NATIONAL COAL WORKERS' HEALTH SURVEILLANCE PROGRAM (CWHSP) EMERGENCY CLEARANCE REQUEST FOR OMB # 0920-0020

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

Section A

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

This is an emergency clearance information collection request (ICR) from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention. The revisions to the data collection instruments are included in this submission and provide an update to the currently approved ICR 0920-0020 Coal Worker's Health Surveillance Program (CWHSP), expiration 5/31/2017. An emergency clearance is warranted because of the changes associated with MSHA final rule 30 CFR 70, 71, 72, 75 and 90. On August 1, 2014 the CWHSP is responsible for expanded medical surveillance activities established by MSHA under final rule 30 CFR 70, 71, 72, 75 and 90. This submission accounts for the inclusion of surface coal miners, the addition of spirometry testing, and symptom and respiratory assessment. This submission reflects an increase of 11,940 burden hours for this approval period due to expansion of the program to include surface miners. In addition, spirometry testing and respiratory symptom assessment is now included and being offered to all miners in accordance with changes to MSHA final rule 30 CFR parts 70, 71, 72, 75 and 90. There is an overall burden cost increase of $291,514 estimated annualized cost to the respondent population due to these changes.

The proposed information collection includes all four components of the Coal Workers' Health Surveillance Program (CWHSP). Those four components include: Coal Workers' X-ray Surveillance Program (CWXSP), B Reader Program, Enhanced Coal Workers' Health Surveillance Program (ECWHSP), and National Coal Workers' Autopsy Study (NCWAS). The CWHSP is a congressionally-mandated medical examination program for monitoring the health of coal miners, established under the Federal Coal Mine Health and Safety Act of 1969, as amended in 1977 and 2006, PL-91-173 (the Act). The Act provides the regulatory authority for the administration of the CWHSP. This Program has been useful in providing information for protecting the health of miners (whose participation is entirely voluntary), and also in documenting trends and patterns in the prevalence of coal workers' pneumoconiosis ('black lung' disease) among miners employed in U.S. coal mines.

A. JUSTIFICATION

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 Federal Coal Mine Health and Safety Act of 1969, as amended in 1977 and 2006, PL-91-173 (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 1Act directs the National

Institute for Occupational Safety and Health (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 Underground Coal Miners" (Attachment 20).

The Act specifies that all underground coal miners be offered periodic medical examinations including a chest radiograph and other necessary tests, at no cost to the miner. Although not previously mandated by law or regulation, periodic medical history and spirometry testing have been recommended by NIOSH for both surface and underground coal miners since 1995 and is offered on a voluntary basis as part of the NIOSH Enhanced CWHSP. The CWHSP administers all aspects of the following activities related to the conduct of both the mandated and discretionary periodic medical examinations for coal miners: 1) testing and certification of A and B Readers (physicians qualified to interpret and classify radiographs for the pneumoconioses); 2) evaluation and approval of x-ray 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 interpretations of chest radiographs; 5) contracting with approved facilities to take radiographs and provide initial interpretations for mines that are out of compliance and are not covered by approved coal mine operator plans; 6) arranging locally available testing under the Enhanced CWHSP, including spirometry, chest x-ray, and blood pressure monitoring for former and actively working surface and underground miners, 7) generation and dissemination of letters that notify participating miners of the results of chest radiographs interpreted for the presence or absence of disease; 8) generation and dissemination of letters that notify miners of their results, including chest radiograph interpretations that identify abnormal findings other than coal workers' pneumoconiosis; and 9) maintenance of databases of information related to all aspects of the Program for purposes of assessing effectiveness, identifying disease trends, assessing the value of dust exposure limits for the mining industry, and storage allowing rapid retrieval of information relative to the taking, interpreting, and notification of results.

The Act also authorizes NIOSH to make necessary arrangements with the next-of-kin for providing a post-mortem examination to be performed after the death of any active or inactive miner, and specifies that the autopsy shall be paid for (through delegation) by NIOSH through NCWAS -- 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.

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 new including 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 testing requirements and the extended coverage for surface miners, NIOSH has modified existing forms and also developed several new forms. This current revision of the OMB-required public burden estimate for information collections associated with NIOSH coal miner health surveillance activities reflects both the previously approved and ongoing research and 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 renewal 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 2011 renewal) to any of the reporting instruments are described below. 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/CoalWorkersHealthSurvProgram.html#nioshresources

Coal Mine Operator's Plan **(Attachment 2)**
Form No. CDC/NIOSH (M) 2.10
This form records plans and arrangements for offering the coal miner examinations. Under 42 CFR Part 37.4, every coal operator and contractor operating at a coal mine must submit a coal mine operator's plan providing information on how they plan to notify their miners of the opportunity to obtain the chest radiographic and spirometry examination. This form is used by coal operators for that purpose and has been updated to include a section for operators to specify NIOSH-approved spirometry testing facilities in proximity to their mine. A form for contract coal operators is described below.

Radiographic Facility Certification Document **(Attachment 3)**

Form No. CDC/NIOSH (M) 2.11
This form records the x-ray facility equipment/staffing information. X-ray facilities seeking NIOSH approval to provide miner x-rays under the CWHSP must complete an approval packet. The word "Radiographic" was added to the title of the form. This was done to distinguish it from a new form being added to the program "Spirometry Facility Certification Document". In addition, an email address has been provided. However, no additional burden to the facility is anticipated due to this revision.

Miner Identification Document **(Attachment 4)**
Form No. CDC/NIOSH (M) 2.9
This form records the miner's demographic and occupational history, as well as information required under regulations from x-ray facilities in relation to coal miner examinations. No changes to the content of the form are being made at this time.

Chest Radiograph Classification Form **(Attachment 5)**
Form No. CDC/NIOSH (M) 2.8
This form records interpretations of the chest radiographs from the physicians. 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 no changes to the content of the form are being made at this time.

Physician Application for Certification **(Attachment 6)**
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. No changes to the content of the form are being made at this time.

Guidelines for Spirometry in the ECWHSP Mobile -- Internal use form – No form number – (**Attachment 7**)
This form is administered by a NIOSH employee (or contractor) in the ECWHSP Mobile Unit during the initial intake process. This information is needed to make sure that the test can be done safely and that the miner is physically capable of performing the spirometry maneuvers. No changes to the content of the form are being made at this time.

Consent, Release and History Form **(Attachment 8)**
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 the occupational history and smoking history. No changes to the content of this form are being made at this time.

42 CFR 37.202 Pathologist Invoice **(Attachment 9)**

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 their individual invoice as long as this statement is added. A sample invoice is included as **Attachment 9**.

42 CFR 37.203 Pathologist Report of Autopsy **(Attachment 10)**

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. A sample invoice is included as **Attachment 10**.

NCWAS Autopsy Checklist -- Internal use form – No form number **(Attachment 11)**

To aid the pathologist, this checklist of the report requirements for the NCWAS pathology report is given to the participating pathologist. Information pertaining to the items on this checklist is maintained in the NCWAS database. All information and specimens (slides and blocks of tissue) are maintained by NIOSH at the Morgantown, West Virginia location. This checklist requires no response; therefore no burden hours are associated with it.

Respiratory Assessment Form **(Attachment 12)**

Form No.

On May 1, 2014, MSHA published final rule 30 CFR 70, 71, 72, 75 and 90. The new MSHA rule adds spirometry testing for chronic obstructive pulmonary disease (COPD) to the previous mandatory chest x-ray examination program, and expands health surveillance program coverage to include respiratory symptom assessment. This new form is designed to assess respiratory symptoms and certain medical conditions and risk factors.

Spirometry Facility Certification Document **(Attachment 13)**

Form No.

On May 1, 2014, MSHA published final rule 30 CFR 70, 71, 72, 75 and 90. The new MSHA rule adds spirometry testing for chronic obstructive pulmonary disease (COPD) to the previous mandatory chest x-ray examination program. This form is analogous to the Radiographic Facility Certification Document (2.11) 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.

Spirometry Pre-test Checklist **(Attachment 14)**
Form No.
This new form is used by individuals conducting spirometry testing as a screening tool to make sure that the test can be done safely and to record certain factors that can affect test results.

Spirometry Notification Form **(Attachment 15)**
Form No.
This new form provides a mailing address for notification of results to the miner, and provides documentation that the required components of the spirometry examination have been transmitted to NIOSH.

Spirometry Results Form **(Attachment 16)**
Form No.
This new form provides NIOSH with the basic information necessary to identify the miner, conduct quality assurance audits, and interpret results. Facilities that do not transmit an electronic database must transmit this form.

