

NATIONAL COAL WORKERS' HEALTH SURVEILLANCE PROGRAM (CWHSP)

Reinstatement for OMB # 0920-0020

Expiration Date: 03/31/2025

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

Supporting Statement A

Project Officer: Tia McClelland, MPH, CPH
Program Manager, CWHSP
Surveillance Branch (SB)
Respiratory Health Division (RHD)
National Institute for Occupational Safety and Health (NIOSH)
1095 Willowdale Rd. MS HG900.2
Morgantown, WV 26505
Ezi2@cdc.gov
304-285- 5788
304-285-6058 (fax)

Date: 11/22/2024

- **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.

Table of Contents

Section A. Justification	Page No.
1. Circumstances Making the Collection of Information Necessary.....	5
2. Purpose and Use of Information Collection.....	6
3. Use of Improved Information Technology and Burden Reduction.....	10
4. Efforts to Identify Duplication and Use of Similar Information.....	10
5. Impact on Small Businesses or Other Small Entities.....	11
6. Consequences of Collecting Information Less Frequently.....	11
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	11
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside of the Agency.....	11
9. Explanation of any Payment or Gifts to Respondents.....	12
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	12
Supplemental Document: NIOSH Standard Security language for Protection of the Privacy and Confidentiality of Information Provided Respondents.....	14
11. Institutional Review Board (IRB) and Justification for Sensitive Questions IRB.....	20
12. Estimates of Annualized Burden Hours and Costs.....	21
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.	28
14. Annualized Cost to the Government.....	29
15. Explanation for Program Changes or Adjustments.....	29
16. Plans for Tabulation and Publication and Project Time Schedule.....	29
17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	29
18. Exceptions to Certification.....	29

List of Attachments

1. Authorizing Authority
2. 42 eCFR Part 37
 b. 60-day FRN
3. Coal Mine Operator Plan – Form No. CDC/NIOSH (M) 2.10
4. Coal Contractor Plan – Form No. CDC/NIOSH (M) 2.18

5. Sample letters to the Coal Mine Operator or Contractor
6. Radiographic Facility Certification Document – Form No. CDC/NIOSH (M) 2.11
7. Sample letter to the Radiographic Facility for Approval
8. Miner Identification Document – Form No. CDC/NIOSH (M) 2.9
9. Sample letter to miners informing of the opportunity to participate
10. Sample letters to participating miners (CWHSP) results
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 Physicians reporting outcomes of B Reader Examinations
14. Sample letter to B Readers (recertification examination)
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 – Spirometry Examination results
19. NCWAS 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. Authorization for Payment of Autopsy – Form No. CDC/NIOSH (M) 2.19
23. Contact Information for Stakeholders
24. OCISO Standard for Limiting the Use of Social Security Numbers in CDC Information Systems
25. OCISO approval for the collection of PII
26. Institutional Review Board Approval
27. CWHSP Request for Medical Records Form_08152024

Justification

This is a request for a reinstatement with changes to existing OMB #0920-0020 approval from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention. Approval is requested for three years from the approval date. No substantive changes are being requested since the last OMB approval in 2022.

This 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 4,018, with an estimated annualized cost to the respondent population of \$177,590.

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, 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 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, blood pressure monitoring, and a health questionnaire 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 former 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 reinstatement ICR is requested for both the regulatory requirements as prescribed in 42 CFR 37, as well as the congressionally-mandated and discretionary reporting instruments; **no substantive changes are being requested**. 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 eligibility. 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/m³ 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 15 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.

Additionally, NIOSH approved radiograph facilities, per 42 CFR part 37, use the form to report the findings of the initial clinical read (required) for each radiograph. It takes the qualified and licensed 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.

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 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.

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.

Authorization for Payment of Autopsy (Attachment 22)
Form No. CDC/NIOSH (M) 2.19

Revised 42 CFR Part 37.204 outlines a need for a physician pathologist to obtain written authorization from NIOSH and agreement regarding payment amount for services specified in § 37.202 (a) by completing the Authorization for Payment of Autopsy form and submitting it to the CWHSP for authorization prior to completing an autopsy on a coal miner. It is completed by the pathologist who intends on conducting an autopsy and the form will collect: demographic information on the deceased miner, characteristics of the miner's pneumoconiosis (if known by the pathologist), demographic and medical licensure information from the requesting pathologist, and proposed payment amount to complete the autopsy in accordance with § 37.203. It is estimated that 15 minutes is required for the pathologist 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.

Request for Medical Records Form (Attachment 27)

This form is required by miners wishing to receive copies of their CWHSP chest x-rays and related files. They must fully complete, sign, and email the form to cwhsp@cdc.gov. The form

can also be mailed or faxed using the address and fax listed on the form. It is estimated that 5 minutes is required for the coal miner to complete this form.

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. However, the CWHSP is working with IT partners and communications specialists to utilize an electronic, secure, more automated system that could be utilized by miners, mine operators, and approved facilities. Currently, 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 with limited data collection technology. 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. Therefore, the program is employing background research to find a system that works well for coal miners and data collection purposes.

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.

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.

We are requesting non-substantive changes to two OMB Approved forms: CDC/NIOSH 2.9 Miner Identification form and CDC/NIOSH 2.15 Spirometry Results Notification form. These forms have been to meet OMB's newly published Race/Ethnicity standards; burden hours are not affected.

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

A 60-day Federal Register Notice (attachment 2b) was published in the Federal Register on September 3, 2024, vol. 89, No. 170, pp. 71274-71275 available at: [2024-19614.pdf](#). CDC did not receive public comments related to this notice .

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)

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 digital image. Currently, B Readers who are contracted to provide classifications of program radiographs are paid \$6,875 on a quarterly basis for a total of \$27,500/year. This payment has been revised several times during the history of the program and may be revised in the future as well. According to the proposed reinstatement to 42 CFR 37, NIOSH will be permitted to allow compensation for pathologists who perform autopsies on coal miners at a market rate, on a discretionary basis, as needed for public health purposes. Currently autopsies generally cost between \$3,000 and \$5,000. Under these revised regulations, pathologists could submit a written request (**Attachment 22**) to conduct an autopsy on a deceased miner as requested by the miner's family, proposing a payment amount which would be reviewed by the CWHSP and approval status would be communicated to the pathologist prior to an autopsy being performed. If approved the pathologist would receive payment after the autopsy was completed and information and materials were received by NIOSH according to 42 CFR 37.203 Autopsy specifications.

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

The Respiratory Health Division's (RHD) Data Security Officer reviewed this submission/project and determined that the Privacy Act is applicable. 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 approved the collection of PII (**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. Finally full SSNs are required to issue payment to pathologists performing autopsies who do not have a Federal Employer Identification Number FEIN, therefore **Attachment 22** requires full SSN from the pathologist.

Partial SSNs are required of the miner (**Attachment 8 and 22**) and full SSN for participating physicians (**Attachment 22**). 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;
- Process pathologist's requested payment for autopsy services.

Each collection instrument containing a space for SSN includes the statement, "Full SSN is optional; last 4 digits are required.", with the exception of **Attachment 22**. 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. The full SSN is required on **Attachment 22** Authorization for Payment of Autopsy as full SSN is required to process payment from NIOSH to the requesting physician pathologist for autopsy services.

Access Controls: The CWHSP database is housed on a OCIO Consolidated SQL 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.

Supplemental Document: NIOSH Standard Security language for Protection of the Privacy and Confidentiality of Information Provided Respondents

Section A10.1 Privacy Act Determination

This submission from Coal Workers' Health Surveillance Program has been reviewed by Respiratory Health Division's (RHD) Data Security Officer who has determined that the Privacy Act [] apply. The activities [] involve the collection of individually identifiable information as full names and partial social security numbers (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. Finally, full SSNs are required to issue payment to pathologists performing autopsies who do not have a Federal Employer Identification Number FEIN, therefore requires full SSN from the pathologist.

