

**NATIONAL COAL WORKERS' HEALTH SURVEILLANCE PROGRAM (CWHSP)
Emergency Clearance Request OMB # 0920-0020**

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

Section B

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June 25, 2014

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Because all components and participants of the CWHSP are voluntary, this collection of information does not employ statistical methods in the selection of respondents. There are a total of 12 CDC/NIOSH-numbered forms that may be completed by various respondents: physicians, miners, coal mine operators, and medical facility administrators. The following discusses respondents and data collection procedures:

1. Respondent Universe and Sampling Methods

Coal Mine Operator's Plan

Form No. CDC/NIOSH (M) 2.10, Rev. 06/2014

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 for that purpose. This form 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

Form No. CDC/NIOSH (M) 2.11, Rev. 06/2014

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

Form No. CDC/NIOSH (M) 2.9, Rev 07/07

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

Form No. CDC/NIOSH (M) 2.8, Rev. 12/2013

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

Form No. CDC/NIOSH (M) 2.12, Rev. 12/2013

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 – Approved as a non-substantive change 06/2013

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

Form No. CDC/NIOSH (M) 2.6, Rev 11/74

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

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 10.

42 CFR 37.203 Pathologist Report of Autopsy

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.

NCWAS Checklist -- Internal use form – No form number

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

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 for COPD.

Spirometry Facility Certification Document

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 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

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

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

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
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. 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 of the requirement to file a coal mine operator's examination plan. Subsequent plans must be filed upon notification by NIOSH at approximate 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 of its terms. In the event that the mine files a faulty plan, NIOSH will contact the mine operator 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, the mine operator is required to provide a roster, listing 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 operator's examination plan is mandatory for the operator and mining contractor.

Following posting of the coal mine operator's examination plan at the mine site, eligible miners may visit the designated NIOSH approved x-ray 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 at no cost to the miner. (See Endnote 1 regarding approved x-ray facilities.) At the x-ray facility, the miner completes the Miner Identification Document, which records the miner's demographic information, contact information, and an occupational history. The chest radiograph, along with the completed Miner Identification Document and the Chest Radiographic Classification Form (which has been completed by a physician at the facility) are forwarded to NIOSH. Similarly, at the spirometry facility, after completion, the Spirometry Notification, Respiratory Assessment, and Results Forms are forwarded to NIOSH.

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 is coded for data entry. After the initial data entry and verification are completed, the Spirometry Facility is notified of satisfactory data transfer, and the electronic data files are added to the Underground Coal Mining System (UCMS) database. NIOSH contacts the miner participant by mail if any clinically important health findings are noted on the chest radiograph other than CWP and offers phone consultation to explain the finding. After completion of any urgent notification, all radiographs are sent to two NIOSH certified B Readers for interpretation. (See Endnote 3 regarding B Readers.)

All subsequent interpretations 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 interpretations 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 interpretations are not in agreement, the radiograph is sent for additional interpretations from B Readers, until agreement is obtained, and 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 Notification Form and either the Spirometry Results Form or the electronic database. 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 will then be notified of results.

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

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). This enhancement of the CWHSP operates utilizing a mobile examination unit which travels to mining regions to provide locally accessible and more comprehensive 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 A.8.b. above. NIOSH collects and analyzes the information obtained. Key contacts for the CWHSP are listed below.

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1. Approved X-Ray Facility -- A radiograph provider (hospital, clinic, private physician) that has submitted to NIOSH a Facility Certification Document (Form 2.11) and has demonstrated that the required x-ray equipment can make high quality diagnostic chest radiographs, as specified in 42 CFR 37.43 and 37.44. These are the only x-ray facilities permitted to submit radiographs under the CWHSP. A list of all approved facilities is available on the Program's website as well as being provided to the coal mine operator when they are notified that it is time to file a Coal Mine Operator's Plan (Form 2.10) or Coal Contractor's Plan
2. A Reader -- A licensed physician who has demonstrated proficiency in classifying chest radiographs for the pneumoconioses as set forth in 42 CFR 37.52, but has not yet secured a passing grade on the NIOSH B Reader Certification Examination.
3. 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 initially 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 in the NIOSH B Reader Re-certification Examination.
4. Approved Spirometry Facility – a spirometry examination provider (hospital, clinic, private physician) that has received NIOSH approval after submitting a Spirometry Facility Certification Document (Form 2.XX) and supporting materials. Only NIOSH-approved spirometry facilities are permitted to perform spirometry examinations under the CWHSP. A list of approved facilities will be made available on the Program's website and to coal mine operators.