

**NATIONAL COAL WORKERS' HEALTH SURVEILLANCE PROGRAM (CWHSP)
Reinstatement with changes for OMB # 0920-0020**

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

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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 chest radiographs interpreted for the presence or absence of disease, 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: prevalence and trends

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

A. Justification

This is an information collection request (ICR) for a reinstatement with changes of the existing OMB #0920-0020 approval from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention. Revisions to the data collection instruments are included in this submission and provide an update to the currently approved Coal Workers' Health Surveillance Program (CWHSP), which was revised under an emergency ICR expiring on 02/28/2015 - the original expiration date (prior to the emergency ICR) was 05/31/2017. The emergency ICR was warranted because of changes associated with MSHA final rule 30 CFR 70, 71, 72, 75 and 90. On August 1, 2014, the CWHSP became responsible for expanded medical surveillance activities established by MSHA under final rule 30 CFR 70, 71, 72, 75 and 90. These expanded medical surveillance activities are hereafter referred to as an additional component of the CWHSP -- the Expanded Coal Workers' Health Surveillance Program. This submission accounts for those expanded activities as well as the previously existing mandated surveillance activities under the CWHSP which had to be revised as well in order to incorporate the Expanded components of the program. Approval is requested for three years from the approval date.

Therefore, this request incorporates all components that now fall under 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 (whose participation, after an initial exam at the time of first employment, is voluntary), 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 20,282, with an estimated annualized cost to the respondent population of \$564,392.

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 mandatory and discretionary 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**).

On May 1, 2014, the Department of Labor published a final rule that revised the existing MSHA standards on miners' occupational exposure to respirable coal mine dust. In publishing the rule, MSHA sought to increase primary disease prevention through a lowered exposure limit for respirable dust and to improve secondary prevention by requiring coal mine operators to offer coal miners an expanded medical surveillance program that includes respiratory symptom assessment and spirometry (in addition to the previous program that included collection of work histories and chest radiographs). The new rule also extends coverage for medical surveillance to include workers at surface coal mines and requires that mine operators use NIOSH-approved facilities to provide these periodic examinations. To respond to these new medical surveillance requirements and the extended coverage for surface miners, NIOSH has modified existing forms and also developed several new forms. This current revision of the public burden estimate for information collection associated with NIOSH coal miner health surveillance activities reflects both previously approved and ongoing surveillance activities as well as the new activities associated with the revised MSHA rule and the NIOSH response to the expanded health surveillance mandate. The information collections associated with the revised MSHA rule include those related to: 1) the process of obtaining NIOSH-approval for medical facilities that perform chest radiography and/or spirometry; 2) documenting mine operator compliance with MSHA-required medical surveillance plans for workers at surface and underground coal mines; and, 3) the performance and reporting of results of miner health examinations by NIOSH-approved facilities.

This reinstatement with changes is requested for both the regulatory requirements as prescribed in 42 CFR 37, as well as the congressionally-mandated and discretionary reporting instruments listed below. Revisions (since the 2014 emergency IFR) to any of the reporting instruments are described in Section A12 . Note that all forms have been revised to state that the full Social Security Number (SSN) is now optional, but that the last four digits are required. In addition, electronic versions of these reporting instruments are available on the CWHSP web site to improve program efficiency and reduce paperwork burden.

See: <http://www.cdc.gov/niosh/topics/surveillance/ords/cwhsp.html>

Reporting Instruments:

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.

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.

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.

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. 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. Formerly called the Interpreting Physician Certification Document, this form has been renamed to more accurately reflect its purpose.

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.

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.

Spirometry Results Notification Form (Attachment 17)

Form No. CDC/NIOSH (M) 2.15

This new form replaces previous versions of forms 2.15, 2.16 and 2.17. It 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.

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.

42 CFR 37.202 Autopsy Invoice (Attachment 20)

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.

42 CFR 37.203 Pathologist Report of Autopsy (Attachment 21)

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.

NCWAS Autopsy Checklist (Attachment 22)

To aid the pathologist, this checklist of report requirements for the NCWAS pathology report is provided.

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/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 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.