Section A10.2 Data Collection

The team will use [] Identifiers to link or match with the individual's name in order to access past or present medical files, vital status, and questionnaires. This provides a means of accurately developing chronologic health data relative to coal miners participating in the program. Direct identifiers are used as a method to provide miners with accurate reporting of medical conditions found through the program. Pathologists' direct identifiers are used to process payment for services provided to the program.

Per the Office of Management and Budget (OMB) Circular A-130, "PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Based on information provided by the ISSO, Privacy Office, system/data owner, or other security or privacy representative, it has been determined that Coal Workers' Health Surveillance Program involves PII. The PII Confidentiality Impact Level has been determined to be [] as guided by RMF 800-37 Rev 2 and FIPS 199, the potential impact is a [] "if the loss of confidentiality, integrity, or availability could be expected to have a [] effect on organizational operations, organizational assets, or individuals".

The Coal Workers' Health Surveillance Program includes the Personal Identity and Authentication Information Type (C.2.8.9) provided in NIST SP 800-60 as established from the "business areas" and "lines of business" from OMB's Business Reference Model (BRM) section of Federal Enterprise Architecture (FEA) Consolidated Reference Model Document Version 2.3, October 2007.

Privacy Impact Assessment (PIA) has been by the CDC Privacy Officer.

The System of Records Notice (SORN) that is applicable to this activity is: [09-20-0149](#) or [09-20-0153](#).

The disposition to be made of the Privacy Act records upon completion of activity performance is:

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

Scientific and Research Project Records

Precedent-Setting Scientific and Research

Records represent scientific data and all aspects of research including project development, demonstration, distribution, assessment, testing, and related tasks. Systems that document the planning, history, results, and outcome of a scientific and or research project conducted as part of CDC/ATSDR's mission or under the supervision of CDC/ATSDR employee(s). These records include but are not limited to planning documents, and/or documents that evaluate or appraise a project or other research during its course. Records include but not limited to original observations, laboratory notebooks, databases that contain scientific observations, modeling and sampling methodologies, and any other research-related documentation.

Master file, system or database that is precedent-setting, received remarkable interest from the public health community and garnered extreme interest by the public, media, and health researchers; these records have long-term evidentiary and informational value.

a. Long-Term ongoing Studies that contain cumulative research data

Authorized Disposition: Ongoing studies are kept in the main database accessible to authorized CWHSP personnel. NIOSH is following the CDC System and Data Modernization plans to catalog research data, provide data flow mapping, and future state design.

b. Completed Studies

Authorized Disposition: PERMANENT: Transfer to NARA a copy of the completed database no longer than one year after the end of the project.

Electronic media will be transferred to NARA formatted in accordance with current applicable regulations regarding transfer of electronic records.

Selection Criteria for Permanently valuable data: Includes, but not limited to, research records meeting one or more of the following criteria:

- Records of scientific investigations that are deemed to be Influential Scientific Information or Highly Influential Scientific Assessments (per Office of Management and Budget (OMB) Bulletin for Peer Review, December 15, 2004):
- Scientific information that CDC reasonably determines will have or does have a clear and substantial impact on important public policies or private sector decisions.
- An evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information.
- A scientific assessment is a subset of "influential scientific information" and is considered "highly influential" by
- the agency or the OIRA Administrator [Office of Information and Regulatory Affairs in OMB] determines the
- dissemination could have a potential impact of more than \$500 million in any one year on either the public or
- 1 This schedule is media neutral therefore includes audiovisual, textual, electronic and other formats.
- CDC/ATSDR Records Control Schedule private sector or that the dissemination is novel, controversial, or precedent setting, or has significant interagency interest.
- Long-term data collections and monitoring efforts of national or international interest.
- Datasets that is irreplaceable, critical to the CDC mission, and in a condition which allows future use.
- Scientific investigations that receive national or international awards of distinction.
- Works of prominent CDC investigators of widely recognized professional stature, or who have received national or international recognition outside their professional discipline.
- Activities that result in a significant improvement in public health, safety, or other vital public interest.

