

**NATIONAL COAL WORKERS' X-RAY SURVEILLANCE PROGRAM (CWXP)
REINSTATEMENT FOR OMB # 0920-0020**

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

Part A

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A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Federal Mine Health and Safety Act of 1977, PL 95-164, (which amended the Federal Coal Mine Health and Safety Act of 1969) (Attachment 1), is intended to protect the health and safety of underground coal miners. This Act provides the basis and mandate for all forms being utilized in conjunction with this data collection for the "National Coal Workers' X-Ray Surveillance Program (CWXSP)." Through delegation of authority, the Act 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 (CWP). These activities are administered through the CWXSP, as specified in the Code of Federal Regulations, 42 CFR 37, "Specifications for Medical Examinations of Underground Coal Miners" (Attachment 2).

The Act specifies that all underground coal miners be offered a chest radiograph examination, at no cost to the miner. The CWXSP administers all aspects of the following activities related to the conduct of these chest x-ray examinations: 1) testing and certification of A and B Readers (physicians qualified to interpret and classify radiographs); 2) evaluation and approval of facilities where radiographs may be taken; 3) approval of coal mine operator plans for providing chest radiographs; 4) arrangement and payment for B Reader interpretations of chest radiographs; 5) contracting with certified facilities to take and provide initial interpretations of radiographs at mines not covered by approved coal mine operator plans; 6) generation and dissemination of letters, to notify participating miners of the results of chest radiographs interpreted for the presence or absence of CWP; 7) generation and dissemination of letters of notification to miners providing results of chest radiograph interpretations where abnormal findings other than CWP are identified; and 8) maintenance of a database 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, as well as storage and rapid retrieval of information relative to the taking, interpreting, and notification of results for chest radiographs.

Renewal is requested for both the regulatory requirements as prescribed in 42 CFR 37, as well as the reporting instruments listed below. Revisions (since the last renewal) to these reporting instruments are also described below.

Roentgenographic Interpretation Form

Form No. CDC/NIOSH (M) 2.8, Rev. 06/02.

Records medical findings detected on chest radiographs - (Attachment 3). 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). To assure adherence to this new ILO system, and efficient recording of the information, an initial draft revision of the Roentgenographic Interpretation Form (M2.8) was reviewed by NIOSH scientific staff, as well as members of the Pneumoconiosis Committee of the American College of Radiology in 2002. All comments and suggestions were carefully considered, and a number of changes were made in developing the final form. Therefore, no changes are being made to this form at this time.

Miner Identification Document

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

Records miner's vital information and work history - (Attachment 4). The Miner Identification Document records demographic and occupational history, as well as information from x-ray facilities in relation to coal miner examinations required under the regulations. In light of a confidentiality issue that arose, and in the interest of improved efficiency, it was considered important to revise this document in 2002. X-ray facilities return this document to NIOSH along with the miner's chest x-ray. It was brought to our attention that the opportunity existed for the facility to modify entries on this document, after the miner has signed it. Release of medical information requires the consent of the miner, according to 42 CFR Part 37.80. NIOSH became aware that, in a few circumstances, x-ray facilities had entered the address of a physician that was not the miner's personal physician. To eliminate this possibility, the section of the document authorizing release of information was deleted. Other revisions were made to improve the format and content of this form, and were completed with extensive input from NIOSH staff and external stakeholders prior to finalization and implementation. 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.

Two minor changes have been made to the document as part of this renewal process. First, we have added boxes to indicate exactly which medical screening the miner completed (analog x-ray, digital x-ray, and/or spirometry). This section will be completed by the coordinator during medical screening in the NIOSH

Mobile Health Screening Unit. It will aid in the final processing of the medical tests and in determining what medical results the miner is to receive. The second change pertains to the back of the form where the example of USA Mine was given under the Mine Name column. Many miners were answering yes, indicating that the mine where they were employed was indeed a USA Mine. What we need in that column is the name of the mine or the name of the mining company. That has been changed for clarification purposes. Neither of these changes will result in an increase in burden time for completion of the form.