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 program. Electronic versions of the forms are provided and the current revisions improve efficiency by enabling the use of digital images and electronic file transfers. However, paper versions of the forms are also needed as this data collection is frequently accomplished at the mine, at radiograph and spirometry facilities, or at the miner's residence where access to electronic data collection technology may be limited or non-existent. 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. 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 described 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; 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.

6. Consequences of Collecting Information Less Frequently

Miner participation in radiographic examinations, spirometry tests, and blood pressure screening is voluntary. 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. The autopsy form is completed only once.

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

a. The 60-day notice was published in the Federal Register for public comment on Monday, December 15, 2014 (Volume 79, Number 240, Page 74094, **Attachment 23**). No comments were received.

b. 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 24** 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 provide classifications of program radiographs are reimbursed \$8.00 per analog film and \$12.00 per digital image. However, 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. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has previously reviewed this project and has determined that the Privacy Act is applicable. 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.

Data on interpreting physicians is covered under Privacy Act system of records 09-20-0001, "Certified Interpreting Physicians File"; data on miners is covered under Privacy Act systems of records 09-20-0149, "Morbidity Studies in Coal Mining, Metal and Non-Metal Mining and General Industry," and system 09-20-0153, "Mortality Studies in Coal Mining, Metal and Non-Metal Mining and General Industry."

IRB Approval

The CWHSP is not considered a research program and does not require Institutional Review Board approval (see **Attachment 25**). 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."

10.1 Privacy Impact Assessment Information

When miners have a chest radiograph taken at an approved-NIOSH facility, they are required to complete a Miner Identification Document (Form CDC/NIOSH (M) 2.9, **Attachment 8**), which historically included the miner's SSN. If a miner has a disease, all of his/her previous radiographs are retrieved to analyze the progression of the disease. When miners have questions about their radiograph,

the SSN that the miners provide allows NIOSH to locate their records. Without the ability to identify a miner and link him/her to all of his/her previous radiographs, NIOSH would have limited ability to understand and monitor the progression of the disease, not only for the individual miner but as it relates to national trends in disease as well. Therefore, at least a partial SSN is necessary to establish identity. Full SSNs have historically been collected for verifying identity. However, all forms have been revised to state that the miner's full SSN is now optional, but that the last four digits are required. The CWHSP currently has medical records on approximately 269,166 miners, consisting of over 469,990 radiographs. All of these records have been archived by SSN. The following is an excerpt from 42 CFR Part 37 which addresses security of transmitting radiographs.

§37.60 Submitting required chest radiograph classification and miner identification documents.

(a) Each chest radiograph required to be made under this subpart, together with the completed Chest Radiograph Classification Form and the completed Miner Identification Document, must be submitted together for each miner to NIOSH within 14 calendar days after the radiographic examination is given and become the property of NIOSH.

(1) When the radiograph is digital, the image file for each radiograph, together with either hard copy or electronic versions of the completed Chest Radiograph Classification Form and the completed Miner Identification Document, must be submitted to NIOSH using the software and format specified by NIOSH either using portable electronic media, or a secure electronic file transfer within 14 calendar days after the radiographic examination. NIOSH will notify the submitting facility when it has received the image files and forms from the examination. After this notification, the facility will permanently delete, or if this is not technologically feasible for the imaging system used, render permanently inaccessible all files and forms from its electronic and physical files.

Spirometry examinations at a NIOSH-approved facility require clinic personnel to administer two questionnaires: 1) the Respiratory Assessment Form (Form No. CDC/NIOSH (M) 2.13, **Attachment 16**); and, 2) a Spirometry Results Notification Form (Form No. CDC/NIOSH (M) 2.15, **Attachment 17**). Facilities must submit the Respiratory Assessment and the Spirometry Results Notification forms to NIOSH. These forms use the miner's name, date of birth, test completion date, and medical record number (assigned by the clinic) to identify the miner. Since spirometry examinations are a relatively new component of the program and the medical record number will be used from the very beginning of

this data collection, this number will be sufficient to identify each miner in order to locate additional test results for comparison in the evaluation of lung function loss. Therefore SSNs will not be collected on forms pertaining only to spirometry testing. The following is an excerpt from 42 CFR Part 37 which addresses confidentiality of spirometry data.

§37.96 Spirometry interpretations, reports, and notifications.

