NATIONAL COAL WORKERS' HEALTH SURVEILLANCE PROGRAM (CWHSP)

Extension for OMB # 0920-0020

Expiration Date: 06/30/2018

Office of Management and Budget Review and Approval
for Federally Sponsored Data Collection

Supporting Statement A

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- **Goal of the study:**

  The Coal Workers' Health Surveillance Program (CWHSP) is a congressionally-mandated medical examination surveillance program for monitoring the health of coal miners. The CWHSP was originally authorized under the 1969 Federal Coal Mine Health and Safety Act and is currently authorized under the 1977 Federal Mine Safety and Health Act and its subsequent amendments (the Act). The Act provides the regulatory authority for the administration of the CWHSP. This program, which operates in accordance with 42 CFR Part 37, is useful in providing information to protect the health of coal miners and to document trends and patterns in the prevalence of coal workers' pneumoconiosis ('black lung' disease) among miners employed in U.S. coal mines.

- **Intended use of the resulting data:**

  Data are used to inform participating miners of the results of medical examinations which include chest radiographs and spirometry testing that are interpreted for the presence or absence of disease and specifically notifying miners of evidence of pneumoconiosis which affords them the opportunity to be assigned to work with lower dust exposure. Data are also used to assess trends in prevalence of lung disease among coal miners.

- **Methods to be used to collect:**

  Mine operators make available testing services to miners at the time of new employment and then on a scheduled basis. Results are processed by NIOSH staff who provide the results to miners.

- **The subpopulation to be studied:**

  Coal miners in the United States

- **How data will be analyzed:**

  Descriptive statistics: prevalences and trends

Table of Contents

List of Attachments

7. Sample letter to the radiographic facility informing them that their radiographic units are approved by NIOSH
8. Miner Identification Document – Form No. CDC/NIOSH (M) 2.9
9. Sample letter to each miner informing of the opportunity to participate in the CWHSP
10. Sample letters to participating miners in the CWHSP providing results of radiograph interpretation; first reporting no disease, second reporting disease.

11. Chest Radiograph Classification Form – Form No. CDC/NIOSH (M) 2.8
12. Physician Application for Certification – Form No. CDC/NIOSH (M) 2.12
13. Sample letters to each physician reporting on outcomes of passing the B Reader Examinations
14. Sample letter to B Readers to inform that the recertification examination is due
15. Spirometry Facility Certification Document – Form No. CDC/NIOSH (M) 2.14
16. Respiratory Assessment Form – Form No. CDC/NIOSH (M) 2.13
17. Spirometry Results Notification Form – Form No. CDC/NIOSH (M) 2.15
18. Sample letter to participating miners in the CWHSP with spirometry examination results
19. Consent, Release and History Form – Form No. CDC/NIOSH (M) 2.6
20. 42 CFR 37.202 Autopsy Invoice --Sample
21. 42 CFR 37.203 Pathologist Report of Autopsy – Sample
22. 60-Day Federal Register Notice
23. Contact Information for Stakeholders
24. OCISO Standard for Limiting the Use of Social Security Numbers in CDC Information Systems
25. Pending PII
26. Institutional Review Board Approval
27. 60 day FRN Public Comments

SUPPORTING STATEMENT
REGULATION 42 CFR 37
COAL WORKERS' HEALTH SURVEILLANCE PROGRAM (CWHSP)
Extension FOR OMB # 0920-0020

Justification

This is an information collection request (ICR) for an extension of the existing OMB #0920-0020 (expiration date 6/30/2018) approval from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention. There are no revisions to the data collection instruments at this time. Approval is requested for three years from the approval date.

This extension request incorporates all components of the CWHSP. Those components include: Coal Workers' X-ray Surveillance Program (CWXSP), B Reader Program, Enhanced Coal Workers' Health Surveillance Program (ECWHSP), Expanded Coal Workers' Health Surveillance Program, and National Coal Workers' Autopsy Study (NCWAS). The CWHSP is a congressionally-mandated medical examination surveillance program for monitoring the health of coal miners. The Program was originally authorized under the 1969 Federal Coal Mine Health and Safety Act and is currently authorized under the 1977 Federal Mine Safety and Health Act and its subsequent amendments (hereafter referred to as the Act). The Act provides the regulatory authority for the administration of the CWHSP (see **Attachment 1**). This program, which operates in accordance with 42 CFR Part 37 (see **Attachment 2**), is useful in providing information to protect the health of coal miners and also to document trends and patterns in the prevalence of coal workers' pneumoconiosis ('black lung' disease) among miners employed in U.S. coal mines. The total estimated annualized burden hours are 20,281, with an estimated annualized cost to the respondent population of $594,228.

