Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA)

Dose Reconstruction Interviews and Forms

Request for Office of Management and Budget (OMB) Review and Approval for a Federally Sponsored Data Collection

(0920-0530) **EXTENSION**

Supporting Statement

Part A

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A. Justification

A. 1. Circumstances Making the Collection of Information Necessary

Background

Dose Reconstruction Telephone Interviews under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) – Three Year Extension

There are no changes to the collection instrument, instruction, frequency of collection, or the use to which the information is to be put. We have made minor, non-substantive changes to the cover letter and cover page to the collection instrument in order to comply with the Plain Writing Act of 2010 (Public Law 111–274).

The Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), Public Law 106-398, 114 Stat. 1654, 1654A-1231 (October 30, 2000) Attachment A, established a compensation program to provide a lump sum payment of $150,000 and 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.

EEOICPA instructed the President to designate one or more Federal Agencies to carry out the compensation program. Accordingly, the President issued Executive Order 13179 (“Providing Compensation to America’s Nuclear Weapons Workers”) on December 7, 2000 (65 FR 77487), assigning primary responsibility for administration of the compensation program to the Department of Labor (DOL). The executive order also directed the Department of Health and Human Services (HHS) to perform several technical and policymaking roles in support of the DOL program.

Among other duties, HHS is required to develop methods to estimate radiation doses (“dose reconstruction”) for certain individuals with

cancer applying for benefits under the DOL program. HHS is also to apply these methods to conduct the program of dose reconstruction required by EEOICPA. On September 28, 2001, this dose reconstruction program was delegated to the National Institute for Occupational Safety and Health (NIOSH), an Institute of the Centers for Disease Control and Prevention. On October 5, 2001, HHS published “Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Act of 2000; Interim Final Rule With Request for Comments.” The preamble described the Paperwork Reduction Act and other information collection requirements involved in the program, and stated that NIOSH was requesting an emergency clearance from the Office of Management and Budget to collect data under the EEOICPA. Emergency clearance was granted on October 30, 2001, and routine clearance was granted May 31, 2002.
The individuals for whom dose reconstruction is performed include all covered employees (as defined in EEOICPA) who are not in the statutorily defined “special exposure cohort” with a specified cancer. Technical limitations of radiation monitoring technology and procedures will require HHS to evaluate each employee’s recorded dose. In most cases, these monitoring limitations will result in possibly undetected or unrecorded doses, which will be estimated using standard dose reconstruction methods and would be added to the dose record.

The procedures and level of effort involved in dose reconstructions depend in part on the quantity and quality of available dose monitoring information, the conditions under which radiation exposure arose, and the forms of radiation to which the individual was exposed. If individuals for whom dose estimates are needed were monitored using present day radiation protection technology and received only external radiation doses, dose reconstruction could be very simple, and might only require adding the radiation doses recorded from radiation badges and adding estimated potential ”missed” doses, where appropriate.

However, dose reconstruction can require extensive research and analysis. Additional work is required if radiation doses were not monitored or there is uncertainty about the monitoring methods involved; if there was potential for internal doses through the ingestion, inhalation or absorption of radioactive materials; or if the processes and circumstances involved in the radiation exposures were complex.

An important aspect of the HHS dose reconstruction process is that it

involves interaction with the covered employee or his or her survivor. NIOSH initially interviews claimants individually and provides them with the opportunity, through a structured interview, to assist NIOSH in documenting the work history of the employee (characterizing the actual work tasks performed), identifying incidents that may have resulted in undocumented radiation exposures, characterizing radiation protection and monitoring practices and identifying co-workers and other witnesses, if NIOSH determines it necessary, to confirm undocumented information. In this process, NIOSH uses a computer assisted telephone interview (CATI) system, which allows interviews to be conducted more efficiently and quickly than would be the case with a paper-based instrument.

Privacy Impact Assessment

A PIA has already been assessed on May 1, 2009 (UPI: 009-20-01-05-02-9522-00; System Name: NIOSH Dose Reconstruction System) (Attachment B).

