

**NATIONAL COAL WORKERS' HEALTH SURVEILLANCE PROGRAM (CWHSP)
RENEWAL FOR OMB # 0920-0020**

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

Section B

Project Officer: Anita L. Wolfe, B.A.
National Institute for Occupational Safety and Health
1095 Willowdale Rd. MS 208
Morgantown, WV 26505
Awolfe@cdc.gov
304-285- 6263
304-285- 6058 (fax)

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Table of Contents

Section B. Collections of Information Employing Statistical Methods	Page No.
B1. Respondent Universe and Sampling Methods	3
B2. Procedures for the Collection of Information	5
B3. Methods to Maximize Response Rates and Deal with Non-response	7
B4. Tests of Procedures or Methods to be Undertaken	7
B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data	7

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 6 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. 07/07

This form records plans and arrangements for offering the coal miner examinations. Under 42 CFR Part 37.4, every coal operator and construction contractor for each underground 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 examination. This form is used for that purpose. No changes are being made to the content of this form at this time.

Facility Certification Document

Form No. CDC/NIOSH (M) 2.11, Rev. 12/2013

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. As part of the implementation for the acceptance of digital chest radiographic images for classification, this form was revised during the last OMB renewal in 2011. Those revisions were based upon extensive discussions with program partners at NIOSH-sponsored public meetings and scientific workshops. NIOSH has also retained expert consultants who have provided detailed comments on the minimum required content for revisions of this form. Paperwork burden has been further minimized by providing check boxes for many responses. A minor revision to this form has been made in this current renewal packet. 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 order to distinguish between units that may be identical except for the serial number. The serial number is not readily visible, so having the room number where the unit is located will aid in identifying individual x-ray units. However, no additional burden to the facility is anticipated.

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. In light of confidentiality issues, and in the interest of improved efficiency, it was considered important to revise this document in 2002. Current experience with the revised form indicates the changes did result in improved form performance, as evidenced by a reduction in clarifications required and errors. 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 underground coal miners. The ILO, with NIOSH involvement and support, completed a revision of its radiographic classification system (ILO 2000) and the form was revised at that time. In addition, to improve efficiency and as part of the NIOSH implementation of the classification of digital chest radiographic images, electronic versions of the form were developed, and were included as part of NIOSH-provided image display and classification software, including a version available free of charge as public domain software (NIOSH B-viewer©).

This current submission includes an edited version of this form which was renamed the “Chest Radiograph Classification Form.” It has been edited to update terminology, eliminating antiquated terms such as “roentgenographic.” In addition, edits to the “Chest Radiograph Classification Form” more clearly emphasize the importance of classifying all appearances on the chest image that are classifiable under the International Labour Office classification system used to evaluate presence and severity of changes associated with dust-induced lung disease (pneumoconiosis). Also, the previous version inadvertently did not provide definitions for symbols ra, rp, tb, and od in section 4B. and this has been corrected. No additional burden to the physician is anticipated.

Physician Application for Certification
Form No. CDC/NIOSH (M) 2.12, Rev. 02/2014

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.

The current submission *includes* an edited version of this form which has been renamed the “Physician Application for Certification”. It has been edited to update terminology, eliminating antiquated terms such as “roentgenographic.” In addition, it includes new language documenting that the applicant agrees to abide by the B Reader code of ethics and to notify NIOSH of various changes in medical licensure status. It also contains new language informing the applicant that if NIOSH becomes aware of a B Reader not following the Code of Ethics, it may, at its discretion, notify appropriate authorities, including the applicable State

Board(s) of Medicine. No additional burden to the physician is anticipated.

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 additional burden is added to the miner as this collection is already accounted for in the spirometry test burden.

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.

2. Procedures for the Collection of Information

Based on notification by MSHA regarding the establishment of, or a change in the

status of, an underground 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. Along with each mine plan, the mine operator is required to provide a roster, listing contact information for each underground 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. Participation is voluntary on the part of the miner; however, filing of the mine operator's examination plan is mandatory for the operator.

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. (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.

When the chest radiographs and 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 electronic file is 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 films 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.

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 CWP.

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.

Contacts: Project Officer:
 Anita L. Wolfe, B.A.
 Public Health Analyst
 Program Operations Coordinator
 Coal Workers' Health Surveillance Program (CWHSP)
 Workforce Screening and Surveillance Team (WSST)
 Surveillance Branch (SB)
 Division of Respiratory Disease Studies (DRDS)

National Institute for Occupational Safety and Health (NIOSH)
1095 Willowdale Road
Morgantown, WV 26505-2888
Phone: (304) 285-6263
Fax: (304) 285-6058
E-mail: Awolfe@cdc.gov

Branch Chief:
Eileen Storey, MD, MPH
Chief, Surveillance Branch
Division of Respiratory Disease Studies (DRDS)
National Institute for Occupational Safety and Health (NIOSH)
1095 Willowdale Road
Morgantown, WV 26505-2888
Phone: (304) 285-6382
E-mail: Estorey@cdc.gov

ENDNOTES

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 Examination Plan (Form 2.10).
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 Recertification Examination.