X-Ray Classification Collection for Metal and Nonmetal Miners

Supporting Statement A

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Goals of the project: This study aims to gather de-identified x-ray findings from medical providers to monitor respiratory health among miners in the metal/non-metal mining industry, focusing on the presence and severity of pneumoconiosis. Data will be submitted securely through REDCap, ensuring encryption and compliance with privacy standards, though no PII will be collected.

Intended use of the resulting data: If a cluster of pneumoconiosis is observed/reported within a given geographical area, then the appropriate state or local public health authority would be alerted for their further investigation. This information will be able to be used to inform broader public health response, to protect the health of workers, and can also help inform mine operators as they monitor the effectiveness of dust control methods used in their mining operations.

Methods to be used to collect data: To facilitate secure and efficient data submission, NIOSH is utilizing Research Electronic Data Capture (REDCap), a secure web-based platform widely used across CDC and NIOSH. Providers will enter information for each metal or non-metal miner who receives a chest x-ray classification from a NIOSH certified B-Reader into the REDCap survey. No PII will be collected.

- **The specific subpopulation to be studied:** Metal and non-metal miners working in the United States. According to the Mine Safety and Health Administration, as of 2023, there were approximately 255,072 employees of metal and non-metal mines in the United States.

- **How data will be analyzed:** Data will be collected and processed using the REDCap environment in aggregated reports, summarizing total reports received, number and proportion with evidence of pneumoconiosis, by commodity. No personal identifiers will be included or used.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This requested data collection is intended to collect de-identified x-ray findings from medical providers to monitor respiratory health among miners in the metal/non-metal sectors, focusing on the presence and severity of pneumoconiosis on chest radiograph. This data collection is intended to continue indefinitely, with renewal as required every three years. In the Mine Safety and Health Administration Regulation, Lowering Miners' Exposure to Respirable Crystalline Silica and Improving Respiratory Protection, 30 CFR Part 60.15 Medical surveillance for metal and nonmetal mines, states that: "The mine operator shall ensure that, within 30 days of the medical examination, the PLHCP (physician or other licensed health care provider) or specialist provides the results of chest X-ray classifications to the National Institute for Occupational Safety and Health (NIOSH), once NIOSH establishes a reporting system." This reporting system is therefore being stood up by NIOSH to collect the chest x-ray classifications from metal/non-metal miners across the United States. This data collection is also supported by statutory language in the 1969 Federal Mine Safety and Health Act, [30 U.S.C. § 813(h)]: "In addition to such records as are specifically required by this Act, every operator of a coal or other mine [emphasis added] shall establish and maintain such records, make such reports, and provide such information, as the Secretary or the Secretary of Health and Human Services may reasonably require from time to time to enable him to perform his functions under this Act. The Secretary or the Secretary of Health and Human Services is authorized to compile, analyze, and publish, either in summary or detailed form, such reports or information so obtained."

NIOSH will cover any costs for the planned reporting system described below. NIOSH does not anticipate substantial incremental cost for implementing this reporting system. Reporting will be implemented via a simple online survey collecting de-identified information from providers of respiratory health examinations as outlined in 30 CFR Part 60. The information collected will not include personally identifiable information (PII) so that the identification of individual miners will not be possible. Data elements to be collected include chest x-ray classification findings, state where miner works, and mining commodity. CDC's instance of Research Electronic Data Capture (REDCap) software will be used for online data collection. The software can be used to collect de-identified data online from external parties. This low-cost, efficient approach will allow us to monitor the number of examinations performed, the number showing findings of pneumoconiosis, as well as findings by commodity and geographic distribution. A limitation in not collecting PII is that it will not allow for communication back to healthcare providers or miners about specific miners' chest x-ray results.

Pneumoconiosis, a dust-induced interstitial lung disease, has been increasing among coal miners, especially in central Appalachia, since the early 2000s. Both coal miners and metal/non-metal miners are exposed to dusts, potentially including respirable crystalline silica, through their typical working conditions. Pneumoconiosis includes silicosis and coal workers' pneumoconiosis, commonly known as black lung. Disease can progress to the most severe form, progressive massive fibrosis. Though there is no cure, some patients with severe pneumoconiosis undergo lung transplants to extend their life. In the United States, there have been 16 lung transplants performed due to coal workers' pneumoconiosis and 16 lung transplants due to silicosis in 2023 alone.