- Significant contributions to new national or international health policies, or had a significant impact on the development of new national or international scientific, political, economic, or social priorities.
- Subjects of widespread national or international media attention.
- Materials related to significant social, political, or scientific controversy.
- Activities subject to extensive Congressional, Department of the Interior, or other government agency scrutiny or investigation.
- Precedents that significantly change CDC scientific investigations.
- All projects published and unpublished publications.

Section A10.3 CDC/NIOSH Security Requirements for Safeguarding Information Assets

Laws and regulations applicable to the Coal Workers' Health Surveillance Program may include but are not limited to: the Privacy Act of 1974; the Federal Information Security Modernization Act of 2014 (FISMA); the Computer Fraud and Abuse Act of 1986; the E-Government Act of 2002; the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003; OMB Circular A-130 (Managing Information as a Strategic Resource), and the corresponding implementing regulations. These laws and regulations identify responsibilities for protecting and managing federal information resources, including personally identifiable information. FISMA's security measures regarding implementation guidance are provided by National Institute of Standards and Technology's (NIST) 800 series Special Publications.

CDC's Office of the Chief Information Officer's (OCIO) Cybersecurity Program Office (CSPO) along with NIOSH OD-IT develop and maintain information governance and security programs to achieve and maintain compliance with applicable Security and Privacy laws, regulations, and HHS/CDC/NIOSH policies. This includes continuous monitoring applied to monitor the security and privacy across the Institute.

CDC and NIOSH minimum requirements for safeguarding information assets based on the identified needs for confidentiality, integrity and availability protection include the CDC IT Security Program Implementation Standards, NIOSH Information Governance Policy (IGP), and NIOSH Enhanced Baseline Security Controls (NEBSC). NIOSH Information Governance Policy (IGP) enforces information governance lifecycle and risk based management across technology, tools, workflows, and organizational units by promoting accountability and decision rights within the Institute to ensure appropriate behavior in the valuation, creation, storage, use, archiving, and deletion of information with specific requirements for information cataloging, provisioning, security, auditing, and use. The NIOSH Enhanced Baseline Security Controls (NEBSC) defines the Institute's baseline specification of minimum time constraints and security requirements according using NIST Special Publication 800-53 baseline controls with appropriate

tailoring for relevant laws, regulations, and industry standards such as GDPR/CCPA, HIPAA/HITECH, OMB Circular A-130, OPEN Government Data Act, Privacy Act to further enhance the protection PII and PHI in supporting worker safety.

Section A10.4 Access and Use

Coal Workers' Health Surveillance Program information shall only be used for the following purposes: *reporting disease findings to miners, to protect the health of coal miners, and document and monitor trends and patterns in the prevalence of coal workers' pneumoconiosis among US coal miners*. 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. Additionally, the data from the CWHSP can be used in numerous ways to evaluate the effectiveness of the health regulations implemented under the Act. It shall not be divulged or made known in any manner for the purpose for which it was obtained, unless written approval from Project Officer, Business Steward/Data Owner, C/I/O or from whom the information was collected. Project officers seeking Coal Workers' Health Surveillance Program data must obtain approval by the Branch Technical Steward prior to data access.

Access to Coal Workers' Health Surveillance Program data is granted to CDC Federal and contract staff on a need to know basis, for the duration required for completing their work. The project officer is responsible for determining access needs. NIOSH will annually review appropriate user access rights to ensure access to the CDC/NIOSH Information Assets remain commensurate with job responsibilities. The Branch Technical Steward ensures that training is provided, and non-disclosure forms are signed prior to users' access to the data.

Users of Coal Workers' Health Surveillance Program data will keep materials with personally identifiable information confidential. Details which could directly or indirectly identify any individual will be not be discussed in public or with staff who have not been granted access to the Coal Workers' Health Surveillance Program data.

Section A10.5 Data Storage and Transmission

Hardcopy of records must be minimized and kept in a locked file cabinet. Portable electronic media shall not be used to store data. They may be used for transporting data and it must be encrypted to meet FIPS 140-3 encryption standard. Any media containing Coal Workers' Health Surveillance Program data will be marked as 'Sensitive but Unclassified' or equivalent marking. Once data is received by NIOSH and verified, the data on the exchange media shall be destroyed.