1. Circumstances Making the Collection of Information Necessary

Coal miners who inhale excessive dust are known to develop a group of diseases of the lungs and airways, including chronic bronchitis, emphysema, and chronic obstructive pulmonary disease, silicosis, and coal workers' pneumoconiosis. Section 203, "Medical Examinations," of the Act **(Attachment 1)**, is intended to protect the health and safety of coal miners. This Act provides the basis for all forms being utilized in conjunction with this data collection. Through delegation of authority, the Act directs NIOSH to study the causes and consequences of coal-related

respiratory disease, and, in cooperation with the Mine Safety and Health Administration (MSHA), to carry out a program for early detection and prevention of coal workers' pneumoconiosis and to provide the opportunity for an autopsy after the death of any active or inactive miner. These activities are administered through the CWHSP, as specified in the Code of Federal Regulations, 42 CFR 37, "Specifications for Medical Examinations of Coal Miners" **(Attachment 2)**.

The CWHSP administers all aspects of the following activities related to the conduct of periodic medical examinations for coal miners: 1) testing and certification of A and B Readers (physicians qualified to interpret and classify radiographs for the pneumoconioses); 2) evaluation and approval of radiograph and spirometry facilities where testing may be offered; 3) evaluation and approval of coal mine operator plans for providing medical examinations; 4) arranging and paying for B Reader classifications of chest radiographs; 5) contracting with approved facilities to take radiographs and provide initial classifications for mines that are out of compliance and are not covered by approved coal mine operator plans; 6) arranging locally available testing under the ECWHSP, including spirometry, chest radiograph, and blood pressure monitoring for former and actively working surface and underground miners through the NIOSH Mobile Units; 7) generation and dissemination of letters that notify participating miners of the results of their medical examinations; and, 8) maintenance of databases of information related to all aspects of the Program for purposes of assessing effectiveness, identifying disease trends, and storage allowing rapid retrieval of information relative to the taking, interpreting, and notification of results.

The Act also authorizes NIOSH to make necessary arrangements with the next-of-kin for providing a post-mortem examination to be performed after the death of any active or inactive miner, and specifies that the autopsy shall be paid for (through delegation) by NIOSH through the NCWAS, which is a component of the CWHSP. Results of NCWAS autopsies are used for research purposes (both epidemiological and clinical) and may also be used by the next-of-kin in support of compensation claims.

This extension is requested for both the regulatory requirements as prescribed in 42 CFR 37, as well as the congressionally-mandated and discretionary reporting instruments. There are no revisions to the data collection instruments at this time. Approval is requested for three years from the approval date.

2. Purpose and Use of Information Collection

Information collected through the CWHSP is utilized for early identification, tracking,

assessment, and ultimately prevention and/or treatment of coal workers' pneumoconiosis. This congressionally-mandated program serves to identify the incidence and possible progression of coal mine dust-induced disease in coal miners. In order to assess progression of disease it is important to obtain longitudinal measurements of past participants.

Upon identification of disease, the program will assist in the clinical management of the miner's health through: 1) notifying the miner of any significant medical findings; and, 2) notifying miners and MSHA of any applicable Part 90 transfer rights. In addition, information obtained through the program provides a basis for statistical evaluation of the effectiveness of various means of controlling dust exposure in the mining industry. These data are neither collected nor generated by any other source, whether government or industry/labor sponsored.
The data from the CWHSP can be used in a number of ways in evaluating the effectiveness of the health regulations implemented under the Act. The Act was intended to prevent coal miners who worked in conditions with up to 2 mg/m^3 of respirable coal mine dust from developing category 2 coal workers' pneumoconiosis during a working lifetime, based upon the data available at the time. By this means, the promulgated health regulations sought to prevent the development of progressive massive fibrosis, which under the Act implies that the miner suffers from total and permanent disability. Thus, among participating miners, each case of category 2, as well as category 3 simple pneumoconiosis or progressive massive fibrosis of any stage, represents a failure of the health regulations, independent of the proportion of miners affected. Evaluation of the distribution and determinants of 'sentinel' cases of pneumoconiosis has emerged as an important surveillance function of the CWHSP, with attendant potential for prevention efforts.

During the early 1970s, one out of every three miners examined in the program with at least 25 years of underground work history had evidence of pneumoconiosis on their chest radiograph. An analysis of over 25,000 miners who participated in the program from 1996 to 2002 indicated that the proportion of individuals affected had greatly decreased to about one in 20. However, it also suggested that certain groups of miners were still at elevated risk. An increased risk of pneumoconiosis was associated with work in certain mining jobs, in smaller mines, in several geographic areas, and among contract miners. For miners being screened through the program in the last 10 years, the rates of black lung in miners with at least 20 years of tenure have doubled. Disease is being detected in younger miners and miners are progressing from the beginning stages of disease to more advanced stages of progressive massive fibrosis at an accelerated rate.

Analysis of regional disease prevalence in conjunction with participation rates can further assist in determining representativeness of the overall disease prevalence rates. Analysis of the consistency of disease patterns and trends aids in assessing the generalizability of the programs

findings. In addition, NIOSH and MSHA have, in recent years, embarked on various programs and enhanced activities intended to increase and broaden CWHSP participation. These activities have further increased the utility of the program's findings.

