

Request for Nonsubstantive Change

3 OMB Approved Forms
Chest Radiograph Classification Form (2.8) (PDF)
Miner Identification Form (2.10) (Word Doc)
Physician Application for Certification (2.12) (Word Doc)

1 Procedure Change
Recertification period for B Readers

OMB Approval #0920-0020 – Expiration date 09/30/2021

Background:

The NIOSH Coal Workers' Health Surveillance Program (CWHSP) is a congressionally-mandated medical examination surveillance program for monitoring the health of coal miners. The CWHSP was originally authorized under the 1969 Federal Coal Mine Health and Safety Act and is currently authorized under the 1977 Federal Mine Safety and Health Act and its subsequent amendments (the Act). The Act provides the regulatory authority for the administration of the CWHSP and the Program operates under the guidelines of 42 CFR Part 37, "Specifications for Medical Examinations of Coal Miners."

Information collected through the CWHSP is utilized for early identification, tracking, assessment, and ultimately prevention and/or treatment of coal workers' pneumoconiosis. The Program serves to identify the incidence and possible progression of coal mine dust-induced disease in individual coal miners. The data from the CWHSP is used in a number of ways in evaluating the effectiveness of the health regulations implemented under the Act. During the early 1970s, one out of every three miners examined in the Program 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 Program from 1996 to 2002 indicated that the proportion of individuals affected has greatly decreased, to about one in 20. However, it also suggested that certain groups of miners are still at elevated risk. An increased risk of pneumoconiosis was associated with work in certain mining jobs, in smaller mines, in several geographic areas, and among contract miners. For miners being screened through the Program in the last 10 years, the rates of black lung in miners with 20+ years of tenure have doubled. Disease is being detected in younger miners and miners are progressing from the beginning stages of disease to the more advanced stage of progressive massive fibrosis at an accelerated rate. Analysis of regional disease prevalence in conjunction with participation rates further assist in determining representativeness of the overall disease prevalence rates. Analysis of the consistency of disease patterns and trends aid in assessing the generalizability of the program findings.

Justification for nonsubstantive changes to 3 forms:

Chest Radiograph Classification Form

Form No. CDC/NIOSH (M) 2.8

Under 42 CFR Part 37, NIOSH utilizes a radiographic classification system developed by the International Labour Office (ILO) in the determination of pneumoconiosis among coal miners. Physicians (B Readers) fill out this form regarding their classifications of the radiographs (each radiograph has two separate classifications; approximately 7% require additional classifications). Based on prior practice, it takes the physician approximately 3 minutes per form.

Changes that were made to the form include:

- Added Examinee's Name to Page 1 and 2 – Hospitals and clinics are often writing the examinee's name on both pages and we cannot identify the examinee (miner) now that only last 4 digits of SSN are required.
- Added Excessive Edge Enhancement – Doctors were frequently writing this problem in the “Other” box related to film quality. Having a check box for “excessive edge enhancement” will save time for the doctors and will allow us to more accurately search for and investigate images with specific quality issues.
- Changed Reader SSN to Reader ID - We do not need the reader's SSN, and we are able to use another identifier that is not personally identifiable or private.

These changes will not result in any additional burden to respondents as the two additions of examinee name should be readily available to the physician classifying the film, the additional quality option of “excessive edge enhancement” will save the physicians time from writing that information in the “Other” box and replacing the Reader SSN with a Reader ID will be a net zero additional burden.

Miner Identification Document

Form No. CDC/NIOSH (M) 2.9

This form records the miner's demographic and occupational history, as well as information required under regulations in relation to coal miner examinations. It takes approximately 20 minutes for completion of this form. In addition to completing this form, acquiring the chest image from the miner takes approximately 15 minutes.

Changes that were made to the form include:

- Added Spirometry Facility and Unit Number – A miner may get both a radiograph and a spirometry exam at the same appointment, however we need to have information on both the facility and units used during the visit. We needed to identify if the miner went to different health facilities or if a different unit number was used for spirometry.

- Moved Miner's Signature to bottom of page 2 – Often miners do not complete the back of this form, potentially because they assume they are finished once they sign the form because the signature is on the bottom of the page 1. By moving the signature to the bottom on the back (page 2) of the form we hope to encourage miners to complete the entire form and then sign it.
- Added Miner's name to page 2 – We could not identify page 2 if it got separated from page 1. This is more common now that we accept forms through our SAMS secure web portal.

These changes will not result in any additional burden to respondents. The facilities have both their radiograph and spirometry NIOSH approval numbers readily available. Moving the signature box to the back of the form is creates no more burden to the miner than having it on the front of the form. Adding the miner's name to the back of the form will take a few seconds, but not enough to change the currently approved burden, and will ensure if forms are separated that we are able to identify the miner and prevent incomplete/missing data.

Physician Application for Certification
Form No. CDC/NIOSH (M) 2.12

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. It typically takes the physician about 10 minutes to complete this form.

Changes that were made to the form include:

- Replaced Reader SSN with Reader ID - We do not need the reader's SSN, and we are able to use another identifier that is not personally identifiable or private.
- Moved Email address – To allow more space to enter email address.
- Added check box to allow physician to choose if their contact information will be displayed on the web site if they are certified as a NIOSH B Reader.
- Added question regarding whether physician holds an active academic teaching appointment at a US medical school. NIOSH needs this information when the CWHSP is adding to the pool of contracted B Readers that classify radiographs as part of the CWHSP this is one of the criteria considered.

These changes will not result in any additional burden to respondents. As stated above, the change from Reader SSN to Reader ID is a net zero burden. Adding the check box related to being listed on the web and answering the questions regarding academic appointments may take a few additional seconds, but is not enough to change the currently approved burden.

Attached are the new versions of each form with the changed areas highlighted. Once these forms are approved, we will submit them for final formatting.

Justification for nonsubstantive change to 1 procedure
Recertification period for B Readers

As stated in an Endnote in the currently approved Supporting Statement B:

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. B Readers 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 on the NIOSH B Reader Re-certification Examination.

We want to change the timeframe for recertification from every 4 years to every 5 years. This change is requested due to numerous requests and comments from current B Readers and we are being responsive to them as stakeholders. We will leave the definition of a B Reader as is other than changing "...and every four years thereafter" to "... and every *five* years thereafter (with a three month grace period)..."

This change will result in a decrease in the burden tables as shown below:

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per response (in hours)	Total Burden Hours
Physicians taking the B Reader Examination	2.12	100 80	1	10/60	17 13

Total burden hours for the entire CWHSP was 20,281 and will now be 20,276.

Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
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2.12	100 80	1	10/60	17 13	\$99	\$1,683 \$1,287
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Total annual burden costs for the CWHSP were \$594,240 and will now be \$593, 844.

Approval of these non substantive changes is requested for **OMB Approval #0920-0020 -- Expiration date 09/30/2021**