Coal Mine Operator's Plan

Form No. CDC/NIOSH (M) 2.10, Rev. 01/78

Records plans and arrangements for obtaining coal miner chest radiographs - no changes are being made to this form at this time (Attachment 5).

Facility Certification Document

Form No. CDC/NIOSH (M) 2.11, Rev. 01/78

Records x-ray facility equipment/staffing information – (Attachment 6).

The CWXSP operates under regulations set forth in 42 CFR Part 37. These regulations were last revised in 1989 with no major changes to Section 37.42 (Approval of roentgenographic facilities) at that time. Extensive experience with Form 2.11 has been obtained, and the form has been quite satisfactory for all parties and does not require revision at this time. However, when the CWXSP converts to digital x-rays, this form will require major revision.

Interpreting Physician Certification Document

Form No. CDC/NIOSH (M) 2.12, Rev. 07/07

Records information on physician qualifications - (Attachment 7).

Several changes have been made to this form. Fields at the bottom that are no longer needed have been removed. When selecting new B Readers for interpreting x-rays in the CWHSP, part of the criteria involves whether the B Reader holds an academic appointment. In the past, this has been ascertained via a telephone call. A section has now been added to the form for this inquiry.

2. Purpose and Use of Information Collection

Information collected through the CWXSP is utilized for the early identification of CWP and ultimately its prevention and/or treatment. This Congressionally-mandated Program serves to identify the incidence and possible progression of CWP in underground coal miners. 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 the miner and MSHA of any applicable dust 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. The current standard was considered to be appropriate, when implemented, for the elimination of cases of CWP in the new worker population and the elimination of most disease progression in the then-current workforce. The serial data generated by this Program provides the necessary basis for continuing analysis of this standard, and for possible future recommendations on revised maximum exposure levels. This data is neither collected nor generated by any other source, whether Government or industry/labor sponsored.

The data from the CWXSP can be used in a number of ways in evaluating the effectiveness of the health regulations implemented under the Federal Mine Safety and Health Act of 1977. This Act, passed in 1969, was intended to prevent underground coal miners 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 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 massive fibrosis of any stage, represents a failure of the health regulations, independent of the proportion of miners affected. As the overall prevalence of disease among program participants has decreased, evaluation of the distribution and determinants of these 'sentinel' cases of pneumoconiosis has emerged as an important surveillance function of the CWXSP, with attendant potential for prevention efforts.

Considerable information about the distribution of participation rates is available for the CWXSP. In eight states, participation ranged from 60 – 100%. Analysis of regional disease prevalence in conjunction with the participation rates can further assist in determining representativeness of the overall disease prevalence rates. Analysis of the consistency of disease patterns and trends can help in assessing the generalizability of the program findings. The current health and exposure findings from the Program and other sources can be productively analyzed in the context of the past distribution and trends in disease and exposure. In addition, NIOSH and MSHA have in recent years embarked on various programs and enhanced activities intended to increase and broaden CWXSP participation, which should further increase the utility of the program findings in evaluating the effectiveness of the current regulations.

The data base generated by the Program serves to provide a means to assess the impact upon the miner's health of confounding environmental or personal factors such as diesel fumes or smoking. The data collected and assessed by this Program, therefore, provides the practical utility which is the intent of the Act and of the implementation regulations, i.e., it serves to protect and preserve the health

of the miner.

This Program is a Federally-mandated program and, as such, will have budgetary support throughout the approval period. If the collection of information is not conducted, the CWXSP will not be operational, and there will be no administration of the mandate. The CWXSP is not considered a research program and does not require IRB approval (see Attachment 8).

According to HHS OGC, NIOSH is not considered an entity covered under HIPAA and we are therefore not required to comply. NIOSH, in performing its statutory duties, does not meet the definition of a health plan, healthcare clearinghouse or healthcare provider who transmits health information in electronic form in connection with certain transactions. These are the covered entities which must comply with HIPAA (45 CFR § 160.102).