Overview of the Data Collection System

NIOSH has developed three different initial telephone interviews - Attachment C- which are used in the dose reconstruction process. The first is used when the claimant is the covered employee. The second is used when the claimant is a family member of the covered employee, since in many instances; the covered employee is deceased or incapacitated. The third interview is for co-workers or supervisors of the covered employee, when the claimant is a family member, since family members may not know all the information necessary for the dose reconstruction.

After the dose reconstruction has been completed, NIOSH contacts the claimants to explain the results of the dose reconstruction. Claimants have the opportunity to ask questions about the information used, the methods, and the results. This is the final opportunity for the claimant to supplement the dose reconstruction record.

Additionally, NIOSH has developed Form OCAS-1 (Attachment D: Statement by the Claimant Closing the Record on a NIOSH Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act) which is signed by the claimant at the end of the dose reconstruction process, before the claim is referred back to DOL for further processing.

Items of Information to be Collected

The PII information that we may collect during this information collection (name, date of birth, social security number, mailing address, phone number, medical records numbers, medical notes, legal documents, employment records, and employment status) is used to perform dose reconstruction under EEOICPA.

Identification of Website(s) and Website content Directed at Children Under 13 Years of Age

This information collection does not involve Web-based collection methods nor does it refer respondents to Web site. In addition, is not directed at children under 13 years of age.

A 2. Purpose and Use of Information Collection

HHS uses information provided by the claimant to evaluate the completeness and adequacy of dose information available, to locate additional exposure or dose-related information, and to estimate doses that were unmonitored.

The initial interview is conducted through a telephone call. The purpose of the initial interviews is to:

- **a.** Explain the dose reconstruction process;
- **b.** Confirm elements of the employment history transmitted to NIOSH by DOL;
- **c.** Identify any relevant information on employment history that may have been omitted;
- **d.** Confirm or supplement monitoring information included in the initial radiation exposure record;
- **e.** Develop detailed information on work tasks, production processes, radiologic protection and monitoring practices, and incidents that may have resulted in undocumented radiation exposures, as necessary; and
- **f.** Identify co-workers and other witnesses with information relevant to the radiation exposures of the covered worker to supplement or confirm information on work experiences, as necessary.

The OCAS-1 form is provided to each claimant once NIOSH has completed a draft dose reconstruction report. The draft report and the OCAS-1 form are mailed to the claimant. The OCAS-1 form is used to certify

the following:

a. Claimant does not possess any additional information to assist NIOSH in completing a dose reconstruction;
b. Claimant understands that NIOSH forwards the final dose reconstruction report to DOL for adjudication;
c. Claimant understands that NIOSH cannot forward the final dose reconstruction report to DOL for adjudication without receipt of a properly-signed OCAS-1, and may administratively close the dose reconstruction if a properly-signed OCAS-1 is not provided within 60 days;
d. Claimant understands that his or her opportunity to seek a review of the NIOSH dose reconstruction occurs only if DOL were to produce a recommended decision to deny the claim;
e. By signing this form, claimant does NOT certify or imply that he or she agrees with NIOSH decisions indicated in the draft NIOSH dose reconstruction report concerning how NIOSH has used or not used information claimant provided for the dose reconstruction; and
f. By signing this form, claimant does NOT certify or imply that he or she agrees with the findings of the NIOSH dose reconstruction.

The information collected in the interviews and through the OCAS-1 form is necessary for completeness and efficiency of the dose reconstruction process at HHS, and for the probability of causation determination and acceptance/rejection of the claim by DOL. As of October 2011, NIOSH has completed more than 33,000 dose reconstructions and returned the claims to DOL for final adjudication.

