NATIONAL COAL WORKERS' X-RAY SURVEILLANCE PROGRAM (CWXSP) RENEWAL FOR OMB # 0920-0020

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

Part B

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Section B. Data Collection Procedures

- B1. Respondent Population and Selection of Respondents
- B2. Procedures for the Collection of Information
- B3. Methods to Maximize Response Rates and Deal with Nonresponse
- B4. Tests of Procedures or Methods to be Undertaken
- B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or References

LIST OF ATTACHMENTS

- 1. Federal Mine Safety and Health Act of 1977, PL-95-164
- 2. 42 CFR Part 37
- 3. Roentgenographic Interpretation Form CDC/NIOSH (M) 2.8
- 4. Miner Identification Document CDC/NIOSH (M) 2.9
- 5. Coal Mine Operator's Plan CDC/NIOSH (M) 2.10
- 6. Facility Certification Document CDC/NIOSH (M) 2.11
- 7. Interpreting Physician Certification Document CDC/NIOSH (M) 2.12
- 8. HSRB exemption
- 9. Federal Register 60 Day Notice
- 10. Contact Information for Stakeholders

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Because the CWXSP is basically a voluntary program, this collection of information does not employ statistical methods in the selection of respondents. There are five forms 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

Roentgenographic Interpretation Form - CDC/NIOSH (M) 2.8 Completed by the physician (A or B reader) interpreting the radiograph to report medical findings.

Miner Identification Document – CDC/NIOSH (M) 2.9 Completed by the miner at the time of the radiograph with work history and other vital information.

Coal Mine Operator's Plan – CDC/NIOSH (M) 2.10

Completed by the coal mine operator, or designee, outlining arrangements for the x-ray examination of mine employees.

Facility Certification Document – CDC/NIOSH (M) 2.11

Completed by the radiology supervisor of the medical facility seeking NIOSH certification to provide radiographs for the CWXSP. Reports facility-related information regarding equipment and staffing.

Interpreting Physician Certification Document – CDC/NIOSH (M) 2.12 Completed by physician seeking NIOSH certification as an A or B reader to interpret chest x-ray films in accordance with regulations. Reports information relating to the physicians qualifications.

2. <u>Procedures for the Collection of Information</u>

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 filing. When a mine has an approved plan on file 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 requested to provide a roster, listing contact information for each underground mine NIOSH sends a letter, along with information about the CWXSP, 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 (Form 2.9), which provides the miner's personal identifiers and contact information, an occupational history, and identification of the employer and x-ray facility where the examination is being made.

When the chest radiograph has been taken it is first interpreted by a NIOSH certified A or B Reader, at the facility. The interpretation is recorded on a Roentgenographic Interpretation Form (Form 2.8). (See Endnote 2 regarding A Readers.) The first certified Reader notifies the miner or the miner's physician of any significant abnormal findings, other than CWP, that were detected on the radiograph. Then, the chest radiograph, along with the completed Miner Identification Document (Form 2.9) and Roentgenographic Interpretation Form (Form 2.8) are forwarded to NIOSH.

When the chest radiographs and accompanying forms arrive at the CWXSP, all submitted materials are reviewed for compliance with applicable regulations, and all information on the two 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 telephone if any clinically important health findings are noted on the chest radiograph other than CWP. After completion of any urgent notification, all films are sent to a NIOSH certified B Reader for a second interpretation. (See Endnote 3 regarding B Readers.)

The second interpretation of the chest radiograph is also recorded on a Roentgenographic Interpretation Form (2.8), and the film and form are returned to NIOSH. The second interpretation is then coded for data entry and the data verified 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 interpretations are in agreement, NIOSH sends a letter advising the miner of the findings. 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 determination.

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

Participation in this program is voluntary for all participants except the mine operators. In an attempt to increase participation by miners, data collection forms are completed by NIOSH staff to the extent possible, and then mailed directly to each miner's residence with descriptive information about the CWXSP. The CWXSP 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 the overall awareness of the causes and consequences of CWP.

4. Tests of Procedures or Methods to be Undertaken

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

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

The design of the instrument and subsequent revisions since 1970 were accomplished by NIOSH employees in conjunction with key stakeholders as outlined under A.8.b (Attachment 10). NIOSH collects and analyzes the information obtained. Key contacts for the CWXSP are listed below.

Contacts: Project Officer:

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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) per 42 CFR 37.42(c), and has demonstrated per 42 CFR 37.41 and 42, that the required x-ray equipment can make high quality diagnostic chest radiographs. These are the only x-ray facilities permitted to submit radiographs under the CWXSP. 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 37.51(a), 2(i) and 2(ii), but has not yet successfully passed the NIOSH B Reader Certification Examination. All chest radiographs submitted to the CWXSP must initially be interpreted at the approved facility by either an A or B Reader.
- 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 37.51(b), 2.
 - B Readers initially must demonstrate a high level of expertise by obtaining a passing grade in 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. B Readers conduct all second and subsequent interpretations for chest radiographs submitted to the CWXSP.