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. This data collection is frequently accomplished at the mine, at the x-ray facility, 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 access to an electronic collection system could represent a barrier to participation. Participation in the Program is a crucial step in prevention of CWP, and any obstacles which would make participation more cumbersome are not acceptable. For this reason, paper-based data collection instruments are needed.

Although the CWXSP is in the process of converting to a digital x-ray system, the Program can currently accept only film screen radiographs, which cannot be submitted electronically. Separate electronic submission of the data on the identification and interpretation of the radiographs would create a risk of improper collation, and the severe consequence of reporting of incorrect medical test results to the miners. Electronic data collection for this particular Program is not feasible at this time. However, in an effort to reduce the data collection burden, forms pre-printed with all available information are provided to the respondents. Additionally, evaluation of electronic radiograph systems is ongoing, and electronic submissions will be accepted by the program as soon as such radiographs can be fully specified and their comparability to film screen systems is scientifically demonstrated. When interpreting x-rays for the CWXSP, B Readers must use the "Guidelines for the Use of the ILO Classification of Radiographs of Pneumoconioses." These Guidelines are based on traditional hard-copy x-rays. No electronic/digital standards are available for general use. NIOSH, working with the ILO, the American College of Radiology, and other key stakeholders, is in the process of identifying the needed digital standards.

Along with the digital standard films, algorithms must be developed for computer equipment and computer software packages in order to properly view digital x-rays.

While detailed specifications for the CWXSP are contained in 42 CFR Part 37, the Federal Mine Safety and Health Act of 1977 (Section 203) does not contain detailed specifications regarding the chest x-rays. The Act merely calls for “chest roentgenogram(s).” Therefore, no change in legislative law will be necessary when the CWXSP changes technology related to chest x-rays – only a change in the regulatory requirement as outlined in Part 37 will be necessary.

There are no legal obstacles to reducing the burden.

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 and labor organizations, as well as periodic review of related literature. Although there have been other studies relating to CWP, NIOSH is the only agency collecting information in this detail or manner, and has sole responsibility for carrying out these provisions of the Act.

Also, the information collected is not available from any other sources. The CWXSP is a unique program and is not a duplication of any existing program.

5. Impact on Small Businesses or Other Small Entities

Participation in the CWXSP, and the completion of forms, is only mandatory for the mine operator; participation by other parties is voluntary. Many physicians and x-ray facilities are incorporated as small businesses. The data collected from participating physicians and clinics has been held to the absolute minimum necessary to properly identify the miner, the radiograph, and the facility, to report abnormalities on the films. As noted above, in an effort to reduce the data collection burden, forms pre-printed with all available information are provided to the respondents.

6. Consequences of Collecting the Information Less Frequently

The frequency of the examinations is established in the Act as every 3½ - 5 years; all data collection is based upon these requirements. This is the minimum frequency required to monitor the onset or progression of disease.

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.

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

- a. The 60-day notice was published in the Federal Register for public comment on August 2, 2007, (Volume 72, Number 148, Page 42414-42415) (Attachment 9). No comments were received from the public.
- b. As stipulated in A.4, there is an ongoing exchange of information with stakeholders and representatives of participant groups. These efforts include consultations with MSHA and labor and industry organizations, as well as periodic reviews of related literature. (See Attachment 10 for contact information.) The CWXSP has been operational since 1970, and various versions of the data collection forms have been used. Modifications to some of the forms were last made and approved by OMB in 2002. This renewal request includes a revision of some of the forms as well. These revisions have been highlighted in the attachments where a marked up copy of the existing form is provided as well as a copy of the new revision. There is concurrence that information obtained through the use of these forms is the minimum necessary to meet the requirements of the Act and still provide necessary identifying information for participants.

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 if requested, a copy of the original radiograph. B Readers who provide interpretations of program radiographs are reimbursed \$8.00 per film.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act is applicable for this data collection. Full names are required to fulfill the mandate of the Federal Mine Safety and Health Act of 1977. There is a need for NIOSH to maintain a database of physicians qualified to interpret and classify x-rays and a need to maintain a surveillance program in which repeated readings are obtained on underground coal miners so that coal workers' pneumoconiosis can be detected and prevented.

