees to the

Special Exposure Cohort ("the Cohort") and developing a process for receiving, evaluating, and processing Cohort submissions received.

Under the Act, claims for members of the Cohort who have any of 22 specified cancers designated by the Act would not require dose reconstructions or a determination by DOL of probability of causation. Congress included in the Cohort certain employees of three DOE facilities, known as the gaseous diffusion plants, as well as employees of a nuclear weapons test site in Amchitka, Alaska. In addition, the President has authority, delegated to HHS, to designate additional classes of employees to be members of the Cohort, subject to Congressional review, if two tests are met:

(1) it is not feasible to estimate with sufficient accuracy the radiation dose that the class received; and

(2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class.

On May 28, 2004, HHS promulgated a regulation to allow it to implement this authority -- Procedures for Designating Classes of Employees as Members to the Special Exposure Cohort under EEOICPA (42 C.F.R. pt. 83). The guidelines used to evaluate the feasibility of reconstructing doses for a proposed Cohort class are established in this rule. It states that dose reconstructions can be performed with sufficient accuracy if: "NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose for every type of

cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any member of the class or if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose."

The regulation provides for petitions in two circumstances. One circumstance is when NIOSH has attempted to conduct a dose reconstruction for a cancer claimant and finds that the dose reconstruction cannot be completed because there is insufficient information to estimate the radiation doses of the claimant with sufficient accuracy. The second circumstance includes all other possibilities. For example, a petition may be submitted representing a class of employees whose members have yet to file claims under EEOICPA, or even have yet to be diagnosed with cancer.

Once the Cohort regulation was promulgated, NIOSH was able to begin considering petitions, working closely with petitioners to assist with their Cohort submissions in order to qualify the submission as a petition for evaluation. To qualify for evaluation, a submission must contain sufficient information to establish that the radiation exposures sustained by employees at a site were not monitored, either through personal or area monitoring; or that such records have been lost, falsified, or destroyed; or that there is no information regarding monitoring, source, source term, or process from the site. This information may

be provided by documents, affidavits, reports from a health physicist or other individual with expertise, or a government report of a scientific or technical nature.

NIOSH uses a hierarchical approach to evaluate the types of information available to reconstruct doses. The primary data used for determining internal exposures are from personal monitoring data, such as urinalysis, fecal samples, and whole body counting results. If these are unavailable, the air monitoring data from breathing zone and area monitoring is used to estimate the potential internal exposure. If personal monitoring and area monitoring are unavailable, internal exposure estimates can be made from modeling potential exposures from the source term and process information. The source term is developed from the quantity of the radioactive material(s) involved or the exposure potential of the radiation generating device.

The same hierarchy is used for determining the external exposures to the cancer site. Personal monitoring data from film badges or thermal luminescent detectors are the primary data used for determining external exposures to the cancer site. If there are no personal monitoring data, exposure rate surveys and source term modeling can be used to determine the potential external exposure. In addition to the occupational external exposures from facility operations, occupational medical exposures from routine X-ray examinations given to the energy employee as a condition of employment are also included in the external

exposures. These exposures are estimated using technical information relative to the type of X-ray equipment used at a point-in-time at the facility. When all of the sources of data described above have been determined to be unsuitable for establishing maximum plausible radiation doses, it can be concluded that doses cannot be reconstructed with sufficient accuracy.

Once a submission has qualified for evaluation, NIOSH evaluates the petition based on the issues discussed above. A completed evaluation report is sent to both the petitioners and the Board. The Board reviews the petition and provides a recommendation to the Secretary of HHS on the feasibility of conducting dose reconstructions for members of the petitioning class. As required by the Act, the final step in the petitioning process is an opportunity for Congress to review certain designations by the Secretary of HHS. These decisions become effective in 30 days, unless Congress provides otherwise.

Current Cohort Information

- Six classes of employees at four sites have been added to the cohort. Three of these classes (Mallinckrodt Chemical Company - Destrehan Street; Iowa Army Ammunition Plant; and Y-12 Facility) were added due to petitions received from former employees, survivors, or their authorized representatives. One class, Linde Ceramics Plant, was added because NIOSH determined that data to estimate radiation doses with sufficient accuracy were not available for a specified time period.

- NIOSH is currently evaluating six submissions and will send completed evaluation reports to the petitioners and the Board. These submissions are Pacific Proving Grounds, Y-12 (Oak Ridge), Rocky Flats Plant, Oak Ridge Institute for Nuclear Studies, Ames Laboratory, and Chapman Valve.
- NIOSH notifies applicants of any requirements that are not met by the submission and assists the applicants with guidance through phone consultations and written communication in developing necessary information. Currently, NIOSH is providing such assistance to applicants involved with 11 submissions. It is not known which, if any, of these submissions will ultimately qualify for evaluation as a Cohort petition.
- To date, 20 submissions have failed to qualify for evaluation as Cohort petitions, and have been closed. Some submissions have been withdrawn by the applicants, and some submissions requested the addition of classes of employees to the Cohort that were already included in the statutory Cohort. Other submissions lacked appropriate evidence despite substantial assistance from NIOSH.
- On December 22, 2005, NIOSH published a notice in the Federal Register requesting public review and comment on proposed changes to the Cohort rule (42 C.F.R. pt. 83) to address changes to the Act authorized by the National Defense Authorization Act for Fiscal Year 2005 (codified as amended in scattered sections of 42 U.S.C.). Comments on the interim final Cohort ruled will be accepted until March 23, 2006.

Advisory Board on Radiation and Worker Health

Finally, the President charged HHS with administering a new Federal advisory committee, the Advisory Board on Radiation and Worker Health ("the Board"), to advise the Secretary of HHS. Members are invited to serve overlapping terms of up to four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. HHS provides administrative services, funds, facilities, staff, and other necessary support services.

HHS nominated and the President appointed the initial member of the Board in 2001. The Board is chaired by Dr. Paul Ziemer, an internationally recognized health physicist, and consists of 12 members representing scientists, physicians, or representatives of nuclear weapons workers --a membership which reflects the Act's requirements that the Board include a balance of scientific, medical, and worker perspectives.

<u>Board Accomplishments</u>

- Since the first Board meeting in January 2002, Board members have met a total of 46 times in workgroups, subcommittees, as the full Board. The most recent meeting occurred this week.
- CDC secured a technical support contractor, Sanford Cohen & Associates (SC&A), on October 10, 2003 to address the Board's request for

assistance in better managing its workload. SC&A is currently assisting the Board with their work on dose reconstruction reviews, site profile reviews, and the Cohort petitioning process.

- The Board has reviewed 60 dose reconstructions and 21 procedures of the NIOSH program. The Board's review of dose reconstruction procedures has been constructive. Many of the review comments raised by the Board's contractor, SC&A, have already been examined and changes for improvement have been made or are underway. Other comments are being addressed with feedback to the Board.
- The Board has made eight recommendations to the Secretary of HHS.

Summary

In conclusion, NIOSH has made much progress in carrying out the responsibilities of HHS under EEOICPA and looks forward to continuing to improve its performance to assist workers who have cancer as a result of exposure to unique hazards in building the Nation’s nuclear defense.

Thank you again for the opportunity to testify. I’m happy to answer any questions you may have.