Coal Contractor Plan **(Attachment 17)**
Form No.
This form records plans and arrangements for offering the coal miner examinations. Under 42 CFR Part 37.4, every coal operator and contractor operating at a coal mine must submit a coal mine operator's plan providing information on how they plan to notify their miners of the opportunity to obtain the chest radiographic and spirometry examination. This form is similar to the Coal Mine Operator's Plan (Form No. CDC/NIOSH (M) 2.10, Rev. 07/07) but is specifically designed for contractors.

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 also imperative to obtain longitudinal measurements of past participants.

Upon identification of disease the Program then assists in the clinical management of the miner's health, through: 1) notification to the miner of any significant medical findings; and 2) notification to 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. This Act, initially passed as the Coal Mine Health and Safety Act of 1969 and amended in 1977 and 2006, was intended to prevent coal miners who worked in conditions with up to 2 mg/m^3 of respirable coal mine dust from developing category 2 coal workers' pneumoconiosis during a working lifetime, based upon the data available at the time. By this means, the promulgated health regulations sought to prevent the development of progressive massive fibrosis, which under the Act implies that the miner suffers from total and permanent disability. Thus, among participating miners, each case of category 2 as well as category 3 simple pneumoconiosis or progressive massive fibrosis of any stage, represents a failure of the health regulations, independent of the proportion of miners affected. Evaluation of the distribution and determinants of 'sentinel' cases of pneumoconiosis has emerged as an important surveillance function of the CWHSP, with attendant potential for prevention efforts.

During the early 1970s, one out of every three miners examined in the Program who had worked at least 25 years underground had evidence of pneumoconiosis on their chest x-ray. An analysis among over 25,000 miners who participated in the Program from 1996 to 2002 indicated that the proportion of individuals affected has 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 the more advanced stage 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 aid in assessing the generalizability of the program findings. In addition, NIOSH and MSHA have in recent years embarked on various programs and enhanced activities intended to increase and broaden CWHSP participation, which has further increased the utility of the program findings in evaluating the effectiveness of current regulations.

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. The CWHSP is not considered a

research program and does not require Institutional Review Board approval (see Attachment 18). Although a component of the NCWAS has been considered research, IRB approval does not apply since 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."

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 x-ray and spirometry facilities, or at the miners' residence, where access to electronic data collection technology may be limited or non-existent. Participating mines and miners are often in rural areas, and requiring an electronic-only collection system could represent a barrier to participation. Participation in the Program is a crucial step in prevention of coal workers' pneumoconiosis, and any obstacles which would make participation more cumbersome are 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, as well as periodic review of related literature. The information collected is not available from any other sources, and no other government agency is currently collecting the information needed to administer this Program. The CWHSP is a unique program and not a duplication of any existing program. 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 these provisions of the Act.

5. Involvement of Small Entities

Participation in the CWHSP, and the completion of forms, is only mandatory for the mine operator; participation by other parties is voluntary. Many physicians and spirometry and x-ray facilities are incorporated as small businesses. The data collected from these participating physicians and clinics have been held to the absolute minimum necessary to properly identify the miner, the radiograph, the spirometry test and the facility, to provide the essential documentation and materials for the purposes of the Program. As noted above, in an effort to reduce

the data collection burden, electronic versions and pre-printed forms with all available information are provided to the applicable participants.

6. Consequences of Collecting the Information Less Frequently

Miner participation in radiographic examinations, spirometry tests, and blood pressure screening, is voluntary. However, the minimum frequency that mine operators must make available radiographic examinations 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 guidelines in 5 CFR 1320.5, "Controlling Paperwork Burdens on the Public."

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

a. Due to the emergency nature of the program announcement, OMB has waived the FRN requirements for this collection. The PRA section of the interim final rule will serve as the 60-day notice for this revision request (Attachment 21).

b. There is ongoing exchange of information with stakeholders and representatives of participant groups. These efforts include consultations with MSHA, ILO, the American College of Radiology (ACR), the American Thoracic Society (ATS) and the European Respiratory Society (ERS), and other professional, labor, and industry organizations, as well as periodic reviews of related literature. NIOSH staff routinely meet with the Mine Safety and Health Research Advisory Committee. NIOSH staff periodically discuss the use of the data collection instruments with radiologists, pathologists, pulmonary specialists, and other occupational safety and health personnel and organizations. (See Attachment 19 for 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 program mission and objectives.