(e) *Confidentiality of spirometry examinations.* Individual medical information and spirometry results are considered protected health information under HIPAA and may only be released as specified by HIPAA or to NIOSH as specified in §§37.93 and 37.96 of this subpart. Personally identifiable information in the possession of NIOSH will be released only with the written consent of the miner or, if the miner is deceased, the written consent of the miner's next of kin or legal representative.

To provide on-site back-up and assure complete data transfer, facilities will retain the forms and results (in electronic or paper format) from a miner's examination until instruction has been received from NIOSH to delete the associated files and forms or, if this is not technologically feasible, render the data permanently inaccessible.

B Reader certification is granted to physicians with a valid U.S. medical license who demonstrate proficiency in the classification of chest radiographs for the pneumoconioses using the International Labour Office (ILO) Classification System. When a physician takes the B Reader Examination, s/he will complete the Physician Application for Certification Document (Form No. CDC/NIOSH (M) 2.12, **Attachment 12**), which includes the physician's SSN. When interpreting radiographs as part of the CWHSP, the physician records his/her classification on the Chest Radiograph Classification Form (Form CDC/NIOSH (M) 2.8, **Attachment 11**) which includes his/her SSN. This is used to track certification status and record which physician classified the radiograph. However, we have given B Readers the option of providing a complete SSN or only the last four digits.

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.

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

The safeguarding measures that will be 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 statements which are to appear on these forms are taken directly from 42 CFR 37.80, which defines the exact degree of safeguarding required by regulation.

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.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

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.

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.

12. Estimates of Annualized Burden Hours and Costs

Estimated Annual Burden Hours

The total annual estimated respondent burden is 20,282 hours. This is an overall increase of 3,924 hours from the emergency ICR. This current estimate is based upon participation rates from past years of the program as well as monitoring of the program since the emergency ICR was approved. 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.

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	5	1	5/60	1
Pathologist	Pathology Report -- No standard form	5	1	5/60	1
Next-of-kin for deceased miner	2.6	5	1	15/60	2
Total					20,282

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 have been revised to collect an email address for the company point of contact to aid in obtaining complete and/or missing information. At the request of a coal operator, one section of the form has been renamed in order to clearly differentiate between the dates for the approval period of the entire plan versus the dates of the 6-month open period for obtaining the examinations. An area for NIOSH staff to designate the appropriate MSHA District number has also been added in order to aid in the compilation and analysis of data. Both forms now include a section to specify NIOSH-approved spirometry testing facilities in proximity to the mine. 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. 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. Space for an email address for the contact at the facility has been added to allow for electronic communications with the facility. In addition, the form has been revised to collect an email address for the supervising clinician in order to aid in obtaining complete and/or missing information. Attachment 7 provides a sample letter that is sent to the radiographic facility informing that the facility's radiographic units are approved by NIOSH. 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. In addition to completing this form, acquiring the chest image from the miner takes approximately 15 minutes. This form has been revised to state that the miner's full SSN is now optional, but that the last four digits are required. A space has been added for the unit number at the facility in which the radiograph was taken. This is needed to identify the location of the radiograph unit in the hospital and distinguish between units that may be identical, except for the serial number. The serial number is not readily visible, so this will aid in identifying individual radiograph units in order to establish quality control for each unit. The street address for the employer has been removed as it is no longer needed for our database. The form has also been revised to collect an email address for the miner to aid in obtaining complete and/or missing information. 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 interpretation.

It is estimated that a total of 14,560 miners might participate in the upcoming year based on FY14 participation in the CWXSP (4,570), plus miners that are known to be eligible to participate in the ECWHSP during the coming year (11,400), plus miners that would be added under the new Expanded CWHSP (6,000) and using the 40% participation rate. **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 has 10 B Readers under contract to provide these classifications. Based on prior practice it takes the B Reader approximately 3 minutes per form/classification. This form has been revised to state that both the miner and the physician's full SSN are now optional, but that the last four digits are required. A space has been added for the unit number at the facility in which the radiograph was taken. This is needed

to identify the location of the radiograph unit in the hospital and distinguish between units that may be identical except for the serial number. The serial number is not readily visible, so this will aid in identifying individual radiograph units in order to establish quality control for each unit. In addition, several already existing fields on the form have been rearranged to ease flow.

