## Request for Nonsubstantive Change to 2 OMB Approved Forms

## CDC/NIOSH (M) 2.9 CDC/NIOSH (M) 2.15

National Coal Workers' Health Surveillance Program (CWHSP)

OMB Approval #0920-0020 – Expiration date 06/30/2018

## Background:

The NIOSH Coal Workers' Health Surveillance Program (CWHSP) is a congressionally-mandated medical examination program for monitoring the respiratory health of 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, 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.

## <u>Justification for nonsubstantive change:</u>

Form CDC/NIOSH (M) 2.9 – Miner Identification Document

This form is used to record the miner's demographic and occupational history, as well as information required under regulations from radiograph facilities in relation to coal miner examinations for the CWHSP.

The current consent box at the bottom of the form states "I wish to participate in the Coal Workers' Health Surveillance Program conducted under Section 203 of the Federal Mine Safety and Health Act of 1977 (30 U.S. 843). I understand that a report of my radiograph will be mailed to me and my health information will be treated in a secure manner and will not be disclosed, unless otherwise compelled by

*law.*" We propose adding the following sentence to that consent box – "*I also understand that my results may be used to assess health and risks related to coal mining.*" By adding this sentence the miner will be informed that NIOSH may use aggregate data from the Program to report on incidence and trends related to coal miners' health.

This change will not result in any additional burden to respondents.

Justification for nonsubstantive change:

Form CDC/NIOSH 2.15 – Spirometry Results Notification Form

The form is used to: 1) collect information that will allow NIOSH to identify the miner in order to provide notification of the spirometry test results; 2) assure that the test can be done safely; 3) record factors that can affect test results; 4) provide documentation that the required components of the spirometry examination have been transmitted to NIOSH for processing; and, 5) conduct quality assurance audits and interpretation of results.

We propose changing the Medical Record Number box with Miner's Social Security Number box. As with all other forms used in the CWHSP there will be a statement included stating, "Full SSN is optional; last 4 digits are required." The Medical Records Number does not provide a unique identification of the miner as it varies by facility. This change will ensure that this form links to other forms coming to us for each miner. Without the ability to identify a miner and link them to all of their previous records, NIOSH would have limited ability to understand and monitor the progression of the disease, not only for the individual miner but as it relates to national trends in disease as well. Therefore, at least a partial SSN is necessary to establish identity.

This change will not result in any additional burden to respondents.

Attached are the new versions of each form with the changed area highlighted.