

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State Officials	State Health Education	51	1	30/60	26
	State Physical Education	51	1	30/60	26
	State Health Services	51	1	30/60	26
	State Nutrition Services	51	1	30/60	26
	State Healthy and Safe School Environment.	51	1	30/60	26
	State Mental Health and Social Services ...	51	1	30/60	26
District Officials	Assist with identifying state-level respondents and with recruiting districts and schools).	51	1	1	51
	District Health Education	685	1	30/60	343
	District Physical Education	685	1	40/60	457
	District Health Services	685	1	40/60	457
	District Nutrition Services	685	1	30/60	343
	District Healthy and Safe School Environment.	685	1	1	685
	District Mental Health and Social Services	685	1	30/60	343
	District Faculty and Staff Health Promotion	685	1	20/60	228
Principals, secretaries or designees.	Assist with identifying and scheduling school-level respondents.	1,043	1	1	1,043
	Assist with identifying district-level respondents and with recruiting schools.	685	1	1	685
Health education lead teachers, principals, or designees.	School Health Education	1,043	1	20/60	348
Physical education lead teachers, principals, or designees.	School Physical Education	1,043	1	40/60	695
School nurses, principals, or designees.	School Health Services	1,043	1	50/60	869
Food service managers, principals, or designees.	School Nutrition Services	1,043	1	40/60	695
Principals or designee	School Healthy and Safe School Environment.	1,043	1	1.25	1,304
Counselors, principals, or designees.	School Mental Health and Social Services	1,043	1	30/60	522
Principals or designees	School Faculty and Staff Health Promotion	1,043	1	20/60	348
Health education teachers	Classroom Health Education	2,002	1	50/60	1,668
Physical education teachers ..	Classroom Physical Education	2,002	1	40/60	1,335
Total	12,575

Dated: February 17, 2011.

Carol E. Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day-11-0020]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on

proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 and send comments to Carol E. Walker, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be

collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Coal Workers' Health Surveillance Program (CWHSP)—OMB 0920-0020, exp. 4/31/2011—Revision The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This submission will incorporate the National Coal Workers' X-Ray Surveillance Program 42 CFR part 37 (0920-0020) and National Coal Workers' Autopsy Study 42 CFR 37.204 (0920-

0021) into one complete package which will be called the Coal Workers' Health Surveillance Program (CWHSP). Upon OMB approval, 0920-0021 will be discontinued. 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, Public Law 95-164 (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. During the early 1970s, one out of every three miners examined through the CWHSP who had worked at least 25 years underground had evidence of pneumoconiosis on their chest x-ray. An analysis among over 25,000 miners who participated in the x-ray Programs from 1996 to 2002 indicated that the proportion of affected individuals had decreased to about one in 20. However, recent surveillance analyses and research studies have confirmed that the prevalence of 'black lung' disease is increasing, there is regional clustering of rapidly progressive pneumoconiosis cases, and coal miners have a higher risk of disease if they perform certain jobs, work in smaller mines, or are from certain geographic areas. Importantly, young coal miners are developing the disabling and lethal forms of 'black lung'.

Coal Workers' Health Surveillance Program (CWHSP)

Demographic and logistical information is gathered from coal mine operators and participating x-ray facilities. Participating miners also provide health and work histories, and participating physicians report radiographic findings. The Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health, Division of Respiratory Disease Studies, 1095 Willowdale Road, Morgantown, WV 26505, also called the Appalachian Laboratory for Occupational Safety and Health (ALOSH), is charged with administration of this Program.

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 Miners' Choice Program has been continued as an extension of the CWHSP (currently called the Enhanced Coal Workers' Health Surveillance Program—ECWHSP). This extension of the CWHSP currently 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.

Under the Act, the provision of periodic chest x-ray examinations is specifically mandated, and the x-rays are to be supplemented by such other tests as the Secretary deems necessary. In addition to radiographically-apparent pneumoconiosis, miners are at risk for the development of chronic obstructive pulmonary disease (COPD). Chest radiographs alone cannot provide a measure of airflow obstruction and therefore often miss important lung disease. For this reason, spirometry, a simple breathing test, is an additional component that is particularly useful for the health assessment of miners. Periodic medical history and spirometry tests have been recommended by NIOSH for both surface and underground coal miners since 1995, to facilitate preventive actions, increase miners' participation in programs for early detection of disease, and improve the derivation of representative estimates of the burden, distribution, and determinants of occupational lung disease in relation to coal mining in the U.S. Finally, unrecognized hypertension has previously been observed among many miners, and the ECWHSP offers blood pressure screening as a safe, simple, and inexpensive test, which can help target initiation of proven health conserving medications.

The National Coal Workers' Autopsy Study (NCWAS) provides standardized lung specimens for ongoing scientific research as well as information to the next-of-kin regarding the presence and extent of coal workers' pneumoconiosis (black lung) in the lungs of the deceased miner. The Consent Release and History Form is primarily used to obtain written authorization from the next-of-kin to perform an autopsy on the deceased miner. Because a basic reason for the post-mortem examination is research (both epidemiological and clinical), a minimum of essential information is collected regarding the deceased miner, including occupational history and smoking history. The data collected are used by scientists for research purposes in defining the diagnostic criteria for pneumoconiosis and in correlating

pathologic changes with exposures and x-ray findings.

There are no costs of the NCWAS to respondents other than their time. Overall, there are no direct costs to CWHSP participants.

The total estimated annualized burden hours is 4120.

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 either 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.

ESTIMATED ANNUALIZED BURDEN

Respondents	Number of respondents	Number of responses per respondent	Average burden/response (in hrs)	Total burden (in hrs)
Invoice-Pathologist	50	1	5/60	4
Report-Pathologist	50	1	5/60	4
Consent, Release and History Form—Next-of-Kin (Form 2.6)	50	1	15/60	13
Roentgenographic Interpretation Form—Physicians (Form 2.8)	10,000	1	3/60	500
Interpreting Physician Certification Document—Physicians (Form 2.12)	300	1	10/60	50
Miner Identification Document—Coal Miners (Form 2.9)	5,000	1	20/60	1,666
Spirometry Test—Coal Miners	2,500	1	20/60	833
X-ray—Coal Miners	5000	1	15/60	750
Coal Mine Operators Plan—Mine Operators (Form 2.10)	200	1	30/60	100
Facility Certification Document—X-ray Facilities (Form 2.11)	100	1	30/60	200
Total				4,120

Dated: February 16, 2011.

Carol E. Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011-4165 Filed 2-23-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control

Special Emphasis Panel: Occupational Safety and Health Training Project Grant, Program Announcement PAR 10-288, initial review.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Times and Dates: 8:30 a.m.–5 p.m., March 17, 2011 (Closed).

Place: Courtyard Marriott, 2700 Eisenhower Avenue, Alexandria, Virginia 22314-4553, Telephone (703) 329-2323.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters to be Discussed: The meeting will include the initial review, discussion, and evaluation of “Occupational Safety and Health Training Project Grant, PAR 10-288.”

Contact Person for More Information: M. Chris Langub, PhD, Scientific Review Officer,

CDC, 1600 Clifton Road NE., Mailstop E74, Atlanta, Georgia 30333, Telephone (404) 498-2543.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 14, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

[FR Doc. 2011-4197 Filed 2-23-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0622]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Color Additive Certification Requests and Recordkeeping

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 28, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0216. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance. Color Additive Certification Requests and Recordkeeping—21 CFR part 80 (OMB Control Number 0910-0216)—Extension.

FDA has regulatory oversight for color additives used in foods, drugs, cosmetics, and medical devices. Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless it