

NATIONAL COAL WORKERS' HEALTH SURVEILLANCE PROGRAM (CWHSP)
Revision for OMB # 0920-0020

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

Section B

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Because this program provides medical monitoring for all coal miners, this collection of information does not employ statistical methods in the selection of respondents. There are a total of 10 CDC/NIOSH-numbered forms, and 1 non-numbered checklist that are completed by various respondents: government employees/contractors, physicians, miners, coal mine operators, coal mine contractors, and medical facility employees. The following discusses respondents and data collection procedures:

1. Respondent Universe and Sampling Methods

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. 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. Completion of these forms with all requested information (including a roster of current employees) takes approximately 30 minutes.

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. 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. It takes approximately 30 minutes for completion of this form.

Miner Identification Document (Attachment 8)

Form No. CDC/NIOSH (M) 2.9

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

takes approximately 20 minutes for completion of this form. In addition, acquiring the chest image from the miner takes approximately 15 minutes. This form has been revised to state that the miner's full Social Security Number (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 specific 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.

Chest Radiograph Classification Form (Attachment 11)

Form No. CDC/NIOSH (M) 2.8

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

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. 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 was 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 them. It typically takes the physician about 10 minutes to complete this form.

Spirometry Facility Certification Document (Attachment 15)

Form No. CDC/NIOSH (M) 2.14

On May 1, 2014, MSHA published final rule 30 CFR 70, 71, 72, 75 and 90. The new MSHA rule added 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 which contains this form. 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. It is estimated that it will take approximately 30 minutes for this form to be completed at the facility.

Respiratory Assessment Form (Attachment 16)

Form No. CDC/NIOSH (M) 2.13

On May 1, 2014, MSHA published final rule 30 CFR 70, 71, 72, 75 and 90. The new MSHA rule added spirometry testing for chronic obstructive pulmonary disease (COPD) to the previously mandated chest radiograph examination program and expanded the health surveillance program coverage to include respiratory symptom assessment. This form is designed to assess respiratory symptoms, certain medical conditions, and risk factors. A field has been added to collect the email address of the participant. It is estimated that it will take approximately 5 minutes for this form to be administered to the miner by an employee at the facility.

Spirometry Results Notification Form (Attachment 17)

Form No. CDC/NIOSH (M) 2.15

This 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. A space has been added for the unit number at the facility in which the examination was taken. This is needed to identify the specific 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.

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 occupational 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 use.

42 CFR 37.203 Pathologist Report of Autopsy (Attachment 21)

42 CFR Part 37.203 provides the autopsy findings. The pathologist must submit information found at autopsy, slides, blocks of tissue, and a final diagnosis indicating presence or absence of pneumoconiosis. The format of the autopsy reports are variable depending on the pathologist conducting the autopsy. Since an autopsy report is routinely completed by a pathologist, the only additional burden is the specific request for a clinical abstract of terminal illness and a 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. All information and specimens (slides and blocks of tissue) are maintained by NIOSH at the Morgantown, West Virginia location. This checklist requires no response and therefore requires no additional burden hours.

2. Procedures for the Collection of Information

Based on notification by MSHA regarding the establishment of, or a change in the status of, a coal mine operation, NIOSH notifies the mine operator/mine contractor of the requirement to file a coal mine operator's/coal contractor's examination plan. Subsequent plans must be filed upon notification by NIOSH at approximately five-year increments. In the event that a mine does not file on time as required, NIOSH is authorized to establish a plan for the mine and inform the operator/contractor of its terms. In the event that the mine files a faulty plan, NIOSH will contact the mine operator/contractor and provide instructions for correcting their submission. Upon approval, NIOSH forwards a copy of the plan

for mandatory posting at the mine site. The miners can then check the posting to determine the time and place where they can receive their free chest radiograph and spirometry test. Along with each mine plan, a roster of employees is required which lists contact information for each mine employee. NIOSH sends a letter, along with information about the CWHSP, to each miner listed on this roster, outlining the time and place where they can receive their free chest radiograph and spirometry test. Participation is voluntary on the part of the miner; however, filing of the mine examination plan is mandatory for each operator and mining contractor.

Following posting of the examination plan at the mine site, eligible miners may visit the designated NIOSH approved radiograph facility to have a chest radiograph made at no cost to the miner and may visit the designated NIOSH approved spirometry facility to have a spirometry test completed at no cost to the miner (See Endnote 1 regarding approved facilities). At the radiograph facility, the miner will complete the Miner Identification Document (Form No. CDC/NIOSH (M) 2.9, **Attachment 8**). This document records the miner's demographic information, contact information, and occupational history. For each chest radiograph obtained at an approved facility, a qualified and licensed physician (or B Reader) who reads chest radiographs in the normal course of practice must provide an initial clinical interpretation and notification to the miner of any significant abnormal findings other than pneumoconiosis. The chest radiograph, along with the completed Miner Identification Document and the Chest Radiographic Classification Form (completed by a physician at the facility), are forwarded to NIOSH. Similarly, at the spirometry facility, the Miner Identification Document, Spirometry Results Notification Form and the Respiratory Assessment are forwarded to NIOSH after completion.