Data exchange shall meet federal encryption standard FIPS 140-3, Security Requirements for Cryptographic Modules. FIPS 140-2 modules can remain active until September 21, 2026.

Original source information from NIOSH laboratories, instruments, sensors, surveys, surveillance, data gathering applications, external owners, and all other sources shall be differentiated and organized according to the NIOSH Information Organization Schema. Source Information Assets shall be immutable and read-only to authorized users and shall be preserved for the lifespan of associated work products to support data lineage. NIOSH users shall replicate source information to work areas for processing and modification.

CDC/NIOSH will retain and destroy records in accordance with CDC Records Control Schedule and other applicable record scheduling procedures prescribed by the General Records Schedule (GRS) and National Archives and Records Administration (NARA).

Section A10.6 Use of Contracts

It is anticipated that the work on the Coal Workers' Health Surveillance Program will be performed by CDC staff and onsite contract staff with the work being performed using the CDC network and ADW's Shared Services.

In the event that an off-site collaborator or contractor performs work on Coal Workers' Health Surveillance Program data, prior to receiving any data, the collaborator or contractor shall meet CDC and NIOSH security privacy requirements, NIOSH Information Governance Policy (IGP) and other requirements as specified in this Confidentiality Security Statement. Collaborator or Contractor shall have an approved NIOSH Authorization including a NIOSH CDC Authority To Operate (ATO) or Authorization to Use (ATU) under either NIST SP 800-53 for Federal Information Systems or NIST SP 800-171 for Covered Contractor Systems, information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information. Cloud hosted systems shall also be FedRAMP Authorized. If a Contractor (and/or any subcontractor) has access to collect, process or maintain government information and/or system or if the contract is a hosted or cloud-based application/system or a Covered Contractor Information System, the NIOSH Standard Contract Language, shall be included as part of the contractual terms and conditions.

Section A10.7 Data Disclosure

Coal Workers' Health Surveillance Program data will only be accessible to external researchers through a Federal Research Data Center (RDC). All requests for Coal Workers' Health Surveillance Program data files must be made through a proposal to the RDC to be reviewed by the RDC, and NIOSH.

De-identified data may be released to the public outside of CDC/NIOSH through publication and the CWHSP's online query tool.

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 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" with the exception of **Attachment 22** where full SSN from the physician pathologist is required to process payment of autopsy services. 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 miners' privacy from the collection of information through voluntary participation.

In accordance with updated Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15; effective March 28, 2024; refer to [89 FR 22182](#)), Federal agencies that collect race and ethnicity data are now required to use one combined question that includes the Middle Eastern or North African category and that collects detailed race and ethnicity data beyond the minimum categories, the CWHSP has revised two OMB Approved forms (CDC/NIOSH 2.9 Miner Identification form and CDC/NIOSH 2.15 Spirometry Results Notification form). The CWHSP updates follow the example of Figure 3. Race and Ethnicity Question with Minimum Categories only. Using the more detailed categories would require the CWHSP to collect additional data that will not be utilized by any parts of the program. Collecting and

entering this additional data would require additional staff hours and would not be an efficient use of resources because the additional data would not be utilized. Data collection according to Figure 3, permits collection of the data needed by the CWHSP.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annual Burden Hours

The total annual estimated respondent burden is 4,018 hours. This is 7,723 hours less than the extension ICR submitted in 2020; x-ray (from March 2020-June 2020) and spirometry (March 2020 – May 2021) services were paused during the pandemic. B Reader examinations at NIOSH in Morgantown, WV, were suspended from March 2020 – August 2022. This estimate is based upon participation rates from the past 5 years (FY19-FY24) of the program for participating miners, number of physicians taking the B Reader examination, and number of facility certifications being completed. 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 237 underground coal mines and 836 surface mines for a total of 1,073. With each of these mines being required to submit a plan approximately every four years, 268 plans would be submitted annually. Likewise, there are approximately 658 coal contractors which would result in 165 annual plans being submitted. * Numbers listed in the burden tables were figured using the actual total number of forms (2.10 (1,114) and 2.18 (339)) received from 7/1/2019 - 7/1/2024. The total number for each form was divided by 5.