NIOSH currently operates the Coal Workers' Health Surveillance Program (CWHSP) which allows NIOSH to monitor pneumoconiosis trends among coal miners, and allows for early intervention if disease is detected in coal miners. Data from the CWHSP shows that about 20% of long-tenured coal miners (those with at least 25 years of coal mining tenure) have evidence of pneumoconiosis on chest radiographs. However, no such system exists to monitor the respiratory health of metal/non-metal miners. Recent research among former metal/non-metal miners seen at a clinic in Colorado showed that 58/223 (26%) had evidence of pneumoconiosis on chest radiograph. The proposed data collection aims to provide an estimate for the prevalence of pneumoconiosis among working metal/non-metal miners across the United States.

2. Purpose and Use of the Information Collection

The purpose of this information collection request is to collect chest radiograph classification information from clinics serving metal/non-metal miners across the United States. This data will enable NIOSH staff to monitor pneumoconiosis disease prevalence among metal/non-metal miners using the aggregate data.

The data collection instrument will address the following topics:

- State or Territory where the miner worked
- Work information – commodity, type of mine
- Standardized radiograph classifications

To facilitate secure and efficient data submission, NIOSH is utilizing Research Electronic Data Capture (REDCap), a secure web-based platform widely used across CDC and NIOSH. Providers will enter information for each metal or non-metal miner who receives a chest x-ray classification from a NIOSH certified B-Reader into the REDCap survey. No PII will be collected. This study aims to gather de-identified x-ray findings from medical providers to monitor respiratory health among miners in the metal/non-metal sectors, focusing on the presence and severity of pneumoconiosis. Using the International Labour Office's classification, providers will report whether pneumoconiosis is present and, if so, report the opacity types. Data will be submitted securely through REDCap, ensuring encryption and compliance with privacy standards, though no PII will be collected. The collected information will support public health surveillance and inform interventions to improve miners' health outcomes without compromising individual privacy. This project is in response to recent MSHA regulatory action, prompting NIOSH to collect this information from providers.

3. Use of Improved Information Technology and Burden Reduction

All data will be collected using REDCap, a secure internet-based survey software system that is approved for use by NIOSH. REDCap provides enterprise-grade security features including data encryption, redundancy, continuous network monitoring, and Single Sign On (SSO).

The instrument software will use computer generated skip patterns to reduce the respondent's overall burden, so clinic staff filling out the forms only see questions that are relevant to them. For example, if a given radiograph's classification indicates that there is no evidence of pneumoconiosis, then no further

specific information about that radiograph and its classification will be asked. The estimated time to complete the electronic survey is approximately 2 to 3 minutes.

4. Efforts to Identify Duplication and Use of Similar Information

This effort is not duplicative. NIOSH is the only federal entity that conducts research to improve occupational safety and health. Within NIOSH, there are no other currently funded projects approved addressing the presence of pneumoconiosis among metal/non-metal miners, and no similar information has been gathered by or maintained by NIOSH or other Federal agencies, nor is the information available from other known sources.

5. Impact on Small Businesses or Other Small Entities

Participation in this information collection does not impose an unreasonable burden to participating clinics, which may be small businesses operating in rural locations, as mining is largely pursued in rural areas. The average time burden for any clinic taking part will not exceed 2 to 3 minutes per each miner's radiograph. There is no cost associated with this data collection.

6. Consequences of Collecting the Information Less Frequently

As outlined in 30 CFR Part 60.15, metal and non-metal miners must be offered medical surveillance, including chest radiographs, at entry to the workforce, within three years after the initial radiograph, and then every 5 years afterwards throughout their careers in the industry. The classifications of these radiographs must then be submitted to NIOSH, which is proposed to occur through this data collection instrument, within 30 days post-radiograph. While the initial radiographs at entry and three years later are mandatory, the remaining radiographs are voluntary. Once a radiograph is taken, the submission of its classification to NIOSH is mandatory. Given this timeline, over the course of a miner's 30-year career, they may be expected to have as many as seven radiographs. As pneumoconiosis is a progressive disease, spacing the radiographs out over time allows for early identification of disease and subsequent intervention. If the radiographs and their subsequent radiographic classifications would be conducted and collected less frequently, then the miners themselves would not receive timely interventions, and the ability to identify increases in pneumoconiosis among these miners would also be lost. This information is intended to help protect miners' respiratory health and guide mine operators in monitoring the effectiveness of dust controls.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5.

