

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

Special Exposure Cohort
1Regulation 42 CFR Part 83
(0920-0639) **EXTENSION**

Supporting Statement
Part A

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- The goal of this Information Collection activity is to enable HHS to efficiently carry out certain of its responsibilities under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA).
- The information that is collected is provided by individuals who are petitioning HHS to add classes of employees to the Special Exposure Cohort (SEC) under EEOICPA.
- Information collection forms are provided to assist petitioners in supplying the information necessary for HHS to determine whether to add a class of employees to the SEC. Use of these forms is voluntary, and petitioners can use alternate formats to submit petitions.
- The information is provided by individuals covered under EEOICPA, namely employees who worked in the production and/or testing of nuclear weapons and subsequently developed cancer, or their survivors.
- The information is used to determine whether the requirements for adding a class of employees to the SEC under EEOICPA are met.

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Attachments

- Attachment A - The Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. §§ 7384-7385 [1994, supp. 2001]
- Attachment A.1 - Final Rule on SEC Procedures May 28, 2004
- Attachment A.2 - Interim Final Rule on SEC Procedures December 22, 2005
- Attachment B - Federal Register Notice
- Attachment C - SEC Petition Form A
- Attachment D - SEC Petition Form B
- Attachment D.1 - SEC Petition Form B Instructions
- Attachment D.2 - Example of Petition without Form B
- Attachment D.3 - Example of Request for Review
- Attachment E - Authorization Form
- Attachment F - IRB Non-Research Determination
- Attachment G - Public comment, ANWAG
- Attachment H - Public comment, citizen

SUPPORTING STATEMENT

Special Exposure Cohort Petitions under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). The estimated annual respondent burden hours has been reduced to reflect the actual level of use of these forms over the past three years. The estimates of annualized costs to respondents and the Federal government have been updated.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

This Information Collection Request (ICR) is for an extension of approved ICR 0920-0639 for three years. ICR 0920-0639 was first approved in May 2004, and has been extended every three years since that date. The Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. §§ 7384-7385 [1994, supp. 2001] (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 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 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, the executive order directed HHS to establish and implement procedures for considering petitions by classes of nuclear weapons workers to be added to the “Special Exposure Cohort” (the “Cohort”), a cohort of various groups of workers selected by Congress whose claims for cancer under EEOICPA can be adjudicated without demonstrating that their cancer was “at least as likely as not” caused by radiation doses they incurred in the performance of duty. In brief, EEOICPA authorizes HHS to designate such classes of employees for addition to the Cohort when HHS lacks sufficient information to estimate with sufficient accuracy the radiation doses of the employees, if HHS also finds that the health of members of the class may have been endangered by the radiation doses they potentially incurred. On May 28, 2004, HHS published the Final Rule of the procedures for adding such classes to the Cohort at 42 C.F.R. pt. 83 (Attachment A.1). HHS published an Interim Final Rule on SEC procedures December 22, 2005 (70 FR 75949) (Attachment A.2) in response to the new requirements of the Ronald W. Reagan National Defense Authorization Act for Fiscal

Year 2005, Public Law 108–375 (codified as amended in scattered sections of 42 U.S.C.) that amended EEOICPA.

The HHS procedures authorizes a variety of individuals and organizations to submit petitions, as follows: (1) one or more nuclear weapons workers or their survivors; (2) labor organizations; and (3) one or more individuals or entities authorized in writing by nuclear weapons workers or their survivors. Petitioners are required to provide a variety of necessary information, as discussed below.

NIOSH has developed two petition forms to assist the petitioners in providing this information efficiently and completely, to meet the petitioning requirements specified by HHS under 42 C.F.R. § 83.9. Petition Form A (Attachment C) is a one-page form that may be used by EEOICPA cancer claimants for whom NIOSH attempted to conduct dose reconstructions and determined that available information is not sufficient to complete the dose reconstruction. Petition Form B (Attachment D), accompanied by separate instructions (Attachment D.1), is intended for all other petitioners. The majority of the petitions received to date have been submitted on Form B. Both of the forms can be downloaded electronically (<http://www.cdc.gov/niosh/ocas/how2add.html>) and submitted electronically to the DCAS email box or mailed through the U.S. Postal Service or some other method. HHS is not requiring petitioners to use the forms. Petitioners can choose to submit petitions as letters or in other formats (see Attachment D.2, e.g.), but petitions must meet the informational requirements referenced above.