This program is federally-mandated and as such is expected to have budgetary support throughout the approval period. If the collection of information is not conducted, the CWHSP will not be operational and there will be no administration of the congressional mandate.

Data collection instruments for the CWHSP include:

Coal Mine Operator Plan **(Attachment 3)**
Form No. CDC/NIOSH (M) 2.10
and
Coal Contractor Plan **(Attachment 4)**
Form No. CDC/NIOSH (M) 2.18
Under 42 CFR Part 37, every coal operator and coal contractor in the U.S. must submit a plan approximately every four years, providing information on how they plan to notify their miners of the opportunity to obtain the medical examination. These forms record plans and arrangements for offering the coal miner examinations. Completion of these forms with all requested information (including a roster of current employees) takes approximately 30 minutes. **Attachment 5** provides a sample letter to Coal Mine Operator or Coal Contractor informing that the plan has been approved by NIOSH; and, a sample letter to Coal Mine Operator or Coal Contractor informing them that it is time to establish a new plan.

Radiographic Facility Certification Document **(Attachment 6)**
Form No. CDC/NIOSH (M) 2.11

Radiographic facilities seeking NIOSH approval to provide miner radiographs under the CWHSP must complete an approval packet. This form records the radiographic facility equipment/staffing information. It takes approximately 30 minutes for completion of this form. **Attachment 7** provides a sample letter that is sent to the radiographic facility informing that the facility's radiographic units are approved by NIOSH.

Miner Identification Document **(Attachment 8)**
Form No. CDC/NIOSH (M) 2.9

This form records the miner's demographic and occupational history, as well as information required under regulations in relation to coal miner examinations. It takes approximately 20

minutes for completion of this form. In addition to completing this form, acquiring the chest image from the miner takes approximately 15 minutes. **Attachment 9** provides a sample letter that is sent to all miners informing them of the opportunity to participate in the CWHSP. **Attachment 10** provides sample letters that are sent to all participating miners in the CWHSP with the results of their radiograph interpretations.

Chest Radiograph Classification Form **(Attachment 11)**
Form No. CDC/NIOSH (M) 2.8

Under 42 CFR Part 37, NIOSH utilizes a radiographic classification system developed by the International Labour Office (ILO) in the determination of pneumoconiosis among coal miners. Physicians (B Readers) fill out this form regarding their classifications of the radiographs (each radiograph has two separate classifications; approximately 7% require additional classifications). Based on prior practice, it takes the physician approximately 3 minutes per form.

Physician Application for Certification **(Attachment 12)**
Form No. CDC/NIOSH (M) 2.12

Physicians taking the B Reader Examination are asked to complete this registration form which provides demographic information as well as information regarding their professional practices. It typically takes the physician about 10 minutes to complete this form. **Attachment 13** provides sample letters that are sent to each physician reporting on the success or lack of success in passing the B Reader Examination. **Attachment 14** provides a sample letter that is sent to B Readers informing the recertification examination is due.

Spirometry Facility Certification Document **(Attachment 15)**
Form No. CDC/NIOSH (M) 2.14

This form is analogous to the Radiographic Facility Certification Document (Form No. CDC/NIOSH (M) 2.11, **Attachment 6**) and records the spirometry facility equipment/staffing information. Spirometry facilities seeking NIOSH approval to provide miner spirometry testing under the CWHSP must complete an approval packet which contains this form. It is estimated that it will take approximately 30 minutes for this form to be completed at the facility.

Respiratory Assessment Form **(Attachment 16)**
Form No. CDC/NIOSH (M) 2.13

This form is designed to assess respiratory symptoms, certain medical conditions which can affect the results of spirometry, and risk factors for respiratory disease. It is estimated that it will take approximately 5 minutes for this form to be administered to the miner by an employee at the facility.

Spirometry Results Notification Form **(Attachment 17)**
Form No. CDC/NIOSH (M) 2.15

This form is used to: 1) collect information that will allow NIOSH to identify the miner in order to provide notification of the spirometry test results; 2) assure that the test can be done safely; 3) record factors that can affect test results; 4) provide documentation that the required components of the spirometry examination have been transmitted to NIOSH for processing; and, 5) conduct quality assurance audits and interpretation of results. It is estimated that it will take the facility approximately 20 minutes to complete this form with an additional 15 minutes to administer the spirometry test. **Attachment 18** provides a sample letter that is sent to all participating miners in the CWHSP with spirometry examination results.

Consent, Release and History Form **(Attachment 19)**
Form No. CDC/NIOSH (M) 2.6

This form documents written authorization from the next-of-kin to perform an autopsy on the deceased miner. A minimum of essential information is collected concerning the deceased miner, including occupation and smoking history. From past experience, it is estimated that 15 minutes is required for the next-of-kin to complete this form.