9. Explanation of any Payment or Gifts to Respondents

Participants (miners) are not paid or given any type of monetary incentive to respond. They do receive the results of their x-ray examination and spirometry test, and if requested, a copy of the original radiograph. Currently, B Readers

who provide interpretations 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 and specimens and $210.00 if an x-ray 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 social security numbers are required for absolute identification in order to fulfill the mandate of the Act. There is a need for NIOSH to maintain a database of physicians qualified to interpret and classify radiographs and a need to maintain a surveillance program in which repeated readings are obtained on coal miners so that coal workers' pneumoconiosis can be detected and prevented.

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."

The social security number has historically been collected for identity verification purposes (see Attachments 4, 5, and 6). Respondents are informed that furnishing it is voluntary and the purpose for which it is requested. The CWHSP currently has medical records on approximately 267,716 miners, consisting of over 466,645 radiographs, and all of these records have been archived by social security number.

When miners have a chest x-ray taken at an approved-NIOSH facility, they are required to complete a Miner Identification Document (2.9), which includes the miner's social security number. If a miner has disease, then all of their previous x-rays are pulled for comparison of progression of disease. If a miner has a question regarding their x-ray, they provide their social security number for NIOSH to locate their records. Without the ability to identify a miner and to link them with all of their previous x-rays, NIOSH would have limited ability to understand and monitor the progression of disease not only for the individual miner but as it relates to national trends in disease as well.

Spirometry examinations at a NIOSH-approved facility require clinic personnel to administer two questionnaires: 1) the Respiratory Assessment Form, and 2) a Spirometry Pre-Test Checklist. Following the spirometry test, clinic personnel must complete the Spirometry Results Form for each miner. Facilities must

submit the Respiratory Assessment, Spirometry Results, and a Spirometry Notification Form to NIOSH. All of these forms use the miner's name, date of birth, test completion date, and medical record number (assigned by the clinic) to identify each miner. This identification system will allow NIOSH to locate previous test results and evaluate the development of lung function losses.

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, they complete the Physician Application for Certification Document (2.12), which includes the physician's social security number. When interpreting x-rays as part of the CWHSP, the physician records their classification on the Chest Radiograph Classification Form (2.8) which includes their social security number. This is used to track their status and record which physician classified the x-ray.

We have explored the possibility of removing the miner SSN from the system but to date we have not found a method that would work in keeping the x-rays associated with a miner all together and with easy access. However, we have given the B Readers the option of whether to provide their SSN or not.

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 access restricted to NIOSH and contractor personnel with a bonafide need for the data in order to perform their official duties. Program computers meet the highest CDC standards for administrative, technical, and physical security. Databases are password protected. A signed medical release or a Privacy Act certification statement will be obtained from the subject individual before release of any information collected. 42 CFR 37.80(a) provides that "Medical information and radiographs on miners will be released by ALOSH 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 a 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 name of 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 x-rays 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 x-ray program when operators

are notified by NIOSH that their mine force is to be examined; (3) Facility Certifications: certifications of approved x-ray locations; (4) Miner X-ray 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 x-ray facilities, x-rays, interpretations of these x-rays, 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 x-rays. 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 a 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. X-rays 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 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 X-ray 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 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 x-rays taken, lists of approved interpreting physicians, productivity figures, lists of NIOSH certified x-ray 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 (**Attachment 12**) asks miners about diseases and non-occupational risk factors that could affect test results. Social security numbers are requested of the miner and participating physicians and are collected on a voluntary basis (Attachments 4, 5, and 6). 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, and
- Identify for tax purposes those physicians receiving payment for services rendered.

The legal authority for the collection of Social Security Numbers is: Public Health Service Act (42 U.S.C. 300KK), Occupational Safety and Health Act (29 CFR § 671), Federal Mine Safety and Health Act of 1977, Sections 203, “Medical Examinations” and 501, "Research" (30 U.S.C. 843, 951), and E.O. 9397 (amended), “Numbering System for Federal Accounts Relating to Individual Persons” (Attachment 1).