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

A. A Federal Register Notice was published for the generic information collection The Federal Register notice was published for this collection on June 16, 2025, Vol. 90, No.114, pp. 25298 (Attachment 2). No public comments were received.

B. No outside consultations occurred, as this data collection effort is in response to the Mine Safety and Health Administration Regulation, Lowering Miners' Exposure to Respirable Crystalline Silica and Improving Respiratory Protection, 30 CFR Part 60.15 Medical surveillance for metal and nonmetal

mines. The survey was reviewed and discussed with internal NIOSH researchers with expertise in radiograph classifications and pneumoconiosis.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payments or gifts for completing either data collection.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

System Security and Privacy Officer (SSPO) determined in conjunction with the CDC Privacy Office that Privacy Act is not applicable. The activities do not involve the collection of individually identifiable information.

Research Electronic Data Capture (REDcap) include the in-place technical, physical, or administrative controls (safeguards).

Research Electronic Data Capture (REDcap) System Security Plan (SSP) defines the process for handling security incidents. The system's team and the Cybersecurity Program Office (CSPO) share the responsibilities for event monitoring and incident response. Direct reports of suspicious security or adverse privacy related events to the component's Information Systems Security Officer (SSPO), CDC helpdesk, or to the CDC Security Incident Response Team (CSIRT). The CDC CSPO reports to the HHS Computer Security Incident Response Center (CSIRC), which reports incidents to US-CERT as appropriate.

The information collected for the project will be maintained or stored locally under strict access controls limited to the local project leader/manager or his/her designate.

Participation in the activities is mandated for medical providers serving miners as outlined in 30 CFR Part 60.15(d)(2). The data collection instrument itself is included in Attachment 4, with Attachment 3 being a request form for clinics which need to access the data collection form.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The proposed data collection was reviewed and found to be exempt by the NIOSH Human Research Protection Program (Attachment 5).

12. Estimates of Annualized Burden Hours and Costs

The burden hours are estimated based on limited pilot testing conducted internally using the survey instrument. In these pilot tests, the amount of time for instruction review, collection of mock information, and the survey completion was between 2-4 minutes. The median time of 3 minutes was used to estimate annual burden hours. Currently, the total number of clinics which will be using this system in the United States is unknown. However, the total number of employed miners in the metal/non-metal industry is known, with 255,702 employed in 2023. MSHA estimated in their regulatory documents that anywhere between 25% to 75% of metal/non-metal miners will participate in this program, leading to an annual average number of radiographs submitted to be 13,500. If we take the total number of clinics to be at least double the number of clinics offering NIOSH-approved radiography listed on NIOSH's website (169), then at least 338 clinics will participate. CDC therefore requests OMB

approval for an estimated 462 annual burden hours. There are no costs to respondents other than their time to participate.

Estimated Annualized Burden (Hours)

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Clinics and staff	Request to Access X-ray Classification Submission	338	1	1/60	6
Clinics and staff	X-ray classification submission for metal and non-metal miners	338	40	2/60	451
Total					462

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to respondents or record keepers. There will be no direct cost to the respondents other than their time to participate in the data collection activity.

14. Annualized Cost to the Government

Exhibit A.14 presents the personnel costs of federal employees involved in program management, data collection, and analyses to the government. The annual cost is estimated at $4,234 annually.

Exhibit A.14. Annualized Cost to The Government

Expense Type	**Expense Explanation**	**Annual Costs (dollars)**
Direct Costs to the Federal Government		
	CDC Epidemiologist (GS-14, 0.03 FTE)	$ 4,234
	TOTAL COST TO THE GOVERNMENT	**$4,234**

15. Explanation for Program Changes or Adjustments

This is a new data/information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Individual data collections under this generic approval will be conducted over time. This data collection is in response to mandated sharing of radiograph classifications from health providers serving metal/non-metal miners, and is therefore an ongoing data collection without a set end date. Data collected will be analyzed in the aggregate and shared with stakeholders through planned regular updates at least annually on the NIOSH website.

Exhibit A.16. Project Time Schedule

Activity	Time Schedule
Begin data collection	0-2 weeks after OMB approval
Regular monitoring/quality assurance of incoming data	0-2 weeks after OMB approval
Analyses	2 months after OMB approval, then ongoing
Product ready for dissemination to industry stakeholders	6 months after OMB approval, then ongoing

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.