Privacy Impact Assessment Information

The system collects PII information that is submitted by former government nuclear weapons workers and/or their families under the EEOICPA to facilitate radiation dose reconstruction to determine eligibility so that a claim for compensation and medical benefits can be filed with the Department of Labor. The mandatory PII information that we collect, maintain and disseminate, (name, date of birth, social security number, mailing address, phone number, medical records numbers, medical notes, legal documents, e-mail address, and employment status) is used to perform dose reconstruction under EEOICPA and by DOL in the analysis required to process financial claims brought against the US government by individual claimants.

Claimants sign a Privacy Act advisement that provides notice that their data will be used on this project (DOL). NIOSH follows the CDC Staff Manual on Confidentiality when dealing with PII.

A 3. Use of Improved Information Technology and Burden Reduction

The initial interview portion of this project uses improved information technology as a means of data collection. Specifically, NIOSH contractor personnel conduct Computer Assisted Telephone Interviews (CATI) to collect information necessary for completion of the dose reconstruction process. The CATI system allows interviews to be conducted more efficiently and quickly than would be the case with a paper-based interview instrument. The average burden for the initial interview is one hour.

A second strategy NIOSH is applying to reduce the interview burden to the claimants is the initial collection and review of government data on the employee subject to the claim. This collection and review of government data is completed prior to the interview with the claimant. The information, which will be summarized for the interviewer, will allow the interview to be tailored to efficiently identify/confirm critical information and facilitate the claimant's memory in response to interview questions.

Form OCAS-1 is a form that must be signed by claimant before DOL can continue adjudication of the claim. The average burden for reading and signing this form is estimated to be less than five minutes. Claimants can submit the form electronically.

A 4. Efforts to Identify Duplication and Use of Similar Information

No other projects are duplicated by the information collection proposed here. No alternate data sources are available to replace the unique information available from claimants. NIOSH has reached this finding through extensive discussions concerning this information collection need with DOE, DOL, and external experts. The finding is further supported by more than a decade of NIOSH experience conducting epidemiologic research on the health of the DOE worker population.

A 5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in the dose reconstruction process under EEOICPA.

A 6. Consequences of Collecting the Information Less Frequently

NIOSH conducts the interview once for each claimant. The interview is essential to the process of conducting a dose reconstruction under EEOICPA and is legally required under 42 CFR 82. There are no legal obstacles to reduce the burden.

A 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The request fully complies with the regulation.

A 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Federal Register Notice

Attached is a copy of the 60 day Federal Register Notice that was published on September 29, 2011 (Vol. 76, page 60496-60497) (Attachment E).

B. Consultations

Pursuant to EEOICPA and Executive Order 13179, this compensation program involves the Departments of Labor, Energy, and Health and Human Services. NIOSH and the Departments of Labor and Energy have discussed information collection plans represented in this request extensively. In addition, NIOSH has discussed the need and approach to interviewing claimants with current DOE contractors operating DOE facilities and members of organized labor representing these workers, members of congressional staff, and academic experts. All parties consulted concur on the need for NIOSH to interview claimants as part of the dose reconstruction process under EEOICPA.

Specifically, the following persons and their institutional colleagues were consulted:

Kate Kimpan, Project Officer, Oak Ridge Associated Universities (ORAU)—Cincinnati Operations Office and ORAU staff involved in efforts to conduct the Computer Assisted Telephone Interviews 4850 Smith Road, Suite 200; Phone: 513-758-1636; Years 2001-2011. Kate.Kimpan@orau.org

Ms. Rachel Leiton, Director, Division of Energy Employees Occupational Illness Compensation Program and Department of Labor officials involved in efforts to implement EEOICPA at the Department of Labor; Phone: 202-693-0081; Year 2001-2011. Leiton.Rachel@dol.gov

A 9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift to respondents.

A 10. Assurance of Confidentiality Provided to Respondents

Program officials made a determination that that the Privacy Act is applicable. The applicable Privacy Act system of records is 09-20-0147, "Occupational Health Epidemiological Studies and EEOICPA Program Records HHS/CDC/NIOSH."

A database software security system is utilized to control access to the system. The system manager authorizes access, which is granted to only a limited number of staff and contractors. Data sets are password protected and/or encrypted.

