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

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

Section A

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SUPPORTING STATEMENT
REGULATION 42 CFR 37
COAL WORKERS' HEALTH SURVEILLANCE PROGRAM (CWHSP)
REINSTATEMENT OF OMB # 0920-0020

This is a reinstatement with changes information collection request from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention. The proposed information collection will incorporate the National Coal Workers' X-Ray Surveillance Program 42 CFR 37 (0920-0020) and National Coal Workers' Autopsy Study 42 CFR Part 37.204 (0920-0021) into one complete package which will be called the Coal Workers' Health Surveillance Program (CWHSP). CWHSP is a congressionally-mandated medical examination program for monitoring the health of underground coal miners, established under the Federal Coal Mine Health and Safety Act of 1969, as amended in 1977 and 2006, PL-91-173 (the Act). The Act provides the regulatory authority for the administration of the CWHSP. This Program, which includes both a health surveillance and an autopsy component, has been useful in providing tools for protecting the health of miners (whose participation is entirely voluntary), and also in documenting trends and patterns in the prevalence of coal workers' pneumoconiosis ('black lung' disease) among miners employed in U.S. coal mines.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Coal miners who inhale excessive dust are known to develop a group of diseases of the lungs and airways, including chronic bronchitis, emphysema, chronic obstructive pulmonary disease, silicosis, and coal workers' pneumoconiosis (CWP). Under Section 203, "Medical Examinations," the Federal Coal Mine Health and Safety Act of 1969, as amended in 1977 and 2006, PL-91-173 (Attachment 1), is intended to protect the health and safety of underground coal miners. This Act provides the basis for all mandatory and discretionary forms being utilized in conjunction with this data collection for the "Coal Workers' Health Surveillance Program (CWHSP)." 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 and to provide for an autopsy after the death of any active or inactive miner. These activities are administered through the CWHSP, 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 periodic medical examinations including a chest radiograph and other necessary tests, at no cost to the miner. Although not currently mandated by law or regulation, periodic medical history and spirometry testing have been recommended by NIOSH for

both surface and underground coal miners since 1995. The CWHSP administers all aspects of the following activities related to the conduct of both the mandated and discretionary periodic medical examinations for coal miners: 1) testing and certification of A and B Readers (physicians qualified to interpret and classify radiographs for pneumoconiosis); 2) evaluation and approval of facilities where testing may be done; 3) evaluation and approval of coal mine operator plans for providing medical examinations; 4) arranging and paying for B Reader interpretations of chest radiographs; 5) contracting with certified facilities to take radiographs and provide initial interpretations for mines not covered by approved coal mine operator plans; 6) arranging locally available testing under the Enhanced CWHSP, including spirometry, chest x-ray, and blood pressure monitoring for both surface and underground miners, 7) generation and dissemination of letters that notify participating miners of the results of chest radiographs interpreted for the presence or absence of CWP; 8) generation and dissemination of letters that notify miners of their results, including chest radiograph interpretations that identify abnormal findings other than CWP; and 9) maintenance of databases 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.

The Act also authorizes the Secretary of HHS to make the necessary arrangements with the next-of-kin for providing a post-mortem examination to be performed after the death of any active or inactive miner, and specifies that the autopsy shall be paid for by the Secretary, who has delegated program administration to NIOSH through the National Coal Workers' Autopsy Study (NCWAS) which is considered a component of the CWHSP. Results of NCWAS autopsies are used for research purposes (both epidemiological and clinical) and may also be used by the next-of-kin in support of Black Lung Benefits claims.

This reinstatement is requested for both the regulatory requirements as prescribed in 42 CFR 37, as well as the Congressionally-mandated and discretionary reporting instruments listed below. This submission will incorporate all of the above components of the CWHSP into one OMB package and approval. In the past the NCWAS was in a separate OMB package (#0920-0021). Following approval of this reinstatement that package will be deleted.

The only revision (since the last renewal) to any of the reporting instruments listed below is on the Facility Certification Document, Form No. CDC/NIOSH (M) 2.11 (see Attachment 6). This form records x-ray facility equipment/staffing information and was revised to reflect the transition of the CWHSP to a digital format.

In addition, electronic versions of these reporting instruments are now available

on the CDC web site to improve program efficiency and reduce paperwork burden. See: http://www.cdc.gov/niosh/topics/surveillance/ords/CoalWorkersHealthSurvProgram.html#nioshresources

Roentgenographic Interpretation Form
Form No. CDC/NIOSH (M) 2.8, Rev. 07/07 - (Attachment 3)
Records medical findings detected on chest radiographs.
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 (M) 2.8 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 further changes to the content of the form are being made at this time. However, to improve efficiency and as part of the NIOSH implementation of the classification of digital chest radiographic images, electronic versions of the form have been developed, and are 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©). Form 2.8 will be accepted from NIOSH A and B Readers as either printed forms or using secure electronic transfers, or on portable media in an acceptable format.

