Generic Clearance for CDC/ATSDR

Formative Research and Tool Development

Title: Development of an updated B Reader Certification Examination

Supporting Statement A

September 19, 2019

Contact Information:

Cara Halldin
CDC/NIOSH/RHD/SB
304-285-5899
challdin@cdc.gov

Table of Contents

- Purpose: Since 1974, NIOSH has administered the B Reader Training and Certification Program which trains and certifies physicians in the identification and classification of lung diseases caused by dust exposures using chest radiography (x-ray). B Readers participate in NIOSH's Coal Workers' Health Surveillance Program, the Department of Labor's Black Lung Benefits Program, as well as other federal and state programs addressing dust-related illnesses, and are also involved with epidemiologic evaluations, surveillance, and worker monitoring programs involving many types of pneumoconioses. The purpose of this request is to enable NIOSH to administer and evaluate the performance of a draft version of a new certification examination.

- Goal: The goal of this request is to administer the draft version of a new certification exam to no more than 50 physician volunteers over a 12-month period after they complete the current certification exam.

- Intended use: The resulting data collected by this exercise will benefit NIOSH in the development and validation of a scoring approach to ensure the performance of the new exam aligns with the current exam before phasing out the current exam. These data will also allow NIOSH to identify parts of the new exam or specific questions which may not perform well and therefore would need to be removed or altered prior to the new exam official release.

- Methods: The examinations are electronic and are taken on CDC/NIOSH computer systems using a software program that was developed and is maintained by NIOSH called BViewer©. This software collects examinee responses for the classification of the chest x-rays. Volunteer's will take the current exam in the morning followed by the new examination in the afternoon using the same computer equipment. A 25 multiple-choice question part of the new exam will be administered in paper-based format after the physician finishes classifying the x-rays.

- Target population: Respondents include physicians who have contacted NIOSH and plan to take the B Reader Certification Examination. They will be invited to also take the draft version of the new exam.

- Analysis plan: Respondents data on the new exam will be summarized for each test section and will be compared to their performance on comparable sections of the current exam using Microsoft Excel and SAS 9.4. Several proposed exam scoring structures/weighting strategies will be tested on data collected from the new exam for all examinee volunteers to ensure similar certification rates will be achieved (compared to the current exam) and minimum competencies are assessed.

A.   JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) requests a 1-year approval for a generic information collection titled Development of an updated B Reader Certification Examination. The information collection supports formative research for the development of an improved physician certification examination.

Background

The NIOSH Coal Workers' Health Surveillance Program (CWHSP) is a congressionally-mandated medical examination surveillance program for monitoring the health of coal miners, specifically pneumoconiosis, a permanent, irreversible lung disease caused by the inhalation of respirable mineral dust. 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."

42 CFR 37.51 outlines that physicians who have demonstrated competence and ongoing proficiency in identifying and classifying the pneumoconioses on chest radiography in a manner consistent with the Guidelines for the Use of the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses are required to provide determinations of pneumoconioses for miners participating in the CWHSP. 42 CFR Part 37.52 outlines that physicians must take and pass "a specially-designed proficiency examination given on behalf of or by NIOSH at a time and place specified by NIOSH" to demonstrate competence in classifying pneumoconiosis and by passing will be certified as a "B Reader". B Reader certification lasts 5 years and must be renewed by passing a recertification exam before the 5-year certification expires. Under 42 CFR Part 37 as well as several other federal regulations[1], B Readers are required to evaluate chest radiographs of dust-exposed workers to identify pneumoconiosis. B Readers are also involved with epidemiologic evaluation, surveillance, and worker monitoring programs involving many types of pneumoconioses.