Data on interpreting physicians will be covered under Privacy Act system of records 09-20-0001, "Certified Interpreting Physicians File"; data on miners will be 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 (SSN) is being collected for identity verification purposes. Respondents are informed that furnishing the SSN is voluntary and the purpose for which it is requested. The CWXSP currently has medical records on approximately 252,780 miners, consisting of over 435,000 x-rays. Historically, all of these records have been archived by SSN. It is therefore, not feasible to convert these records to a different system at this time.

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. Computer databases are password protected. A notarized signature or a Privacy Act certification statement will be obtained from the subject individual before release of any of the information collected.

42 CFR 37.80(a) provides that "Medical information and roentgenograms 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(a), which defines the exact degree of safeguarding required by regulation.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

Social Security Numbers are requested of the miner, and participating physicians and are collected on a voluntary basis. These are collected to:

- Provide a means of accurately developing dose-response 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;
- 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.

12. Estimates of Annualized Burden Hours and Costs

- a. It is estimated that a total of 15,525 responses may be received each year through all aspects of data collection associated with the CWXSP. The total annual estimated respondent burden is 2,329 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.

Type of Respondent	Form Name and No.	Number of Respondents	Number of Responses per Respondent	Hours/Response	Response Burden (in hrs)
Physicians (B Readers)	Roentgenographic Interpretation Form – CDC/NIOSH (M) 2.8	10,000	1	3/60	500
Miners	Miner Identification Document – CDC/NIOSH (M) 2.9	5,000	1	20/60	1,666
Coal Mine Operators	Coal Mine Operator’s Plan – CDC/NIOSH (M) 2.10	200	1	30/60	100
Supervisors at X-ray Facilities	Facility Certification Document – CDC/NIOSH (M) 2.11	25	1	30/60	13
Physicians (B Readers)	Interpreting Physician Certification Document – CDC/NIOSH (M) 2.12	300	1	10/60	50
Total		15,525			2,329

- b. The estimated annualized cost to the respondent population is \$72,403 based on the average costs per burden hour and the burden hours as shown below.

Type of Respondent	Number of Responses	Frequency of Response	Total Burden (in hrs.)	Hourly Wage Rate*	Respondent Cost
Physicians - B Reader (Form 2.8)	10,000	1	500	\$67	\$33,500
Miners (Form 2.9)	5,000	1	1,666	\$19	\$31,654
Coal Mine Operators (Form 2.10)	200	1	100	\$36	\$3,600
Radiology Supervisor at X-ray Facility (Form 2.11)	25	1	13	\$23	\$299
Physician – B Reader (Form 2.12)	300	1	50	\$67	\$3,350
Total	15,525		2,329		\$72,403

* Hourly wage rates taken from Bureau of Labor Statistics, National Occupational Employment and Wage Estimates (www.bls.gov/oes)

13. Estimates of Other Annual Cost Burden to Respondents or Recordkeepers

There are no other cost burdens to respondents or recordkeepers.

14. Annualized Cost to the Government

The annualized cost to the Government is approximately \$500,000, which includes printing and distribution of forms (\$5,000), data management and personnel charges (\$390,000), travel-related costs (\$4,000), and all other services and costs associated with the operation of the Program (\$101,000). The CWXSP is a Federally-mandated Program, and as such, will have budgetary support throughout the approval period.

15. Explanation for Program Changes or Adjustments

We are requesting a **program change** for an increase of 1,083 burden hours for this approval period due to the increase in the number of participating miners.

Other form changes are explained below:

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

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16. Plans for Tabulation and Publication and Project Time Schedule

Internal summaries are prepared at quarterly intervals to provide information on program activity and to indicate rates of disease progression in the population. Only summary data are included in these reports. Epidemiologic data will be presented at scientific meetings as various trends are discovered. This is an ongoing mandated project which began in 1970, and will continue according to regulation. A three (3) 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 the last renewal packet. 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 CWXSP was granted.

18. Exceptions to Certification

No exception is requested.