When the chest radiographs, spirometry test results and all accompanying forms arrive at NIOSH, all submitted materials are reviewed for compliance with applicable regulations, and all information on the collection instruments are coded for data entry. After the initial data entry and verification are completed, the Spirometry Facility is notified of satisfactory data transfer, and all electronic data files (both spirometry and radiograph) are added to the Underground Coal Mining System (UCMS) database. As an additional assurance that the miner has been notified, NIOSH will contact miner participants by mail if any clinically important health findings are noted on the chest radiograph other than CWP; a phone consultation to explain the finding will be offered. All radiographs are sent to two NIOSH certified B Readers for classification according to the ILO System. (See Endnote 2 regarding B Readers).

All subsequent classifications of the chest radiographs are also recorded on the Chest Radiographic Classification Form and are then coded for data entry and added to the UCMS database. A computer program compares the first and second classifications of the radiograph to determine if there is agreement with respect to the presence or absence and severity of CWP as specified by regulation 42 CFR

37. If the first two classifications are not in agreement, the radiograph is sent for additional classification from B Readers until consensus is obtained. At that point, the miner is notified of the final determination.

Spirometry results are first verified for name, birth date, medical record number, and demographic information on the Spirometry Results Notification Form (Form No. CDC/NIOSH (M) 2.15, **Attachment 17**). Once this information is confirmed, the spirometry results are evaluated for any quality assurance factors that may affect reporting of results using computer programs and experienced spirometry personnel. Spirometry results are coded for interpretation and saved in the UCMS database. Miners are then notified of results.

3. Methods to Maximize Response Rates and Deal with Non-response

After a mandatory examination at the time of first employment in coal mining, participation in this program is voluntary for miners. In an attempt to increase participation by miners, data collection forms are prefilled to the extent possible, and then mailed directly to each miner's residence with descriptive information about the CWHSP. The CWHSP also provides an outreach program through exhibits and presentations at coal mining shows, conferences, black lung clinics, and health fairs in an effort to increase overall awareness of the program as well as the causes and consequences of coal-related respiratory disease.

From October 1, 1999 through September 30, 2002, the Mine Safety and Health Administration (MSHA), in consultation with NIOSH, conducted a pilot health surveillance program for both underground and surface miners (The Miners' Choice Program). The concept of the Miners' Choice Program is being continued as an extension of the CWHSP (currently called the Enhanced Coal Workers' Health Surveillance Program – ECWHSP). The enhanced program utilizes a mobile examination unit which travels to mining regions to provide locally accessible health surveillance, including chest radiography, spirometry, and blood pressure screening. In addition, past participants of the ECWHSP may be notified of scheduled screenings to aid NIOSH in adequately assessing progression of disease by obtaining longitudinal measurements of previous participants.

4. Tests of Procedures or Methods to be Undertaken

No new tests of procedures are planned. This is a federally-mandated program which has operated since 1970 and as such will have budgetary support throughout the approval period.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The design of the collection instruments and subsequent revisions since 1970 were accomplished by NIOSH employees in conjunction with key stakeholders as

outlined under A8.b. NIOSH collects and analyzes the information obtained. Key contacts for the CWHSP are listed below.

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ENDNOTES

1. Approved Facility -- A radiograph or spirometry provider (hospital, clinic, private physician) that has submitted to NIOSH a Radiographic Facility Certification Document (Form No. CDC/NIOSH (M) 2.11, **Attachment 6**) or a Spirometry Facility Certification Document (Form No. CDC/NIOSH (M) 2.14, **Attachment 15**) and has demonstrated meeting all requirements as specified in 42 CFR 37.43 and 37.44. These are the only facilities permitted to submit radiographs or spirometry tests under the CWHSP. A list of all approved facilities is available on the program's website and is provided to the coal mine operator/contractor when they are notified that it is time to file an examination plan.
2. B Reader -- A licensed physician who has demonstrated a high level of proficiency in classifying chest radiographs for the pneumoconioses as set forth in 42 CFR 37.52. B Readers must demonstrate a high level of expertise by obtaining a passing grade on the NIOSH B Reader Certification Examination, and every four years thereafter must demonstrate ongoing competence by obtaining a passing grade on the NIOSH B Reader Re-certification Examination.