42 CFR 37.202 Autopsy Invoice **(Attachment 20)**

42 CFR Part 37.200 specifies the procedures for the NCWAS. Specifically, Part 37.202 addresses payment to pathologists for autopsies performed. The invoice submitted by the pathologist must contain a statement that the pathologist is not receiving any other compensation for the autopsy. Each participating pathologist may use his/her individual invoice as long as this statement is added. It is estimated that only 5 minutes is required for the pathologist to add this statement to the standard invoice that s/he routinely uses.

42 CFR 37.203 Pathologist Report of Autopsy **(Attachment 21)**

42 CFR Part 37.203 provides the autopsy findings. The pathologist must submit information found at autopsy, slides, blocks of tissue, and a final diagnosis indicating presence or absence of

pneumoconiosis. The format of the autopsy reports are variable depending on the pathologist conducting the autopsy. Since an autopsy report is routinely completed by a pathologist, the only additional burden is the specific request for a clinical abstract of terminal illness and the final diagnosis relating to pneumoconiosis. Therefore, only 5 minutes of additional burden is estimated for the pathologist's report.

3. Use of Improved Information Technology and Burden Reduction

The collection procedures presently being utilized have been determined to be the most effective methods of data collection for the purpose of this particular program. Electronic versions of the forms are provided. However, paper versions of the forms are also needed as this data collection is frequently accomplished at the mine site, at radiograph and spirometry facilities, or at the miner's residence where access to electronic data collection technology may be limited or nonexistent. Participating mines and miners are often in rural areas where requiring an electronic-only collection system could present as a barrier to participation. Participation in the program is a crucial step in prevention of coal workers' pneumoconiosis and any obstacle that would make participation more cumbersome is not acceptable. For this reason, the option of paper-based data collection instruments is required.

4. Efforts to Identify Duplication and Use of Similar Information

NIOSH employs ongoing efforts to identify and/or be aware of duplication(s) of the data collection activity associated with its mandated responsibilities under the Act for the CWHSP. These efforts include consultations with MSHA, industry and labor organizations, physicians and clinics providing clinical services to the miners, as well as periodic reviews of related literature. The information collected is not available from any other source and no other government agency is currently collecting the information needed to administer this program. **The CWHSP is a unique program and is not a duplication of any other existing programs**. Although there have been other studies relating to coal mine dust-induced disease, NIOSH is the only agency collecting information in this detail or manner and has sole responsibility for carrying out the provisions mandated in the Act.

5. Impact on Small Businesses or Other Small Entities

Participation in the CWHSP and the completion of forms is only mandatory for the mine operator and/or the mine contractor and a miner upon first entry into the mining industry; participation by other parties is voluntary. Many physicians and spirometry/radiograph facilities are incorporated as small businesses. The data collected from participating physicians and

clinics is held to the absolute minimum to permit proper identification of the miner, the radiograph, the spirometry test, the facility, and equipment used. Each of these documents and materials are essential for the purposes of the program. In an effort to reduce data collection burden, electronic versions and pre-printed forms including all available information are provided to applicable participants for their use. However, as stated above electronic data collection technology may be limited or non-existent to this population.

6. Consequences of Collecting Information Less Frequently

Miner participation in radiographic examinations, spirometry tests, and blood pressure screening is voluntary, with the exception of a mandatory examination upon first entry into the mining industry. However, the minimum frequency that mine operators and/or mine contractors must make radiographic examinations available for miners is mandated in the Act as every 3½ – 5 years. Current CWHSP data collection is based upon this requirement, which is considered to be the minimum frequency required to monitor the onset or progression of coal-related respiratory disease.

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

The collection of information is consistent with and fully complies with the regulation 5 CFR 1320.5.

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

The 60-day notice was published in the Federal Register on April 12, 2018, Volume 83, Number 71, Page 15840-41**)**. CDC received three non-substantive comments (Att. 27) and replied with a standard CDC response.

There is ongoing exchange of information with stakeholders and representatives of participant groups. These efforts include consultations with MSHA, ILO, American College of Radiology (ACR), American Thoracic Society (ATS), European Respiratory Society (ERS), and other professional, labor, and industry organizations, as well as periodic reviews of related literature. NIOSH staff routinely meets with the Mine Safety and Health Research Advisory Committee (MSHRAC). In addition, NIOSH staff periodically discusses the use of the data collection instruments with radiologists, pathologists, pulmonary specialists, and other occupational safety and health personnel and organizations. (See **Attachment 23** for stakeholder contact information.)

The CWHSP has been operational since 1970 and various versions of the data collection forms have been used. There is concurrence that information obtained through the use of these forms is the minimum necessary to meet the requirements of the Act while still providing the information necessary for meeting the program's mission and objectives.

9. Explanation of any Payment or Gifts to Respondents

Participating miners are not paid or given any type of monetary incentive to respond. They do receive the results of their radiograph examination and spirometry test, and, if requested, a copy of the radiograph. Currently, B Readers who are contracted to provide classifications of program radiographs are paid $5,750 on a quarterly basis for a total of $23,000/year. This payment has been revised several times during the history of the program and may be revised in the future as well. Under regulation, pathologists receive a single payment of $200.00 for completing and submitting an autopsy report with specimens and $210.00 if a radiograph accompanies the report.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC/ATSDR Privacy Act Officer has previously reviewed this submission and determined that the Privacy Act does apply. Data management procedures have not changed since previous approval and the instruments have not been through extensive revisions.