Since 1974, NIOSH has maintained and administered the B Reader Training and Certification Program which provides training material for physicians to learn to identify and classify lung diseases caused by dust exposures using chest radiography. Physicians can demonstrate on going competency in this skill by passing the initial certification examination and passing the

---

1   20 CFR 718, Standards for Determining Coal Miners' Total Disability or Death Due To Pneumoconiosis; 29 CFR 1910.1053 Occupational Safety and Health Standards General Industry (Respirable Crystalline Silica); 29 CFR 1910.1001 Occupational Safety and Health Standards for General Industry Subpart Z (Asbestos); 29 CFR 1915.1001 Occupational Safety and Health Standards for Shipyard Employment Subpart Z (Asbestos); 29 CFR 1926.1101 Occupational Safety and Health Standards for Construction Subpart Z (Asbestos); 29 CFR 1926.1153 Safety and Health Regulations for Construction (Respirable Crystalline Silica);30 CFR 90 Mandatory Health Standards—Coal Miners Who have Evidence of the Development of Pneumoconiosis; 42 CFR 37 Specifications for Medical Examinations of Coal Miners

recertification exam prior to the expiry of their 5-year certification. The initial certification exam (Analog-based B Reader Exam) requires the physician to complete ILO classifications for 125 chest radiographs using a computer reading station equipped with medical grade monitors for viewing the radiographs (see **Attachments 1 and 2**—BViewer© screenshots and CDC/NIOSH (M) 2.8: Radiograph interpretation form). The number of B Readers has been on a steady decline since the mid-1990s, falling from more than 700 B Readers to 172 in 2019.

The B Reader training material and examination was originally developed using analog film-based chest radiographs. The use of digital radiography has almost completely replaced analog film in the U.S., such that over 99% of chest radiographs submitted to the CWHSP are digitally-acquired. Therefore, to modernize the certification process to best align with current standards of practice, NIOSH has worked, with the assistance of the American College of Radiology, over the past several years to develop a new training syllabus and examination using digitally-acquired chest radiographs.

It is now necessary to pilot the draft version of this new examination to determine its performance and select a scoring approach which aligns with the existing program and best demonstrates physician's ability to classify the pneumoconioses on chest radiography. This project seeks to invite (see **Attachment 3**— Script inviting participation via phone or email) physicians who plan to take the existing examination (Analog-based B Reader Exam) to also take draft of the new examination (2019 Digital B Reader Exam) such that an examinees performance on both exams can be compared and by analyzing the results of multiple test-takers, NIOSH can determine an appropriate scoring algorithm and identify any questions or parts of the test that may need further attention. The 2019 Digital B Reader Exam will require the physician to complete ILO classifications for up to 80 chest radiographs using the same computer reading station as the Analog-based B Reader Exam and complete 25 multiple choice questions (See **Attachment 4**—Example multiple choice questions)

The information collected for a project will be maintained or stored locally under strict access controls limited to the local project leader/manager or his/her designate. Under no circumstances will an individual be identified using a combination of variables such as gender, race, birth date, and/or other descriptors.

2. Purpose and Use of Information Collection

The B Reader Training and Certification program is covered under the Coal Workers' Health Surveillance Program OMB Approval #0920-0020 – Expiration date 09/30/2021.

The purpose of this project is to generate general methodological data on the performance of the new draft examination in comparison with the current Analog-based B Reader Exam. Physicians who are interested in becoming certified B Readers take the current Analog-based B Reader Exam at NIOSH and the exam is offered on a monthly basis or at the request of the physician given notice and availably of staff. Once a candidate physician contacts NIOSH to schedule a date/time to sit for the exam they will be invited to participate in the project and take the draft of the new examination (2019 Digital B Reader Exam) on the same day that they sit for the Analog-based B Reader Exam. Participation will be voluntary. During this project period, certification determinations for the physicians will continue to be made based upon their performance on the Analog-based B Reader Exam, but data from both exams will be used to determine the performance of the 2019 Digital B Reader Exam.

There is no alternative source of data that could be used in substitution of this data collection proposal. NIOSH cannot replace the Analog-based B Reader Exam with the 2019 Digital B Reader Exam without demonstrating their equivalence.

Data from the 2019 Digital B Reader Exam will be analyzed to ensure an appropriate passing score is assigned, as well as identify parts of the exam that are not discriminatory for passing/failing the exam (e.g. if all examinees fail a specific section then that section is not discriminating between those who demonstrate competency and those who do not).