In addition to the petition forms, HHS is requiring the use of an Authorization Form (Attachment E) by employees or their survivors when they choose to authorize another party to petition on behalf of the class of employees of which the authorizing employee is a member.

NIOSH requests an Extension to the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) Special Exposure Cohort (OMB Control No. 0920-0639 / Expiration Date 7/31/2016) so that NIOSH can continue to collect the information necessary to receive and evaluate petitions from individuals who are requesting the addition of classes of workers to the Special Exposure Cohort.

2. Purpose and Use of the Information

The petition is essential to the process of considering the addition of a class of employees to the Cohort under EEOICPA and is legally required under EEOICPA (42 U.S.C. § 7384q(a)(3)) and as proposed under 42 C.F.R. pt. 83. HHS will use information provided by the petitioner(s) to:

- a. identify the petitioner(s), obtain their contact information, and establish that the petitioner(s) is qualified and intends to petition HHS;
- b. establish an initial definition of the class of employees being proposed to be considered for addition to the Cohort;
- c. determine whether there is justification to require HHS to evaluate whether or not to add the proposed class to the Cohort; such an evaluation involves potentially extensive data

collection, analysis, and related deliberations by NIOSH, the presidentially appointed Advisory Board on Radiation and Worker Health (“Board”), and HHS;

d. target the evaluation by HHS to examine relevant potential limitations of radiation monitoring and/or dosimetry-relevant records and to the potential for related radiation exposures that might have endangered the health of members of the class.

Petitioners using Form A (those for whom NIOSH has already determined it lacks sufficient information to complete the petitioner-claimant’s dose reconstruction) would only provide information relevant to item “a” above. In the process of attempting the dose reconstruction for the petitioner-claimant, NIOSH would have already obtained information addressing items “b-d.”

The mandatory use of the authorization form by individuals to authorize others to petition on behalf of a class of employees will ensure that the authorizing individual is clearly informed of the rights he is imparting on the party being authorized, and that HHS has sufficient information to identify authorized parties and document their authorization.

3. Use of Improved Information Technology and Burden Reduction

Petitioners will be allowed to submit petitions electronically, although they may have to submit some information in hard copy (e.g., affidavits and copies of reports, addressed under § 83.9(c)). The average burden for petitions depends on whether or not the petition is based on a NIOSH finding that it cannot complete a dose reconstruction for the petitioner. For such petitions, the average burden of reading and completing petition Form A, or of providing such information without the form, is estimated at three minutes. For other petitions, the average burden of completing petition Form B is estimated at 5 hours. The majority of the burden to this latter group would arise from the efforts of these petitioners to collect, versus report, required information.

The informational requirements for petitions under 42 C.F.R. § 83.9 are designed to minimize the burden on petitioners, while obtaining information essential to enable HHS to apply resources efficiently and effectively to meet its mandatory responsibility under EEOICPA to consider Cohort additions. In addition, HHS has decided to produce two separate forms, rather than one form for all users, to eliminate irrelevant form instructions and content for the two distinct sets of potential petitioners, as outlined above.

Finally, the use of the petition forms, which is voluntary, is intended to help petitioners submit necessary information as efficiently as possible. The form reduces the need for petitioners to consider how to organize their information and increases the likelihood that they will provide sufficient, minimal, and appropriate information in their initial submission. Petitioners who do not provide sufficient and appropriate information initially will have to supplement their initial submission to qualify their petition for evaluation by HHS.

4. Efforts to Identify Duplication and Use of Similar Information

No other projects are duplicated by the information collection proposed here. The Cohort was

created statutorily in October 2000 with the enactment of EEOICPA. The requirement for classes of employees to submit petitions to be considered for addition to the Cohort was mandated by EEOICPA (42 U.S.C. § 7384q(a)(3)) and is implemented under 42 C.F.R. pt. 83. For petitioners who have already provided relevant information to NIOSH as claimants requiring dose reconstructions under 42 C.F.R. pt. 82, NIOSH has restricted informational requirements under 42 C.F.R. § 83.9 to exclude information already collected during the dose reconstruction process.

5. Impact on Small Businesses or Other Small Entities

The HHS rule would allow various types of small entities to submit petitions on behalf of classes of nuclear weapons employees, when authorized by employees or their survivors, possibly including: voluntary associations of workers and their survivors, labor organization local affiliates, law firms representing one or more employees and/or survivors of employees, or other individuals or entities, as provided for under 42 C.F.R. § 83.7. Petition requirements are minimally burdensome to all petitioners, including these small businesses and entities.