Approval has been granted from OCISO to collect, process, and store SSNs within the parameters stipulated in the OCISO Standard for Limiting the Use of Social Security Numbers in CDC Information Systems **(Attachment 24**. In addition, OCISO has previously approved the collection of PII and is currently reviewing **(Attachment 25).**

Full names and partial SSNs are required for absolute identification in order to fulfill the mandate of the Act. In order for coal workers' pneumoconiosis to be detected or prevented, NIOSH needs to maintain a database of physicians who are qualified to interpret and classify radiographs. In addition, NIOSH also needs to maintain a surveillance program in which repeated readings are obtained on coal miners over time.

Partial SSNs are required of the miner and participating physician **(Attachments 8, 11, and 12)**. As outlined above, these are collected to:

- Provide a means of accurately developing chronologic health data relative to coal miners participating in the program;
- Permit accurate miner identification for the purpose of determining past and present vital status and medical records including prior radiographs;
- Permit accurate reporting to miners of medical conditions found through the program;
- Accurately identify interpreting physicians to establish continuity of readings;
- Confirm physician eligibility to participate in the program.

Each collection instrument containing a space for SSN includes the statement, "Full SSN is optional; last 4 digits are required." Participation by the miner in the CWHSP (and therefore providing any information associated with that participation) is voluntary, except for the initial examination which is required within 30 days of employment in the industry. There is no impact on the miner's privacy from the collection of information through voluntary participation.

Access Controls: The CWHSP database is housed on a SQL 2008 server with Transparent Data Encryption (TDE). The entire database is encrypted.

The safeguarding measures that are in effect to protect the records include locked files in locked rooms with restricted access to NIOSH and contractor personnel who need the data to perform official duties. Program computers meet the highest CDC standards for administrative, technical, and physical security. Databases are password protected. The process for handling security incidents is defined in the system's Security Plan. Event monitoring and incident response is a shared responsibility between the system's team and the Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy related events should be directed to the component's Information Systems Security Officer, CDC Helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

A signed medical release or a Privacy Act certification statement will be obtained from the subject before release of any collected information. 42 CFR 37.80(a) provides that "Medical information and radiographs on miners will be released by NIOSH only with the written consent from the miner, or if the miner is deceased, written consent from the miner's widow, next of kin, or legal representative." Participants in this program are assured against unauthorized disclosure through statements on the individual forms.

The CWHSP follows a system of records retention as described below:

4-56 National Coal Workers' Autopsy Program Database, (N1-442-91-11, Item 7):

This system is composed of records in the National Coal Workers' Autopsy Program.

a. Input documents. Hard copy files on National Coal Workers Autopsy Study Program including complete autopsy report file.

Authorized Disposition: Destroy when no longer needed for administrative use and scientific research. NOTE: NIOSH will maintain records and specimens within the agency for as long as it is determined that there is continuing research and administrative use for the records. The data will be of scientific importance enabling NIOSH researchers to have access to original data when undertaking specific studies.

b. Master File. The National Coal Workers' Autopsy Study Program contains the name of the deceased miner, date of birth, SSN, date and place of death, name and address of mine, job title, smoking history, years in mining, and pathology data from the autopsy protocol, including pathologist's summaries of findings, coded by ICD-8 or ICD-9 codes. This is an ongoing, mandated program.

c. Documentation of Master File Records. Includes pertinent information regarding tape specification, variable names, column layouts for each file, and hard-copy version of relevant code book.

Authorized Disposition: PERMANENT. Transfer to NARA in conjunction with records described under Item 4-55.b. above.

d. Outputs. No routine output is generated by this program. Autopsy results are infrequently reported to appropriate extramural, legal or administrative authority upon receipt of appropriate releases.

Authorized Disposition: Destroy when no longer needed for administrative purposes.

4-56 National Coal Workers’ X-ray Surveillance Program, Databases, (N1-442-91-11, Item 8):

The records are in a program denoted Coal Workers’ X-ray Surveillance Program mandated by the Coal Mine Health and Safety Act of 1969. This item covers the following databases: (1) Certified Interpreting Physicians' File circa 1978 to present: databases which contain information on physicians certified as "A" and "B" readers (i.e., physicians who interpret miner radiographs for evidence of CWP) as per provisions of the Federal Mine Safety and Health Act of 1977; (2) Mine Operator Plans: the plans developed by the mines for providing the radiograph program

when operators are notified by NIOSH that their mine force is to be examined; (3) Facility Certifications: certifications of approved radiograph locations; (4) Miner Radiograph Interpretation Results, and; (5) demographic data and occupational history of participants.

a. Input Documents. Included are such items as forms which contain information regarding demographics and qualifications of "A" and "B" physicians and certified radiograph facilities, radiographs, classifications of these radiographs, and miner identification documents containing identifying information on the miner and a brief occupational history on coal mining jobs ascertained from each miner at time of examination.