12. Estimates of Annualized Burden Hours and Costs

a. The total annual estimated respondent burden is 16,358 hours. This estimate is based upon participation rates from past years of the Program. This respondent cost is based only on the time incurred by the respondents in order to complete the necessary forms and/or examination.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden/ Response (in hrs)	Total Burden (in hrs)
Coal mine operators	Coal Mine Operator's plan - Form 2.10	575	1	30/60	288
X-ray facility supervisor	Radiograph Facility Certification Document- Form 2.11	40	1	30/60	20
Coal miner	Miner Identification Document- Form 2.9	10,383	1	20/60	3,461
B Reader physicians	Chest Radiograph Classification Form - Form 2.8	200	104	3/60	1,040
Physicians taking B reader examination	Physician Application for Certification - Form 2.12	50	1	10/60	8
Next-of-kin of deceased miner	Consent, Release and History Form - Form 2.6	5	1	15/60	1
Spirometry facility employee	Respiratory Assessment Form- 2.13	10,383	1	5/60	865
Spirometry facility supervisor	Spirometry Facility Certification Document - Form 2.14	200	1	30/60	100
Spirometry technician	Spirometry Pre-test	10,383	1	5/60	865

	Checklist - Form 2.15				
Spirometry facility employee	Spirometry Notification Form - Form 2.16	10,383	1	10/60	1,730
Spirometry technician	Spirometry Results Form - Form 2.17	10,383	1	10/60	1,730
Contractor	Coal Contractor Plan- Form 2.18	383	1	30/60	192
X-ray - Coal Miners	No form required	10,383	1	15/60	2,596
Spirometry Test - Coal Miners	No form required	10,383	1	20/60	3,461
Pathologist - Invoice	No form required	5	1	5/60	0.4
Pathologist - Report	No form required	5	1	5/60	0.4
Total					16,358

This estimate is based on the following:

Coal Mine Operators Plan (2.10) (Attachment 2) - Under 42 CFR Part 37.4, every coal operator and construction contractor for each coal mine must submit a coal mine operator's plan every 3 years, providing information on how they plan to notify their miners of the opportunity to obtain the chest radiographic examination. The increase in the number of respondents is in accordance with changes to MSHA final rule 30 CFR parts 70, 71, 72, 75 and 90. To complete this form with all requested information (including a roster of current employees) takes approximately 30 minutes.

Radiographic Facility Certification Document (2.11) (Attachment 3) - X-ray facilities seeking NIOSH-approval to provide miner x-rays under the CWHSP must complete an approval packet. The forms associated with this approval process require approximately 30 minutes for completion. This form has been revised since the last OMB approval. This form is to be filled out one time per facility. The currently approved ICR accounts for 100 radiograph facilities so this form will only be used for new facilities. Based on the new IFR we estimate that 40 new facilities will join per year for the next 5 years. A space has been added for the room number in which each x-ray unit listed for approval is located. This is needed to identify the location of the x-ray unit in hospitals 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 x-ray units. No additional burden to the facility is anticipated.

Miner Identification Document (2.9) (Attachment 4) - 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 x-ray facilities in relation to coal miner examinations. The increase in the number of respondents is in accordance with changes to MSHA final rule 30 CFR parts 70, 71, 72, 75 and 90. In addition to completing this form, acquiring the chest image takes approximately 15 minutes.

Chest Radiograph Classification Form (2.8) (Attachment 5) - 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 interpretations of the x-rays (each x-ray has at least two separate interpretations). As stated above, this form has been revised since the last OMB approval which as a result of a calculation error, accounted for 10,000 respondents. We have updated the number of respondents to 200 which is an accurate representation of the number of physicians (B Readers). Based on prior practice it takes the physician approximately 3 minutes per form. No additional burden to the physician is anticipated.

Physician Application for Certification (2.12) (Attachment 6) - Physicians taking the B Reader Examination are asked to complete this registration form that takes approximately 10 minutes. As stated above, this form has been revised since the last OMB approval. This form is to be filled out one time per physician. The currently approved ICR accounts for 100 physicians so this form will only be used for new physicians. Based on the new IFR we estimate that 50 new physicians will join per year for the next 5 years. No additional burden to the physician is anticipated.

Spirometry Facility Certification Document (2.14) (Attachment 13) - Spirometry facilities seeking NIOSH approval to provide spirometry examinations under the CWHSP must complete an approval packet. The form and gathering supporting documentation associated with this approval process requires approximately 30 minutes to complete. This is a new form and is in accordance with changes to MSHA final rule 30 CFR parts 70, 71, 72, 75 and 90.