The information collected in the interview includes identifiable personal information, although not sensitive. It is maintained indefinitely in secure, limited access computer files (the information will be collected using a Computer Assisted Telephone Interview (CATI)) as well as in paper files maintained in locked file cabinets within a secured, limited access facility. Access is limited to NIOSH employees and contractors involved in the dose reconstruction process. In addition, summarized information from the interview will be provided to the Department of Labor (DOL) as an element of a dose reconstruction report NIOSH completes to conclude each dose reconstruction.

IRB Approval

Attachment F, the IRB Non-Research Determination HSRB 09-OCAS-NR01 documentation, is dated October 26, 2011, for this information collection. The NIOSH IRB Human Subjects Review Board (HSRB) determined that this activity of obtaining exposure information from energy employees to determine possible compensation did not meet the DHHS 45CFR 46.102(d) definition of research. This is because the intent of the activity is not to contribute to generalizable knowledge. The activity was determined to be human subjects non-

research not requiring IRB review.

Privacy Impact Assessment Information

A. This submission has been reviewed by ICRO, who determined that the Privacy act does apply. The applicable System of records Notice is 09-20-0147 (Occupational Health Epidemiological Studies and EEOICPA Program Records, HHS/CDC/NIOSH).

B. The following controls are used for this PII:

a. Administrative Controls
- The system security plan used is controlled by ITSO
- NIOSH received the authority to operate the security system used for the storage of this information on August 14, 2009
- Files are backed up incrementally each night and a full backup occurs on the weekends
- Backup files are stored off-site at Iron Mountain
- Records will be retained and destroyed in accordance with the applicable CDC Records Control Schedule
- NIOSH and contractor staff adhere to all PII and records management policies
- Methods are in place to ensure least privilege

b. Technical Controls
- User Identification
- Passwords
- Firewall
- Virtual Private Network (VPN)
- Encryption
- Smart Cards (in-progress)
- Use of the CDC policy guide: CDC Staff Manual on Confidentiality

c. Physical Controls
- Guards
- Identification Badges
- Key Cards
- Close Circuit TV

C. NIOSH initially interviews claimants individually and provides them with the opportunity, through a structured interview, to assist NIOSH in documenting the work history of the employee (characterizing the actual work tasks performed), identifying incidents that may have

resulted in undocumented radiation exposures, characterizing radiation protection and monitoring practices and identifying co-workers and other witnesses, if NIOSH determines it necessary, to confirm undocumented information. In this process, NIOSH uses a computer assisted telephone interview (CATI) system, which allows interviews to be conducted more efficiently and quickly than would be the case with a paper-based instrument.

For this initial interview, NIOSH has developed three different initial telephone interviews - Attachment C- which are used in the dose reconstruction process. The first is used when the claimant is the covered employee. The second is used when the claimant is a family member of the covered employee, since in many instances; the covered employee is deceased or incapacitated. The third interview is for co-workers or supervisors of the covered employee, when the claimant is a family member, since family members may not know all the information necessary for the dose reconstruction.

Attachment C also contains a copy of the letter and cover sheets to the interview questions. These items provide information on the interviews, what the claimant can expect, and how the collected information will be used.

Additionally, NIOSH has developed the OCAS-1 Form (Attachment D: Statement by the Claimant Closing the Record on a NIOSH Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act) which is signed by the claimant at the end of the dose reconstruction process, before the claim is referred back to DOL for further processing.

After the dose reconstruction has been completed, NIOSH contacts the claimants to explain the results of the dose reconstruction. Claimants have the opportunity to ask questions about the information used, the methods, and the results. This is the final opportunity for the claimant to supplement the dose reconstruction record. At this time, NIOSH also explain the purpose of the OCAS-1 Form to the claimant.

D. The accompanying letter and cover sheet to the initial interview clearly state that the claimant’s participation in the interview is voluntary. During the start of the interview, claimants are informed that the information collected will be treated in a secure manner.