Authorized Disposition:

(1) Original radiographs. Maintain within agency until no longer needed for administrative use and scientific research. NOTE: NIOSH will maintain records within agency as long as there is continuing research and administrative use for the records. Retained data should be of scientific importance, enabling NIOSH researchers to have access to original data when undertaking specific studies. Radiographs must also be maintained because of the possibility of litigation.

(2) Other hard copy data. After records have been microfilmed, destroy upon verification of copy quality or when no longer needed for administrative purposes.

b. Master File. The master file is a set of record systems. Each set contains records for a specific examination program over a defined interval. Each data set is maintained in a unique format, developed according to the data collection requirements prevailing at the time of data collection.

c. Documentation of master file records. Includes pertinent information regarding tape specification, variable names and column layouts for each file, and a hard copy version of relevant code book. Each subsystem is maintained in a specific, unique, format.

d. Output Documents.

(1) Copies of Letters of Notification of Radiograph Results to Mine Safety and Health Administration (MSHA), the miner, and his/her designated physician.

Authorized Disposition: Microfiche (or other equivalent storage medium) will be maintained within the agency until no longer needed for administrative purposes. NOTE: Data will be of importance as long as program exists.

(2) Other Miscellaneous Documents. Letters to miners informing them of the need to have radiographs taken, lists of approved interpreting physicians, productivity figures, lists of NIOSH certified radiograph facilities, routine initial certification approval and modification notices.

(3) Record Copy of Publications. Reports to MSHA, publications in scientific journals, reports for NIOSH use, and final results of special statistical analyses performed at the request of various researchers. Approximately 10 to 20 requests are received monthly to perform statistical analyses (using SAS or PLI programs). Examples are information on prevalence of the disease by age or by region.

(4) Additional Copies of Publications.

Authorized Disposition: Destroy when no longer needed for administrative purposes.

CDC will retain and destroy records in accordance with the applicable CDC Records Control Schedule.

The system's Security Plan defines the process for handling security incidents. The system's team and the Office of the Chief Information Security Officer (OCISO) share the responsibilities for event monitoring and incident response. Direct report of suspicious security or adverse privacy related events to the component's Information Systems Security Officer, CDC Helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to the US-CERT as appropriate.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions IRB

The CWHSP is not considered a research program and does not require Institutional Review Board approval (see **Attachment 26**). Although a component of the NCWAS has been considered research, IRB approval does not apply since all participants are deceased and 45 CFR 46 defines a human subject as "... a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information."

Justification for Sensitive Questions

Approval has been granted from OCISO to collect, process, and store SSNs within the parameters stipulated in the OCISO Standard for Limiting the Use of Social Security Numbers in CDC Information Systems **(Attachment 24)**. In addition, OCISO has previously approved the collection of PII **(Attachment 25).**

The Respiratory Assessment form (Form No. CDC/NIOSH (M) 2.13, **Attachment 16**) asks miners about diseases and non-occupational risk factors that could affect test results. This information is required in order to correctly assess test results.

As stated above, each collection instrument containing a space for SSN includes the statement, "Full SSN is optional; last 4 digits are required." Participation by the miner in the CWHSP (and therefore providing any information associated with that participation) is voluntary, except for the initial examination which is required within 30 days of employment in the industry. There is no impact on the miner's privacy from the collection of information through voluntary participation.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annual Burden Hours

The total annual estimated respondent burden is 20,281 hours. This is the same as in the last approved ICR. This estimate is based upon participation rates from past years of the program. These annualized burden hours are based on both the time incurred by respondents in order to complete the necessary forms as well as the time incurred for obtaining the radiograph and performing the spirometry testing.

Estimated annualized burden hours for form completion is based on the following:

Coal Mine Operator Plan (Form No. CDC/NIOSH (M) 2.10, Attachment 3)
Coal Contractor Plan (Form No. CDC/NIOSH (M) 2.18, Attachment 4)

Under 42 CFR Part 37, every coal operator and coal contractor in the U.S. must submit a plan approximately every four years, providing information on how they plan to notify their miners of the opportunity to obtain the medical examination.

These forms record plans and arrangements for offering the coal miner examinations and are used by coal operators and contractors for that purpose. Both forms include a section to specify NIOSH-approved spirometry testing facilities in proximity to the mine. Completion of these forms with all requested information (including a roster of current employees) takes approximately 30 minutes. Based on data received from MSHA, there are approximately 425 underground coal mines and 1125 surface mines for a total of 1,550. With each of these mines being required to submit a plan approximately every four years, 388 plans would be submitted annually. Likewise, there are approximately 2,300 coal contractors which would result in 575 annual plans being submitted.