In order to sit for the B Reader Exam, NIOSH requires physicians to be licensed—no specific specialty is required. Most B Readers are radiologists, pulmonologist, or occupational medicine physicians. This same

3. Use of Improved Information Technology and Burden Reduction

The examinations are electronic and are taken on CDC/NIOSH computer systems using a software program that was developed and is maintained by NIOSH called BViewer© (See **Attachment 1** — BViewer © program screen shots). This software collects examinee responses for the classification of the chest x-rays and has reduced the overall testing time when compared to manually filling out responses using pen/paper. Volunteers will take the current exam in the morning and new examination in the afternoon using the same computer equipment. At this time due to the need to maintain the integrity of the exam images, the exam must be given on a CDC/NIOSH computer system and there is not a web-based option for examinees to have greater flexibility exam location. However, in order to minimize the time burden on volunteers and incentivize participation, NIOSH is proposing to offer to travel a CDC/NIOSH staff member and testing computer system to an academic or medical facility nearest the volunteer for exam administration for up to 25 examinees, prioritizing physicians in small private practices to best minimize the impact on small entities.

4. Efforts to Identify Duplication and Use of Similar Information

Data collected on the 2019 Digital B Reader Exam cannot be used or modified for use in other purposes. NIOSH, in collaboration with the American College of Radiology, has developed this exam and must maintain the integrity by not sharing exam questions or answers or releasing test radiographs. Therefore, there are no similar data or information available on this specific topic.

5. Impact on Small Businesses or Other Small Entities

Some physician volunteers may practice in small/private practice setting; therefore we have proposed to offer to travel a CDC/NIOSH computer system to an academic or medical facility nearest the volunteer for exam administration. We would offer this option for up to 25 examinees, prioritizing physicians in small private practices to best minimize the impact on small entities by reducing travel time to NIOSH-Morgantown.

6. Consequences of Collecting the Information Less Frequently

No more than 50 physicians will participate by taking the 2019 Digital B Reader Exam one time over the course of 9 months. Without data collected on the performance of the 2019 Digital B Reader Exam, NIOSH is not able to validate and release the new exam, and therefore the training material and examination will remain in an outdated format that becomes less clinically relevant as time goes on. Overtime this will affect physicians' ability to train and become certified B Readers, thus further degrading the population of B Readers in the U.S. that can participate in federally mandated screening and workers' compensation programs that have been previously discussed. This will severely limit and potentially bias worker's ability to obtain accurate respiratory health information.

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

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 Agencies

The Federal Register notice was published for this collection on July 18, 2016, Vol. 81, No. 137, pp. 46680. No public comments were received.

9. Explanation of Any Payment or Gift to Respondents

We propose different incentives for (1) volunteers who travel to NIOSH-Morgantown and those who (2) NIOSH staff will travel with a CDC/NIOSH computer system to a location closer to the volunteer.

1. Typically, the Analog-based B Reader Exam is offered at the NIOSH-Morgantown facility in the morning. Those who volunteer to stay and take the 2019 Digital B Reader Exam will need to take this exam in the afternoon and thus would likely incur an additional night in a hotel and half to full additional day of lost productivity. Given this population of physicians can have an hourly salary above $200, we are proposing to provide this population of volunteers with a $500 token of appreciation which will at least cover their additional travel expenses.

2. If NIOSH staff travel to a location close to the volunteer, we propose a $160 token of appreciation to the volunteer, reflective of a $40/hour for an exam that we estimate will take about 4 hours to complete.

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

Data collected by this project will be collected alongside and maintained in the same manner as Coal Workers' Health Surveillance Program OMB Approval #0920-0020 – Expiration date 09/30/2021. In that approval, privacy act applies since full names and partial SSNs are required for absolute identification in order to fulfill the mandate of the Act. The form (**Attachment 5—**2.12 CWHSP Physician Cert) under OMB #0920-0020, is used to collect information on physicians taking the examinations. Because the volunteers are seeking to obtain B Reader certification

(through taking the Analog-based B Reader Exam) it is necessary to collect this information in order to process and store their examination and certification results in a manner consistent with our program's practice This information is only collected under OMB #0920-0020. No additional personally identifiable information will be collected as part of this genIC.

CDC will treat data/information in a secure manner and will not disclose, unless otherwise compelled by law.

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

IRB Approval

The Coal Workers' Health Surveillance Program, to which the B Reader Training Syllabus and Examination fall under, has received a non-research determination (HSRB 11-DRDS-NR03) as a surveillance activity (**Attachment 6—IRB Non-research Determination**).