A 11. Justification for Sensitive Questions

There are no questions of a sensitive nature in the interviews or on Form OCAS-1.

A 12. Estimates of Annualized Burden Hours and Costs

A. The initial interview time will vary widely on a case-by-case basis, depending on the claimant's relationship to the employee covered by the claim, the claimant's knowledge and preparation, the length and complexity of the work history of the employee covered by the claim, and the extent and quality of information obtained by NIOSH prior to the interview. The 60-minute average burden was estimated assuming a typical case in which the claimant is the employee covered by the claim, NIOSH has complete employment information from the DOL and partial dose-related work history, radiation safety, and dosimetry information from readily available DOE and NIOSH sources.

The 5 minutes average burden for the claimant to review and sign the dose reconstruction conclusion form (OCAS-1) is based on pre-tests of NIOSH staff of various backgrounds, education, and occupations. Staff read the form carefully in an average of 2.5 minutes. This time was doubled for the estimated burden to allow for the potentially more deliberative consideration a claimant might accord the form.

The estimated annual burden of this data collection is described in the table below.

Type of Data Collection	Number of Respondents	Number of Responses per Respondent	Average Hours per response (in Hours)	Total Annual Burden Hours
Initial interview	4,200	1	1	4,200
Conclusion form OCAS-1	8,400	1	5/60	700
TOTAL				4,900

B. The annual costs to respondents associated with this burden are as follows:

The initial interview time will vary widely on a case-by-case basis, depending on the claimant's relationship to the employee covered by the claim, the claimant's knowledge and preparation, the length and complexity of the work history of the employee covered by the claim, and the extent and quality of information obtained by NIOSH prior to the interview. The cost to respondents associated with the initial interview is based on 4,200 annual respondents and an average length of 60-minutes for the interview while assuming a typical case in which the claimant is the employee covered by the claim. The cost to the same number of respondents associated with completing the dose reconstruction conclusion form (OCAS-1) is based on 5 minutes average burden for the claimant to review and sign the dose reconstruction conclusion form (OCAS-1). This is based on pre-tests of NIOSH staff of various backgrounds, education, and occupations.

Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate*	Total Respondent Cost
Initial interview	4,200	$7.25	$30,450
Conclusion form OCAS-1	700	$7.25	$ 5,075
TOTAL			$35,525

*Current National minimum wage

A 13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no other annual cost burden to respondents or record-keepers.

A 14. Annualized Cost to the Government

All itemized and total costs are estimated over 6 year period:

Initial interview:

Contractor hours: 90,000 x 2 hours (per interview) x $30/hour = $5,400,000

Operational costs: $50,000 phones & computers + $240,000 lease space + $810,000 phone charges = $1,100,000

Total costs: $6,500,000

Total annualized costs: $1,083,333

Closing form (OCAS-1):

Form printing, envelope & postal charges: $64,800

Total costs: $64,800

Total annualized costs: $10,800

Information Collection Element	Annualized Cost
Initial Interview	$1,083,333
Closing Form (OCAS-1)	$10,800
TOTAL	$1,094,133

A 15. Explanation for Program Changes or Adjustments

This was a new data collection which began under the authority of the emergency clearance granted by OMB on October 30, 2001. There have been no program changes or adjustments since the date of the last request for an extension of this information collection. The burden estimates have remained the same based on the maturity of EEOICPA and the dose reconstruction program.

A 16. Plans for Tabulation and Publication and Project Time Schedule

This information collection is not intended for publication. Information collected will be used to complete individual dose reconstructions fulfilling legal requirements established under 42 CFR 82. Information collection commenced in November, 2001, following receipt of initial requests for dose reconstruction from DOL. Information collection is required for each dose reconstruction submitted to HHS on an ongoing basis throughout the operation of the DOL compensation program, which will continue indefinitely.

A 17. Reason(s) Display of OMB Expiration Date is Inappropriate

Approval to not display the expiration date is not being sought.

A 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.