Radiographic Facility Certification Document (Form No. CDC/NIOSH (M) 2.11, Attachment 6)

This form records the radiograph facility equipment/staffing information. Radiograph facilities seeking NIOSH-approval to provide miner radiographs under the CWHSP must complete an approval packet. It takes approximately 30 minutes for completion of this form. An estimate of 40 new facilities will join in the upcoming year.

Miner Identification Document (Form No. CDC/NIOSH (M) 2.9, Attachment 8)

Miners who elect to participate in the CWHSP must fill out this document which requires approximately 20 minutes. This document records demographic and occupational history, as well as information required under the regulations from radiograph facilities in relation to coal miner examinations. It is estimated that a total of 14,560 miners might participate in the upcoming year based on FY17 participation in the CWHSP and using the overall 40% of the total mining industry participation rate. In addition to completing this form, acquiring the chest image from the miner takes approximately 15 minutes.

Chest Radiograph Classification Form (Form No. CDC/NIOSH (M) 2.8, Attachment 11)

Under 42 CFR Part 37, NIOSH utilizes a radiographic classification system developed by the International Labour Office (ILO) in the determination of pneumoconiosis among coal miners. Physicians (B Readers) fill out this form regarding their classifications of the radiographs (each radiograph has at least two separate classifications; approximately 7% require additional classifications). The CWHSP uses an average of 10 B Readers to provide these classifications. Based on prior practice it takes the B Reader approximately 3 minutes per form/classification. By using a participate number of 14,560, multiplied by 2

classifications and adding the 7% (1,019) that require additional classifications, the total number of anticipated classifications would be 30,139. When the 30,139 classifications are distributed among the 10 CWHSP-contracted B Readers, the number of responses per respondent is 3,014.

Physician Application for Certification (Form No. CDC/NIOSH (M) 2.12, Attachment 12)

Physicians taking the B Reader Examination are asked to complete this registration form which provides demographic information as well as information regarding professional practices. It takes approximately 10 minutes to complete this form and is filled out one time per physician. It is estimated that 100 new physicians will sit for the examination in the coming year.

Spirometry Facility Certification Document (Form No. CDC/NIOSH (M) 2.14, Attachment 15)

This form is analogous to the Radiographic Facility Certification Document (Form No. CDC/NIOSH (M) 2.11, **Attachment 6**) and records the spirometry facility equipment/staffing information. Spirometry facilities seeking NIOSH approval to provide miner spirometry testing under the CWHSP must complete an approval packet. It is estimated that it will take approximately 30 minutes for this form to be completed at the facility. Recruiting approximately 100 spirometry facilities would adequately serve the U.S. coal miner population.

Respiratory Assessment Form (Form No. CDC/NIOSH (M) 2.13, Attachment 16)

This form is designed to assess respiratory symptoms and certain medical conditions and risk factors of the miners participating in the CWHSP. It is estimated that it will take approximately 5 minutes for this form to be administered to the miner by an employee at the facility. This annual burden is based on the estimated participation rate of 14,560 miners as previously explained.

Spirometry Results Notification Form (Form No. CDC/NIOSH (M) 2.15, Attachment 17)

This form is used to: 1) collect information that will allow NIOSH to identify the miner in order to provide notification of the spirometry test results; 2) assure that the test can be done

safely; 3) record certain factors that can affect test results; 4) provide documentation that the required components of the spirometry examination have been transmitted to NIOSH for processing; and, 5) conduct quality assurance audits and interpretation of results. This annual burden is based on the estimated participation rate of 14,560 miners as previously explained. It is estimated that it will take the facility approximately 20 minutes to complete this form. In addition to completing this form, acquiring an acceptable spirometry test from the miner takes approximately 15 minutes.

Consent, Release and History Form (Form No. CDC/NIOSH (M) 2.6, Attachment 19)

This form documents written authorization from the next-of-kin to perform an autopsy on the deceased miner. A minimum of essential information is collected regarding the deceased miner including the occupational history and smoking history. From past experience, it is estimated that 15 minutes is required for the next-of-kin to complete this form. There have been no autopsy specimens sent to the CWHSP in the past few years.

42 CFR 37.202 Autopsy Invoice (Attachment 20)

42 CFR Part 37.200 specifies the procedures for the NCWAS. Specifically Part 37.202 addresses payment to pathologists for autopsies performed. The invoice submitted by the pathologist must contain a statement that the pathologist is not receiving any other compensation for the autopsy. Each participating pathologist may use his/her individual invoice as long as this statement is added. It is estimated that only 5 minutes is required for the pathologist to add this statement to the standard invoice that s/he routinely uses.

42 CFR 37.203 Pathologist Report of Autopsy (Attachment 21)

42 CFR Part 37.203 provides the autopsy specifications. The pathologist must submit information found at autopsy, slides, blocks of tissue, and a final diagnosis indicating presence or absence of pneumoconiosis. The format of the autopsy reports are variable depending on the pathologist conducting the autopsy. Since an autopsy report is routinely completed by a pathologist, the only additional burden is the specific request for a clinical abstract of terminal illness and final diagnosis relating to pneumoconiosis. Therefore, only 5 minutes of additional burden is estimated for the pathologist's report.