Miner Identification Document
Form No. CDC/NIOSH (M) 2.9, Rev 07/07- (Attachment 4)
Records miner's vital information and work history.
The Miner Identification Document records demographic and occupational history, as well as information required under the 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. To improve efficiency and as part of the implementation of the classification of digital chest radiographic images, an electronic version of form 2.9 is also available and may be submitted as printed forms or using secure electronic transfers, or on portable media in an acceptable format.

Coal Mine Operator's Plan
Form No. CDC/NIOSH (M) 2.10, Rev. 07/07 (Attachment 5)
Records plans and arrangements for obtaining coal miner examinations.
No changes are being made to the content of this form at this time. To improve

efficiency, an electronic version of form 2.10 is also available and may be submitted as printed forms or using secure electronic transfers, or on portable media in an acceptable format.

Facility Certification Document
Form No. CDC/NIOSH (M) 2.11, Rev. 02/12 – (Attachment 6)
Records x-ray facility equipment/staffing information.
As part of the NIOSH implementation of the acceptance of digital chest radiographic images for classification, Form 2.11 has been revised, based upon extensive discussions with program partners at NIOSH-sponsored public meetings and scientific workshops. [NIOSH Publication No. 2008-139: Application of the ILO International Classification of Radiographs of Pneumoconioses to Digital Chest Radiographic Images, A NIOSH Scientific Workshop. NIOSH Publication No. 2009-140: NIOSH B Reader Certification Program: Looking to the Future.] 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. Electronic versions of form 2.11 may be submitted as printed forms or using secure electronic transfers, or on portable media in an acceptable format.

Interpreting Physician Certification Document
Form No. CDC/NIOSH (M) 2.12, Rev. 07/07 - (Attachment 7)
Records information on physician qualifications.
No changes to the content of the form are being made at this time. To improve efficiency, an electronic version of form 2.10 is also available and may be submitted as printed forms or using secure electronic transfers, or on portable media in an acceptable format.

Consent, Release and History Form
Form No. CDC/NIOSH (M) 2.6, Rev 11/74 (Attachment 8)
Documents written authorization from the next-of-kin to perform an autopsy on the deceased miner.
No changes to the content of the form are being made at this time. A minimum of essential information is collected regarding the deceased miner including the occupational history and smoking history.

42 CFR 37.204(a) Invoice - Reporting
42 CFR Part 37.204 specifies the procedure for payment to pathologists for autopsies performed.
As specified in 42 CFR Part 37.204 the invoice submitted by the pathologist must contain a statement that the pathologist is not receiving any other compensation for the autopsy. A sample invoice is attached (Attachment 9).

42 CFR 37.204(c) Report of Autopsy.

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. However, a checklist of the report requirements for the NCWAS program (Attachment 10) is given to the 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 in the Morgantown, West Virginia location.

2. Purpose and Use of Information Collection

Information collected through the CWHSP is utilized for early CWP identification, tracking, assessment, and ultimately prevention and/or treatment. This Congressionally-mandated Program serves to identify the incidence and possible progression of CWP in underground and surface 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 underground miners and MSHA of any applicable 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 exposure limit was considered to be appropriate when implemented, for the elimination of advanced 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 evaluation of this limit, and for possible future recommendations on revised maximum exposure levels. These data are neither collected nor generated by any other source, whether Government or industry/labor sponsored.

The data from the CWHSP can be used in a number of ways in evaluating the effectiveness of the health regulations implemented under the Act. This Act, initially passed as the Coal Mine Health and Safety Act of 1969 and amended in 1977 and 2006, 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 CWHSP, with attendant potential for prevention efforts.

Considerable information about the distribution of participation rates is available for the CWHSP. In six states, participation ranged from 40 – 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 ongoing 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 CWHSP participation, which has further increased the utility of the program findings in evaluating the effectiveness of the current regulations.

This Program is a Federally-mandated program and, as such, is expected to have budgetary support throughout the approval period. If the collection of information is not conducted, the CWHSP will not be operational, and there will be no administration of the Congressional mandate. The CWHSP is not considered a research program and does not require Institutional Review Board approval (see Attachment 11). Although the NCWAS component is considered research, IRB approval does not apply. 45 CFR 46 defines a human subject as "... a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information."

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. Electronic versions of the forms are provided, and this current revision improves efficiency by enabling the use of digital images and electronic file transfers. However, paper versions of the forms are also needed, as 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 requiring 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, retention of paper-based data collection instruments is needed.
As part of the use of improved information technology, the CWHSP, after extensive discussions and input with program partners and stakeholders, is now implementing use of digital chest radiographic images for classification of the pneumoconioses, in addition to the continued acceptance of traditional film radiographs. The International Labour Office (ILO) has modified the "Guidelines for the Use of the ILO Classification of Radiographs of Pneumoconioses" to accept the use of digital radiographs, and is providing a set

of electronic/digital standard images for general use in applying the classification to digital chest radiographic images. Proposed regulations have been developed specifying equipment, methods, and procedures in order to properly view and classify digital radiographs.

While detailed specifications for the CWHSP are contained in 42 CFR Part 37, the Federal Mine Safety and Health Act Public Law 91-173, as amended by Public Law 95-164 (Section 203) does not contain detailed specifications regarding the chest radiographs. The Act merely calls for "chest roentgenogram(s)." Therefore, no legislative change will be necessary as the CWHSP expands the permissible technology related to chest radiographs – only a change in the regulatory requirement as outlined in Part 37 is 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, industry and labor organizations, as well as periodic review of related literature. The information collected is not available from any other sources, and no other government agency is currently collecting the information needed to administer this program. The CWHSP is a unique program and not a duplication of any existing program. 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.

5. Impact on Small Businesses or Other Small Entities

Participation in the CWHSP, 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 have been held to the absolute minimum necessary to properly identify the miner, the radiograph, and the facility, to report abnormalities on the films, and to provide the essential documentation and materials for the purposes of the autopsy. As noted above, in an effort to reduce the data collection burden, electronic versions and pre-printed forms with all available information are provided to the respondents.

6. Consequences of Collecting the Information Less Frequently

Miner participation in radiographic examinations, spirometry tests, and blood pressure screening, is voluntary. However, the minimum frequency that mine operators must make available radiographic examinations for underground miners

is mandated in the Act as every 3½ - 5 years. Current CWHSP data collection is based upon this requirement, which is considered to be the minimum frequency required to monitor the onset or progression of radiographic evidence of pneumoconiosis. The autopsy form is completed only once. There are no legal obstacles to reduce the burden.

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 February 24, 2011, (Volume 76, Number 37, Page 10369-10371) (Attachment 12). No comments were receieved.

b. As stipulated above in A.1, A.4, and A.6, there is an ongoing exchange of information with stakeholders and representatives of participant groups. These efforts include consultations with MSHA, ILO, and professional, labor, and industry organizations, as well as periodic reviews of related literature. NIOSH staff meet with the Mine Safety and Health Research Advisory Committee. NIOSH staff periodically discuss the use of the data collection instruments with radiologists, pathologists, pulmonary specialists, and and other occupational safety and health personnel and organizations. (See Attachment 13 for contact information.) The CWHSP has been operational since 1970, and various versions of the data collection forms have been used. There is concurrence that information obtained through the use of these forms is the minimum necessary to meet the requirements of the Act while still providing the information necessary for meeting program mission and objectives.

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 analog film and $12.00 per digital image. Pathologists receive a single payment of $200.00 for completing and submitting an autopsy report and specimens.

10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this project and has determined that the Privacy Act is applicable. 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 radiographs 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) has historically been collected for identity verification purposes. Respondents are informed that furnishing the SSN is voluntary and the purpose for which it is requested. The CWHSP currently has medical records on approximately 260,865 miners, consisting of over 452,730 radiographs, and all of these records have been archived by SSN.

When miners have a chest x-ray taken at an approved-NIOSH facility, they are required to complete a Miner ID Form (2.9), which includes the miner SSN. The SSN is used to group x-rays for a miner. If a miner has disease, then all of their x-rays are pulled for comparison of progression of disease. If a miner has a question regarding their x-ray, they provide their SSN for us to locate their records. Without the ability to identify a miner and to link them with all of their x-rays, NIOSH would have limited ability to understand and monitor the progression of CWP not only for the individual miner but as it relates to national trends in disease as well.

B Reader approval is granted to physicians with a valid U.S. medical license who demonstrate proficiency in the classification of chest radiographs for the pneumoconioses using the International Labour Office (ILO) Classification System. When a physician takes the B Reader Examination, he/she completes the Interpreting Physician Certification Document (2.12), which includes the physician's SSN. As part of the CWHSP, the physician records their classification on the Roentogenographic Interpretation Form (2.8). The physician's SSN is used to track their status and record which physician classified the x-ray.

We have been exploring the possibility of removing the miner SSN from the system but to date we have not found a method that would work in keeping the x-rays associated with a miner all together and with easy access. However, we are currently working on the option of removing the B Reader's SSN from the

system. Since NIOSH tests each reader and certifies their reader Status (A or B) we could provide them with a unique number which could be used instead of their SSN. We have not made a final determination regarding this field but feel that this one is more likely a candidate for removal.