Spirometry Pre-Test Checklist (2.15) (Attachment 14) - Clinic personnel are required to complete this form for each miner prior to administering the spirometry test. This information is used by the clinic personnel to determine if the miner can perform the spirometry test safely and identify any factors that may affect the spirometry results. Completion of the form will take approximately 5 minutes. This is a new form and is in accordance with changes to MSHA final rule 30 CFR parts 70, 71, 72, 75 and 90.

Spirometry Testing -- Miners participating in the CWHSP component of the Program are offered a spirometry test which requires no additional paperwork on the part of the miner, but does require approximately 15 to 20 minutes for the test itself. This is a new form and is in accordance with changes to MSHA final rule 30 CFR parts 70, 71, 72, 75 and 90.

Spirometry Results Form (2.17) (Attachment 16) - Spirometry facilities that do not submit spirometry results using a NIOSH-approved electronic database will submit this form for each miner. This information allows NIOSH to identify the miner, conduct quality assurance audits, and interpret results. It will take approximately 10 minutes to complete the form. This is a new form and is in accordance with changes to MSHA final rule 30 CFR parts 70, 71, 72, 75 and 90.

Spirometry Notification Form (2.15) (Attachment 15) - Spirometry facilities must submit this form to NIOSH upon completion of a spirometry examination. Miners must fill out their mailing address for notification of results; this will take approximately 2 minutes. The remainder of the information documents that the facility completed and transmitted the required components of the spirometry examination. Completion of the entire form will require 10 minutes. This is a new form and is in accordance with changes to MSHA final rule 30 CFR parts 70, 71, 72, 75 and 90.

Respiratory Assessment Form (2.13) **(Attachment 12) -** This form is designed to assess respiratory symptoms and certain medical conditions and risk factors. Completion of the entire form will require 5 minutes. This is a new form and is in accordance with changes to MSHA final rule 30 CFR parts 70, 71, 72, 75 and 90.

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Pathologist Invoice (Sample provided in Attachment 9) - 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 their 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 they routinely use. Due to a rounding error in the current ICR, the burden hours have decreased from 0.5 to 0.4.

Pathologist Report of Autopsy (Sample provided in Attachment 10) - 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. Due to a rounding error in the current ICR, the burden hours have decreased from 0.5 to 0.4.

NCWAS Autopsy Checklist (Attachment 11) - To aid the pathologist, a checklist of the report requirements for the NCWAS program is given to the participating

pathologist. Information pertaining to the items on this checklist is maintained in the NCWAS database. This checklist requires no response; therefore no burden hours are associated with it.

Consent, Release and History Form (2.6) (Attachment 8) - 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.

b. The estimated annualized cost to the respondent population for the medical examinations is $442,296 based on the average costs per burden hour and the burden hours as shown below.

Type of Respondents	No. of Respondents	No. of Responses per Respondent	Total Burden (in hrs)	Hourly Wage Rate	Respondent Cost
Coal mine operators	575	1	288	$38	$10,944
X-ray facility supervisor	40	1	20	$38	$760
Coal miner	10,383	1	3,461	$26	$89,986
B Reader physicians	200	104	1,040	$92	$95,680
Physicians taking B reader examination	50	1	8	$92	$742
Next-of-kin of deceased miner	5	1	1	$12	$12
Spirometry facility employee	10,383	1	865	$15	$12,975
Spirometry facility supervisor	200	1	100	$38	$3,800
Spirometry technician	10,383	1	865	$15	$12,975
Spirometry facility employee	10,383	1	1,730	$15	$25,965
Spirometry technician	10,383	1	1,730	$15	$25,965
Contractor	383	1	192	$26	$4,992
X-ray - Coal Miners	10,383	1	2,596	$26	$67,470
Spirometry Test - Coal Miners	10,383	1	3,461	$26	$89,986
Pathologist - Invoice	5	1	0.4	$68	$34
Pathologist - Report	5	1	0.4	$68	$34
Total					$442,296

* 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
- X-ray 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 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 $1,295,724 which includes printing and distribution of forms, data management and personnel charges (including contractors), travel-related costs, autopsy-related services and expenses, and all other services and costs associated with all components of the Program. 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 11,940 burden hours for this approval period due to expansion of the program to include surface miners. In addition, spirometry testing and respiratory symptom assessment is now including and being offered to all miners in accordance with changes to MSHA final rule 30 CFR parts 70, 71, 72, 75 and 90. There is an overall burden cost increase of $291,514 estimated annualized cost to the respondent population due to these changes.

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.