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. This form has been revised to state that the physician's full SSN is now optional, but that the last four digits are required and a field has been added to collect an email address. Since some physicians are licensed in more than one state, additional spaces have been added to record all state licenses. When classifying radiographs, B Readers routinely initial the classification form instead of supplying a complete signature. A space has been added for physicians to enter the initials they plan to use when classifying radiographs. A question regarding whether the physician is employed by a federal government agency has been added in order to avoid any conflict of interest issues. In addition, a section has been added on the back of this form outlining the established B Reader Code of Ethics and possible consequences for not adhering to policy. **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.

During FY14, there were 74 B Reader Examinations given. In anticipation of offering a new digital examination, 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)

The new MSHA rule adds spirometry testing for chronic obstructive pulmonary disease (COPD) to the previously mandated chest radiograph examination program. 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. This form has been revised to collect an email address for

the supervising clinician in order to aid in obtaining complete and/or missing information.

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)

The new MSHA rule adds spirometry testing for chronic obstructive pulmonary disease (COPD) to the previously mandated chest radiograph examination program and expands health surveillance program coverage to include respiratory symptom assessment. This form is designed to assess respiratory symptoms and certain medical conditions and risk factors. 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. A field has been added to collect the email address of the participant.

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 new form will replace previous forms 2.15, 2.16 and 2.17. It 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. A space has been added for the unit number at the facility in which the examination was taken. This is needed to identify the location of the unit in the hospital and distinguish between units that may be identical except for the serial number. The serial number is not readily visible, so this will aid in identifying individual units in order to establish quality control for each unit. A field has been added to collect the email address of the participant. 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.

This annual burden is based on the estimated participation rate of 14,560 miners as previously explained. .

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.

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.

NCWAS Autopsy Checklist (Attachment 22)

To aid the pathologist, a checklist of report requirements for the NCWAS program is provided. Information pertaining to the items on this checklist is maintained in the NCWAS database. This checklist requires no response and therefore no additional burden hours are associated with it.

Estimated Annual Burden Costs

The estimated annualized cost to the respondent population for completion of forms and medical examinations is \$564,392 based on the average costs per burden hour and the average burden hours as shown in the table below. This is an overall increase of \$122,096 from the emergency ICR. This current estimate is based on participation rates from past years of the program as well as monitoring of the program since the emergency ICR was approved. 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	\$38	\$7,372
Radiograph facility supervisor	2.11	40	1	30/60	20	\$38	\$760

Coal miner (includes contract miners)	2.9	14,560	1	20/60	4,854	\$26	\$126,204
Coal miner chest image (includes contract miners)	N/A	14,560	1	15/60	3,640	\$26	\$94,640
B Reader physicians	2.8	10	3014	3/60	1,507	\$92	\$138,644
Physicians taking B reader examination	2.12	100	1	10/60	17	\$92	\$1,564
Spirometry facility employee	2.13	14,560	1	5/60	1,214	\$15	\$18,210
Spirometry facility supervisor	2.14	100	1	30/60	50	\$38	\$1,900
Spirometry technician	2.15	14,560	1	20/60	4,854	\$15	\$72,810
Coal miner spirometry test (includes contract miners)	N/A	14,560	1	15/60	3,640	\$26	\$94,640
Coal Mine Contractors	2.18	575	1	30/60	288	\$26	\$7,488
Next-of-kin of deceased miner	2.6	5	1	15/60	2	\$12	\$24
Pathologist - Invoice	N/A	5	1	5/60	1	\$68	\$68
Pathologist - Report	N/A	5	1	5/60	1	\$68	\$68
Total							\$564,392

* 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, Internal Medicine, Outpatient Care Centers
- 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 \$2,262,097 which includes all components of the CWHSP: printing and distribution of forms; data management and personnel charges (including contractors); travel-related costs; 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

This renewal reflects an increase of 3,924 burden hours from the emergency ICR that was previously approved. This current estimate is based upon participation rates from past years of the program as well as monitoring of the program since the emergency ICR was approved. There is an overall annual burden cost increase of \$122,172 to the respondent population due to a more recent estimate of participation with the addition of surface miners and spirometry to the surveillance program.

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

No exception is requested.