We recently moved the CWHSP database from a SQL 2000 server to a SQL 2008 server with Transparent Data Encryption (TDE). The entire database is now encrypted.

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. Program computers meet the highest CDC standards for administrative, technical, and physical security. Databases are password protected. A 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 including prior radiographs;
- 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 23,250 responses may be received each year through all aspects of data collection associated with the CWHSP. The total annual estimated respondent burden is 4,470 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 and/or examination.

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	1,667
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	100	1	30/60	50
Physicians (B Readers)	Interpreting Physician Certification Document – CDC/NIOSH (M) 2.12	300	1	10/60	50
Spirometry Test – Coal Miners	No form involved	2,500	1	20/60	833
X-ray – Coal Miners	No form involved	5,000	1	15/60	1250
Pathologist	(Invoice)	50	1	5/60	4
Pathologist	(Final diagnosis)	50	1	5/60	4
Next-of-Kin	Consent, Release, and History Form - CDC.NIOSH (M) 2.6	50	1	15/60	13
Totals		23,250			4,471

This estimate is based on the following:

- Pathologist Invoice - It is estimated that only 5 minutes is required for the pathologist to put a statement on the invoice affirming that no other compensation is received for the autopsy.

- Pathologist Report - Since an autopsy report is routinely completed by a pathologist, the only additional burden is the specific request of abstract of terminal illness and final diagnosis relating to pneumoconiosis. Therefore, only 5 minutes of additional burden is estimated for the autopsy report.
- Consent, Release and History Form (2.6) - From past experience, it is estimated that 15 minutes is required for the next-of-kin to complete this form.
- Roentgenographic Interpretation Form (2.8) - Physicians (B Readers) fill out this form regarding their interpretations of the x-rays (each x-ray has at least two separate interpretations). Based on prior practice it takes the physician approximately 3 minutes per form.
- Interpreting Physician Certification Document (2.12) - Physicians taking the B Reader Examination are asked to complete this registration form that takes approximately 10 minutes.
- Miner Identification Document (2.9) - Miners who elect to participate in the CWHSP must fill out this document which requires approximately 20 minutes. The actual shooting of the chest image takes approximately 15 minutes.
- Miners participating in the ECWHSP portion of the Program are asked to perform a spirometry test which requires no additional paperwork, but does require approximately 15 to 20 minutes for the test itself. The 2500 respondents listed in the burden table below account for about ½ of the total participants.
- Coal Mine Operators Plan (2.10) - Mine operators are required to file a Mine X-ray Plan with NIOSH every 3 years. To complete this form with all requested information (including a roster of current employees) takes approximately 30 minutes.
- Facility Certification Document (2.11) - X-ray facilities seeking NIOSH-approval to provide miner x-rays under the CWHSP must complete an approval packet. It is anticipated that since the CWHSP will soon be accepting digital images as well as the traditional analog x-ray films, the number of x-ray facilities participating will increase over the next several years. This increase is reflected in this submission. The forms associated with this approval process require approximately 30 minutes for completion.

b. The estimated annualized cost to the respondent population for the medical examinations is $113,467 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	1,667	$19	$31,654
Coal Mine Operators (Form 2.10)	200	1	100	$36	$3,600
Radiology Supervisor at X-ray Facility (Form 2.11)	100	1	50	$23	$1,150
Physician – B Reader (Form 2.12)	300	1	50	$67	$3,350
Spirometry Test – Coal Miners	2,500	1	833	$19	$15,827
X-ray – Coal Miners	5,000	1	1250	$19	$23,750
Pathologist – Invoice	50	1	4	$60	$240
Pathologist – Final diagnosis report	50	1	4	$60	$240
Next-of Kin (Form 2.6)	50	1	13	$12.00	$156
Total	23,250				$113,467

* The rate of pay for pathologists was determined by comparing what a government pathologist is paid (GS-14, $47 per hour) and raising the cost to reflect private industry wages. This amount is considered to be accurate. The rate of $12 as an hourly wage for the Next-of-Kin is considered to be an accurate wage. All other hourly wage rates were 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 $1,146,488 which includes printing and distribution of forms ($16,000), data management and personnel charges ($723,814), travel-related costs ($101,000), autopsy-related services and expenses ($1,000), and all other services and costs associated with the operation of the Program ($304,674). The CWHSP 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 an increase of 2141 burden hours for this approval period due to the increase in the number of participating miners, and an increase in the number of applications from newly eligible digital x-ray facilities. This increase also reflects the increase related to the combining of the two OMB submissions (0920-0020 and 0920-0021) into one comprehensive CWHSP packet.

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 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 2004. 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 CWHSP was granted.

18. Exceptions to Certification

No exception is requested.