6. Consequences of Collecting the Information Less Frequently

The petition process does not require repeated data submissions by the petitioner(s).

7. Special Circumstances Relating to the Guidelines of 5 C.F.R. § 1320.5

The request fully complies with the regulation.

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

8a. Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register March 24, 2016, Vol. 81, No. 57, pp 15722-15723 (see Attachment B). Two comments were received (see Attachments G and H). Responses to these comments are as follows:

Attachment G

This comment asserts that it would take a petitioner no less than 45 hours to prepare a request for a review of a final HHS decision to deny the addition of a class to the SEC. This burden hour estimate appears to have been based on the reported experience of one petitioner; a second petitioner also supported the comment, but did not provide a burden hour estimate.

NIOSH evaluated the eight previous requests for reviews that were submitted to HHS by petitioners. The number of pages included in each of these previous request letters is shown in the following table:

YEAR OF REQUEST	NUMBER OF PAGES	ESTIMATED HOURS (1 hr/page unless otherwise noted)
2005	1	1
2007	7	7
2011	2	2
2012	8	8
2012	3	3
2012	7	7
2013	3	3
2013	185	45 (per commenter)

The median of the estimated number of hours in this distribution (5.0) will be used as the revised estimate for burden hours associated with drafting a request for HHS review of a decision to deny the addition of a class to the SEC.

Attachment H

This comment estimates that it has taken over 48 hours to request a review of a HHS denial to add a class to the SEC, but does not provide any support for this estimate. The commenter has not previously submitted a request to HHS for a review of a denial to add a class to the SEC. The commenter asserts that the requirement that a SEC petition must qualify for evaluation is not found in the implementing regulations (presumably 42 C.F.R. pt. 83). This assertion is without merit, as the requirements pertaining to what a petition must include to qualify for evaluation are found at 42 C.F.R. 83.9.

Additional references in this comment to the Information Quality Act, Good Guidance Procedures and the Administrative Procedures Act are insufficiently explained to be interpretable.

8b. Consultations

Pursuant to EEOICPA and Executive Order 13179, this compensation program involves the Departments of Labor, Energy, and Health and Human Services. All agencies that have a role related to the SEC under EEOICPA have concurred with the contents of the Final Rule and reviewed the Interim Final Rule. In addition, NIOSH established the current informational requirements, in part, in response to public comments received in response to the first NPRM issue to promulgate 42 C.F.R. pt. 83 on June 25, 2002, and the second NPRM issued on March 7, 2003. NIOSH convened four public meetings near nuclear weapons production sites across the country to obtain public comments as well as comments from the Advisory Board which is made up of members of the public with relevant medical, scientific, and worker backgrounds. NIOSH has not received comments from the public or the Advisory Board that indicate a modification of the forms used by petitioners is needed.

Specifically, the following persons and their institutional colleagues have been 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

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. ehdmm@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

This submission has been reviewed by ICRO, who determined that the Privacy Act does apply. The applicable System of Records Notice (SORN) is 09-20-0147, "Occupational Health Epidemiological Studies and EEOICPA Program Records and WTC Health Program Records, HHS/CDC/NIOSH" as published most recently in the Federal Register on June 14, 2011.

No assurance of confidentiality is provided to respondents (petitioners).

The NIOSH Institutional Review Board has determined that the activities conducted under the EEOICPA SEC rule (42 C.F.R. pt. 83) do not meet the criteria of research as defined by HHS. (Attachment F)

10.1 Privacy Act Impact Assessment Information

This information is treated in the manner prescribed by the Privacy Act and in accordance with the routine uses permitted under SORN 09-20-0147.

The information collected in the petitions includes information in identifiable form, specifically names and contact information, including addresses, phone numbers, and email

addresses, and, if applicable, the NIOSH claim tracking number. All information collected is provided voluntarily by petitioners. The information collected is more fully described in the various forms provided to petitioners (Attachments C, D, and E). The identity of petitioners is protected by redacting any identifying information prior to posting information about the petition on the program's website. Information collected is maintained indefinitely in secure, limited access computer files as well as in paper files located in locked file cabinets within a secured, limited access facility. Access is limited to NIOSH employees and contractors involved in the petition evaluation process, and members of the Board involved in the review of petitions. All contractors have had security training and must sign a confidentiality agreement that all sensitive information will be handled in a secure manner, under NIOSH policies.