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 14 new facilities will join in the upcoming year. A sample letter to the radiographic facility informing them that their radiographic unit(s) are approved by NIOSH is included in **Attachment 7**.

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 on average that a total of 4,345 miners might participate in the upcoming year based on FY19–FY24 total count participation number of 21,725 in the CWHSP. 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 participation number of 4,345, multiplied by 2 classifications and adding the 7% (304) that require additional classifications, the total number of anticipated classifications would be . When the 8,994 classifications are distributed among the 10 CWHSP-contracted B Readers, the number of responses per respondent is 899.

Additionally, NIOSH approved radiograph facilities, per 42 CFR part 37, use the form to report the findings of the initial clinical read (required) for each radiograph. It takes the qualified and licensed physician approximately 3 minutes per form (240 burden hours).

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 110 physicians will sit for the examination in the coming year.

B Reader Physician Challenge to Disciplinary Action and Appeal of Decertification Decision (No form required)

The amended 42 CFR 37.52 addresses the process for certifying B Readers' proficiency in the use of systems for classifying the pneumoconioses and the process by which NIOSH would pursue disciplinary action (suspend or revoke B Reader certification) if a B Reader was found to be routinely submitting incorrect pneumoconiosis classifications as well as the B Reader's appeal process options. Of the 190 B Readers currently certified and the approximately additional 200 who will be certified over the next 10 years, the CWHSP anticipates that no more than 3 B Readers may be disciplined over time. Of those, the CWHSP expects 2 B Readers to challenge or appeal the decision to take disciplinary action; if all decisions are challenged and the final decision to revoke certification is appealed, NIOSH would receive up to 8 letters (for each of the 4 final disciplinary decisions). CWHSP estimates that the challenge or appeal letter will take no more than 30 minutes to complete, totaling 4 hours annually. There will be no form associated with this collection.

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. It is estimated that approximately 15 new spirometry facilities will be recruited in the coming year.

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 average from the number

miners who participated in spirometry (3,096 total count) over the past 5 years (FY19-FY24).

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 619 (3,096 5-year total) 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. The CWHSP expects an average of 4 autopsy requests annually.

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 if 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. The CWHSP expects an average of 4 autopsy requests annually.

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. The CWHSP expects an average of about 4 autopsy requests annually.

Authorization for Payment of Autopsy (Form No. CDC/NIOSH (M) 2.19, Attachment 22)

Revised 42 CFR Part 37.204 outlines a need for a pathologist to obtain written authorization from NIOSH and agreement regarding payment amount for services specified in § 37.202 (a) by completing the Authorization for Payment of Autopsy form and submitting it to the CWHSP for authorization prior to completing an autopsy on a coal miner. This form will be completed by the pathologist who intends on conducting an autopsy and the form will collect: demographic information on the deceased miner, characteristics of the miner's pneumoconiosis (if known by the pathologist), demographic and medical licensure information from the requesting pathologist, and proposed payment amount to complete the autopsy in accordance with § 37.203. The number of autopsy requests will vary substantially between years. For example, more requests might be granted following a mine disaster. Over a period of years, NIOSH expects an average of about 4 requests for prior authorization annually. It is estimated that 15 minutes is required for the pathologist to complete this form.

Request for Medical Records Form (Attachment 27)

This form is required by miners wishing to receive copies of their CWHSP chest x-rays and related files. They must fully complete, sign, and email the form to cwhsp@cdc.gov. The form can also be mailed or faxed using the address and fax listed on the form. It is estimated that 5 minutes is required for the coal miner to complete this form.