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Coal Mine Operator	2.10	388	1	30/60	194
Coal Mine Contractor	2.18	575	1	30/60	288
Radiograph Facility Supervisor	2.11	40	1	30/60	20
Coal Miner	2.9	14,560	1	20/60	4,854
Coal Miner – Radiograph	No form required	14,560	1	15/60	3,640
B Reader Physician	2.8	10	3014	3/60	1,507
Physicians taking the B Reader Examination	2.12	100	1	10/60	17
Spirometry Facility Supervisor	2.14	100	1	30/60	50
Spirometry Facility Employee	2.13	14,560	1	5/60	1,214
Spirometry Technician	2.15	14,560	1	20/60	4,854
Coal Mine – Spirometry	No form required	14,560	1	15/60	3,640
Pathologist	Invoice--No standard form	1	1	5/60	1
Pathologist	Pathology Report -- No standard form	1	l	5/60	1
Next-of-kin for deceased miner	2.6	1	1	15/60	1

Total		20,281

B. Estimated Annual Burden Costs

The estimated annualized cost to the respondent population for completion of forms and medical examinations is $594,228 based on the average costs per burden hour and the average burden hours as shown in the table below. This is an increase of $29,836 due to increases in hourly wages. This estimate is based upon participation rates from past years of the program. This annualized cost is based on both the time incurred by respondents in order to complete the necessary forms as well as the time incurred for getting the radiograph and performing the spirometry testing.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Coal mine operators	2.10	388	1	30/60	194	$40	$7,760
Radiograph facility supervisor	2.11	40	1	30/60	20	$40	$800
Coal miner (includes contract miners)	2.9	14,560	1	20/60	4,854	$27	$131,058
Coal miner chest image (includes contract miners)	N/A	14,560	1	15/60	3,640	$27	$98,280
B Reader physicians	2.8	10	3014	3/60	1,507	$99	$149,193
Physicians taking B reader examination	2.12	100	1	10/60	17	$99	$1,683
Spirometry facility employee	2.13	14,560	1	5/60	1,214	$16	$19,424
Spirometry	2.14	100	1	30/60	50	$43	$2,150

facility supervisor							
Spirometry technician	2.15	14,560	1	20/60	4,854	$16	$77,664
Coal miner spirometry test (includes contract miners)	N/A	14,560	1	15/60	3,640	$27	$98,280
Coal Mine Contractors	2.18	575	1	30/60	288	$27	$7,776
Next-of-kin of deceased miner**	2.6	5	1	15/60	1	$12	$12
Pathologist - Invoice	N/A	5	1	5/60	1	$74	$74
Pathologist - Report	N/A	5	1	5/60	1	$74	$74
Total							$594,228

The hourly wages were taken from Bureau of Labor Statistics, National Occupational Employment and Wage Estimates -- Current Employment and Wages from Occupational Employment Statistics (OES) Survey (www.bls.gov/oes).

- Coal Mine Operators based on Coal Mining, 1st Line Supervisor
- Radiograph Facility Supervisor based on Radiation Therapists at Outpatient Care Centers
- Coal Miners based on Coal Mining, Roof Bolters
- B Reader Physicians based on Physician, Surgeon, Outpatient Care Centers
- Spiro facility supervisor based on Medical and Health Services Manager
- Non-supervisory employees in spirometry facilities based on general medical assistants
- Pathologist based on Physician and Surgical Other, General Hospitals

** Next-of-kin based on studies of the local cost of living, such as those conducted by the Economic Policy Institute which suggest a living wage standard of at least $12 per hour

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

There are no other cost burdens to respondents or record keepers.

14. Annualized Cost to the Government

The annualized cost to the government is approximately $2,499,239 which includes all components of the CWHSP: printing and distribution of forms; data management and personnel charges (including contractors); travel-related costs; services and supplies, autopsy-related services and expenses; and all other associated services and costs. The CWHSP is a federally-mandated program, and as such, will have budgetary support throughout the approval period.

15. Explanation for Program Changes or Adjustments

The estimated annualized cost to the respondent population for completion of forms and medical examinations is $594,228 based on the average costs per burden hour and the average burden hours as shown in the table below. This is an increase of $29,836 due to increases in hourly wages (see 12. B. above).

16. Plans for Tabulation and Publication and Project Time Schedule

Internal summaries are periodically prepared to provide information on program activity and to indicate rates of disease in the population. Only summary data are included in these reports. Epidemiologic data will be presented at scientific meetings and peer-reviewed publications will be published as various trends are discovered. This is **an ongoing mandated project** which began in 1970, and will continue according to regulation. A three year clearance is requested.

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

An exemption from displaying the OMB expiration date was requested and approved in 2004. The data collection for this program is a constant and consistent collection. In order to make the most efficient use of stockpiled forms, approval not to print the expiration date on all forms associated with the CWHSP was granted.

18. Exceptions to Certification

There are no exceptions to the certification.