Sensitive Questions

There are no sensitive questions within this proposed project.

A.12. Estimates of Annualized Burden Hours and Costs

The annualized response burden is estimated at 20,000 hours.

We anticipate approximately 50 information collections per year. These may include eligibility screening collections, surveys or interviews, and focus groups.

Exhibit A.12.A   Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
Physician test takers traveling to the NIOSH-Morgantown facility to take the exam	2019 Digital B Reader Exam	25	1	4	100
Physician test takers that NIOSH staff will travel to an academic or medical institution near	2019 Digital B Reader Exam	25	1	4	100

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
their home and provide the exam					
Total		**50**	1	4	**200**

A.12.B Estimated Annualized Costs

Collections by health jurisdictions are generally funded through cooperative grants and these will be noted in the specific collection requests. The annualized cost to the respondent is segmented accordingly in Exhibit A.12.B.

The United States Department of Labor, Bureau of Labor Statistics May,2015 http://www.bls.gov/oes/current/oes291069.htm.) data were used to estimate the hourly wage rate for the general public and for private providers for the purpose of this generic request. Each project will have cost specific to the category of the respondents. Because it is not known what the wage rate category will be appropriate for the specific projects (or even whether they will be employed at all), the figure of $20.00 per hour was used as an estimate of average hourly wage across the country.

Exhibit A.12.B.   Annualized Cost to Respondents

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Data collection (Physicians and Surgeons)	200	$91.46	$18,292

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

CDC does not anticipate providing start up or other related costs to private entities.

A.14. Annualized Costs to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	CDC Project Officer (GS-12/13, 0.25 FTE)	$20,320

	CDC Data Manager (GS-9/10, 0.125 FTE)	$6,755
	CDC Travel (25 trips)	$25,000
	Subtotal, Direct costs	$52,075
	TOTAL COST TO THE GOVERNMENT	$52,075

A.15. Explanation for Program Changes or Adjustments

This is a new generic information collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Up to 50 physicians will participate in this project over the course of the first 9 months following approval. Data will be analyzed and used to assess the comparability of the Analog-based B Reader Exam and 2019 Digital B Reader Exam and assign an evidence-based passing score. The 2019 Digital B Reader Exam will then be officially implemented with a 3-6 month phase out of the Analog-based B Reader Exam. Data on the passing score and statistics on the pass/fail rate and over all population performance will be published and periodically updated on the NIOSH B Reader website (https://www.cdc.gov/niosh/topics/chestradiography/breader.html) and through medical journal articles like those previously published (Wagner et al 1992; Halldin et al *in press* 2019).

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

The display of the OMB expiration date is not inappropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

REFERENCE

20 CFR 718, Standards for Determining Coal Miners' Total Disability or Death Due To Pneumoconiosis

29 CFR 1910.1053 Occupational Safety and Health Standards General Industry (Respirable Crystalline Silica)

29 CFR 1910.1001 Occupational Safety and Health Standards for General Industry Subpart Z (Asbestos)

29 CFR 1915.1001 Occupational Safety and Health Standards for Shipyard Employment Subpart Z (Asbestos)

29 CFR 1926.1101 Occupational Safety and Health Standards for Construction Subpart Z (Asbestos)

29 CFR 1926.1153 Safety and Health Regulations for Construction (Respirable Crystalline Silica)

30 CFR 90 Mandatory Health Standards—Coal Miners Who have Evidence of the Development of Pneumoconiosis

42 CFR 37 Specifications for Medical Examinations of Coal Miners

Halldin C.N., Hale J., Weissman D., Attfield A., Parker J.E., Petsonk E.L., Cohen R.A., Markle T., Blackley D.J., Wolfe A.L., Tallaksen R, Laney A.S. The NIOSH B Reader Certification Program---An Update Report (1987–2018) and Future Directions. *In Press*. *JOEM*.

Wagner, G. R., Attfield, M. D., Kennedy, R. D., & Parker, J. E. (1992). The NIOSH B reader certification program. An update report. *Journal of occupational medicine.: official publication of the Industrial Medical Association, 34*(9), 879-884.