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	268	1	30/60	134
Coal Mine Contractor	2.18	68	1	30/60	34
Radiograph Facility Supervisor	2.11	14	1	30/60	7
Coal Miner	2.9	4,345	1	20/60	1,448
Coal Miner – Radiograph	No form required	4,788	1	15/60	1,197
B Reader Physician	2.8	10	899	3/60	450
Qualified and Licensed Physician (NIOSH Approved Radiograph Facility)	2.8	4,788	1	3/60	240
Physicians taking the B Reader Examination	2.12	110	1	10/60	18
Spirometry Facility Employee	2.13	619	1	5/60	52
Spirometry Facility Supervisor	2.14	15	1	30/60	8
Spirometry Technician	2.15	619	1	20/60	206
Coal Miner – Spirometry	No form required	619	1	15/60	155
Coal miner (includes contract miners)	Request for Medical Records Form	779	1	5/60	65
Authorization for Payment of Autopsy	2.19	4	1	15/60	1
Pathologist	Invoice--No standard form	4	1	5/60	1
Pathologist	Pathology Report -- No standard form	4	1	5/60	1
Next-of-kin for deceased miner	2.6	4	1	15/60	1

Total		4,018
-------	--	-------

A. Estimated Annual Burden Costs

The estimated annualized cost to the respondent population for completion of forms and medical examinations is \$177,590 based on the average costs per burden hour and the average burden hours as shown in the table below. This is \$178,866 less than the last full ICR in 2020 due to general contraction in the coal mining industry (fewer active mines and fewer eligible miners), fewer facilities attempting the facility approval process, and the COVID-19 pandemic. 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	268	1	30/60	134	\$39	\$5,226
Coal Mine Contractors	2.18	68	1	30/60	34	\$33	\$1,122
Radiograph facility supervisor	2.11	14	1	30/60	7	\$50	\$350
Coal miner (includes contract miners)	2.9	4,345	1	20/60	1,448	\$33	\$47,784
Coal miner chest image (includes contract miners)	N/A	4,788	1	15/60	1,197	\$33	\$39,501
B Reader physicians	2.8	10	899	3/60	450	\$99	\$44,550
Qualified and Licensed Physician (NIOSH Approved)	2.8	4,788	1	3/60	240	\$99	\$23,760

Radiograph Facility)							
Physicians taking B reader examination	2.12	110	1	10/60	18	\$99	\$1,782
Spirometry facility employee	2.13	619	1	5/60	52	\$21	\$1,092
Spirometry facility supervisor	2.14	15	1	30/60	8	\$65	\$520
Spirometry technician	2.15	619	1	20/60	206	\$21	\$4,326
Coal miner spirometry test (includes contract miners)	N/A	619	1	15/60	155	\$33	\$5,115
Coal miner (includes contract miners)	Request for Medical Records	779	1	5/60	65	\$33	\$2,145
Next-of-kin of deceased miner**	2.6	4	1	15/60	1	\$20	\$20
Autopsy Prior Authorization	2.19	4	1	15/60	1	\$99	\$99
Pathologist - Invoice	N/A	4	1	5/60	1	\$99	\$99
Pathologist - Report	N/A	4	1	5/60	1	\$99	\$99
Total							\$177,590

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**: mean hourly wage for May 2023 (most recent data listed). (https://www.bls.gov/oes/current/oes_nat.htm)

- Coal Mine Operators based on First-Line Supervisors of Construction Trades and Extraction Workers (47-1011) \$39.11
- Radiograph Facility Supervisor based on Radiation Therapists (29-1124) \$50.20
- Coal Miners based on Roof Bolters, Mining (47-5043) \$33.42
- B Reader Physicians and Pathologists based on Physicians and Surgeons, All

- Other (29-1069) \$99.28
- Spirometry facility supervisor based on Medical and Health Services Manager (11-9111) \$64.64
- Non-supervisory employees in spirometry facilities based on general medical assistants (31-9092) \$20.84

** 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 \$20 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 \$2,246,138 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 \$177,590 based on the average costs per burden hour and the average burden hours as shown in the table above. This is \$178,866 less than the last full ICR in 2020 due to general contraction in the coal mining industry (fewer active mines and fewer eligible miners), fewer facilities attempting the facility approval process, and the COVID-19 pandemic.

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.

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.