11. Justification for Sensitive Questions

There are no sensitive questions.

12. Estimates of Annualized Burden Hours

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

The 3 minutes average burden for petitioners to complete Petition Form A is based on a pre-test of the form by NIOSH staff of various backgrounds, education, and occupations. All staff read and completed the form carefully in less than 3 minutes.

Petition Form B can be completed in 5 hours or less, depending on the number of petitioners, the circumstances on which the petition is based, and the extent to which the relevance and interpretation of any documentation provided in support of the petition has to be explained by the petitioner(s). NIOSH staff read the instructions and completed Form B, using fictional information, in less than 32 minutes. Assuming that petitioners may be more cautious in reading instructions and completing the form, NIOSH estimates petitioners might require a maximum of 60 minutes to complete the form. The collection or organization of documentation in support of such petitions could require as little as 15 minutes, when the petitioner(s) already have possession of sufficient documentation, or as much as 4 hours if the petitioners must make a maximum effort, which would entail preparing and obtaining notarization of two separate statements from two individuals (1 hour for the preparation of a written statement x 2 = 2 hours; 1 hour to obtain notarization of the statement x 2 = 2 hours). Hence, the total burden of collecting information (at maximum) and completing Form B is estimated as 4 hours to collect information and 1 hour to complete Form B.

The 5 hours estimated for a petitioner to request a review of a HHS decision to deny the addition of a class to the SEC was based on an analysis of previous requests of this type, and public comments received (see Section 8a, above).

The 3 minutes to complete the Authorization Form is estimated based on the pre-test of Petition Form A, which requires the user to read and consider more instructions and explanation.

Form Name (CFR Reference)	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Avg. Burden per Respondent (in hours)	Total Burden (in hours)
Form A 42 CFR 83.9	Petitioners using Form A	2	1	3/60	0.1
Form B 42 CFR 83.9	Petitioners using Form B	5	1	5	25
42 CFR 83.9	Petitioners using a submission format other than Form B (as permitted by rule)	1	1	6	6
42 CFR 83.18	Petitioners appealing final HHS decision (no specific form is required)	2	1	5	10
Authorization Form 42 CFR 83.7	Claimant authorizing a party to submit petition on his/her behalf	3	1	3/60	0.15
TOTAL					41

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

Respondents	Number of Respondents	Total Burden Hours	Hourly Rate*	Respondent Cost
Form A	2	0.1	\$7.25	\$0.72
Form B	5	25	\$7.25	\$181.25
Format other than Form B	1	6	\$7.25	\$43.50
Request for appeal of final decisions	2	10	\$7.25	\$72.25
Authorization form	3	0.15	\$7.25	\$1.09
TOTAL				\$298.81

*Current Federal minimum wage for covered, non-exempt employees, effective July 24, 2009 - Fair Labor Standards Act (FSLA) (www.dol.gov)

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

None.

14. Annualized Cost to the Federal Government

Summary Table

Information Collection Element	Annualized Cost
Petition Form A and B and Authorization Form	\$15.00
Personnel	\$10,720.00
TOTAL	\$10,735.00

Basis for Cost Estimates

Production and distribution of Petition Forms A and B and Authorization Form:

Form printing, envelopes & postal charges: \$15
Total annual costs: \$15

Personnel Costs

GS-9 Health Communication Specialist
400 hours (\$26.80 per hour) \$10,720.00
Total annual costs \$10,720.00

15. Explanation for Program Changes or Adjustments

Cost estimates have been updated to reflect current Civil Service salaries.

The number of estimated respondents in this request have decreased since the previous Information Collection Request was approved, and is based on the actual number of Sec petitions and other forms received over the previous 3 year period.

The number of burden hours estimated for a petitioner to request a review of a HHS decision to deny the addition of a class to the SEC was increased from 45 minutes to 5 hours based on an analysis of previous requests of this type, and public comments received (see Section 8a, above).

16. Plans for Tabulation and Publication and Project Time Schedule

Information collection is not intended for publication. Information collected will be used to consider whether or not to add classes of employees to the Special Exposure Cohort according to legal requirements established under 42 C.F.R. pt. 83. Information collection is required for each petition submitted to HHS throughout the period of operation of this federal compensation program, which will likely 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.