Information Collection Request

EXTENSION

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

Dose Reconstruction Interviews and Forms
OMB No. 0920-0530, expires 02/28/2015

Supporting Statement Part A

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January 7, 2015

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Attachments

SUPPORTING STATEMENT

Dose Reconstruction Interviews and Forms under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) – **Extension**
There are no changes to the questions contained in the package. The estimated number of burden hours has been revised to reflect the current rate of claims processing.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. §§ 7384-7385 (Attachment A.1), which originated as P.L. 106-398 (Attachment A.2) 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) (Attachment A.3), 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. HHS published the final rule on "Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000" on May 4, 2002, as 42. C.F.R. 82 (Attachment A.4)

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.

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.

2. Purpose and Use of the Information

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.

Specifically, 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
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 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
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 September 2014, NIOSH has completed more than 40,000 dose reconstructions and returned the claims to DOL for final adjudication.

3. Use of 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.

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.

5. Impact of Small Businesses or Other Small Entities

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

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.

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

The request fully complies with the regulation.

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

8a. Federal Register Notice

Attached is a copy of the 60 day Federal Register Notice that was published on November 3, 2014 (Vol. 79, pages 65218-65219) (Attachment B). No public comments were received.

8b. Consultations

Pursuant to EEOICPA and Executive Order 13179, this compensation program involves the Departments of Labor, Energy, Justice 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:

Mr. Shelby Hallmark, Director, Office of Workers Compensation Programs and approximately a dozen Department of Labor officials leading efforts to implement EEOICPA at the Department of Labor; Phone: 202-693-0856; Year 2001. Hallmark.Shelby@dol.gov

Dr. Paul Seligman, Acting Director of the Office of Worker Advocacy and approximately ten Department of Energy officials leading efforts to implement EEOICPA at the Department of Energy; Phone: 202-586-1293; Year 2001. paul.seligman@eh.doe.gov

Dr. Paul Seligman, Acting Director of the Office of Worker Advocacy and approximately 100 contractor management officials of contractors operating DOE facilities; Phone: 202-586-1293; Year 2001. paul.seligman@eh.doe.gov

Mr. Jim Ellenberger, Former Assistant Director, Department of Occupational Safety and Health, and approximately 15 representatives of the AFL-CIO; Phone: 703-938-9674; Year 2001. JEllenberger@compuserve.com

Mr. Josh Silverman, Ph.D., Staff to Senator Reid, and approximately 15 House and Senate staff; Phone 202-224-7007; Year 2001. josh.silverman@eh.doe.gov

Dr. David Michaels, Ph.D., MPH, Research Professor, Department of Environmental and Occupational Health, George Washington University School of Public Health; Former Assistant Secretary for Environment, Safety, and Health, Department of Energy; Phone: 202-994-2461; Year 2001. eohdmm@gwumc.edu

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

Program officials made a determination that that the Privacy Act is applicable.

IRB Approval
The NIOSH IRB (Humans Subjects Review Board) determined that this data collection is not research involving human subjects (Attachment E).

10.1 Privacy Impact Assessment Information

This data collection involves the collection of information in identifiable form.

Overview of the data collection system
The data from the CATI is collected during telephone interviews with energy employees and survivors, using a standardized set of questions. The responses to the interview questions are entered into a computerized data base as the interview is being conducted.

The completed Form OCAS-1s are scanned into a claims tracking data base as they are received from claimants. The receipt of the Form OCAS-1 permits the case to be returned to DOL for final adjudication.

Description of the information to be collected
The CATI collects information on the energy employee's employment history, radiation monitoring information, work tasks, production processes, radiologic protection practices, exposure incidents, and the identity of co-workers and other witnesses.

The Form OCAS-1 is used to certify that the claimant does not possess any additional information to assist NIOSH in completing a dose reconstruction.

How the information will be shared and for what purpose
The information collected by the CATI is reviewed by NIOSH during the completion of the radiation dose reconstruction to identify any information relevant to estimating the energy employee's radiation dose. The information becomes part of the analysis record for each case, and is included in the file that is submitted to DOL for final adjudication.

The information on the Form OCAS-1 is used by NIOSH to determine that the dose reconstruction for the case has been completed. It is included in the case file that is submitted to DOL for final adjudication.

Impact the proposed collection will have on the respondent's privacy
The data collection does not involve sensitive information beyond that required to process the claim under EEOICPA. The data is protected and shared only with other parties to the extent necessary to carry out functions required by EEOICPA.

Whether individuals are informed that providing the information is voluntary or mandatory
The Privacy Act Advisement and interview script for the CATI informs respondents that their participation is voluntary. The Form OCAS-1 informs the respondent that their claim will be submitted to DOL if signed and returned. The claim is administratively closed if the form is not signed and returned.

Opportunities to consent, if any, to sharing and submission of information
The opportunity to consent to sharing and submission of information is not provided. Information submitted is required to initiate a claim under EEOICPA. The Privacy Act advisement informs claimants of the entities with which information may be shared.

How the information will be secured
The information is maintained in secure, limited access computer files. Access is limited to NIOSH employees and contractors involved in the dose reconstruction process. Any paper files are maintained in locked file cabinets within a secured, limited access facility, and shredded after verification of the electronic record.

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.

Whether a system of records is being created under the Privacy Act
The applicable Privacy Act system of records is 09-20-0147, "Occupational Health Epidemiological Studies, EEOICPA Program Records and WTC Health Program Records, HHS/CDC/NIOSH."

11. Justification for Sensitive Questions
There are no questions of a sensitive nature in the interviews or on Form OCAS-1.

12. Estimates of Annualized Burden Hours and Costs

A. 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	3,600	1	1	3,600
Conclusion form OCAS-1	3,600	1	5/60	300
TOTAL				3,900

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.

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

Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate*	Total Respondent Cost
Initial interview	3,600	$7.25	$26,100
Conclusion form OCAS-1	300	$7.25	$ 2,175
TOTAL			$28,275

*Current National minimum wage

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

There are no capital/start-up or ongoing operation/maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Summary Table

Information Collection Element	Annualized Cost
Initial Interview	$293,000
Closing Form (OCAS-1)	$ 10,800
TOTAL	$303,800

Basis for Cost Estimates

Initial interview:

contractor hours: 3,600 x 1 hour (per interview) x $30/hour = $108,000
operational costs: $10,000 phones & computers + $40,000 leased space + $135,000 phone charges = $185,000
total annualized costs: $293,000

Closing form (OCAS-1):

form printing, envelope & postal charges: $10,800
total annualized costs: $10,800

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 since that date. The burden estimates were revised downward (from 22,500 cases annually requiring dose reconstruction to 15,000 annually) based on moderately lower rate of claims submissions than estimated by DOL prior to initiation of this compensation program. As the program has matured, the number of new cases requiring dose reconstruction has continued to drop, to the current rate of approximately 200 per month (2,400 per year). There is an average of 1.5 claimants per case (there can be multiple eligible survivors per case if the energy employee is deceased). The rate at which claimant interviews are conducted is now relatively stable at 200 cases x 1.5 claimants per case = 300 per month (3,600 per year).

16. Plans for Tabulation and Publication and Project Time Schedule

Information collection is not intended for publication. Information collected will be used to complete individual dose reconstructions fulfilling legal requirements established under 42 C.F.R. 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.

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

Display is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Exceptions are not requested.