



February 27, 2025

*Submitted via Regulations.gov*

NIOSH Docket Office  
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**Re: (CDC-2024-0103; NIOSH-355) Expansion of NIOSH B Reader Certification Eligibility; Request for Information; Comments of the American College of Radiology**

The American College of Radiology (ACR)—a professional association representing more than 40,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to file comments with the Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) regarding the agency’s Request for Information (RFI), “Expansion of NIOSH B Reader Certification Eligibility” published in the Dec. 17, 2024, *Federal Register* (CDC-2024-0103; NIOSH-355). The ACR has a long history of collaboration with CDC/NIOSH to support B Reader certification and related occupational surveillance programs to ensure demand for International Labour Organization (ILO) classifications of chest radiographs can be met by a well-trained, highly qualified physician workforce. The ACR has for many years offered the nation’s premier educational course to prepare prospective B Readers to take NIOSH’s certification exam, and recently we contributed syllabus updates under contract with the agency.

The NIOSH RFI focused on the controversial concept of expanding B Reader certification eligibility beyond radiologists and other physicians to non-physician Nurse Practitioner (NP) and Physician Assistant (PA) personnel. The purpose of the expansion discussed in the RFI would be to increase the B Reader population; however, the evidence does not support the assumed inability of physicians to meet current demand levels. Expanding eligibility to non-physicians would contradict various HHS and Department of Labor regulations and the U.S. Government’s own guidelines for federal agencies that provide x-ray services.<sup>1</sup> More importantly, it would promote substandard and inconsistent care of questionable accuracy and integrity, which would be an indefensible disservice to patients in the surveilled occupations, their families, and their employers.

**B Reader Demand**

The Department of Labor’s Mine Safety and Health Administration (MSHA) published a final rule on April 18, 2024, titled “Lowering Miners’ Exposure to Respirable Crystalline Silica and Improving Respiratory Protection,” in which it responded to concerns regarding access to B Readers:

*“After consulting NIOSH, MSHA determined there are B Readers with remote reading capabilities available to meet the demands of the final rule. Therefore, MSHA finds that the*

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<sup>1</sup> <https://www.epa.gov/sites/default/files/2015-05/documents/fgr14-2014.pdf>

*limited number of B Readers in certain geographic locations will not be an obstacle for (mine) operators. MSHA further concludes that any increase in demand for these services can be addressed by providers.”<sup>2</sup>*

Real-world experiences of certified B Readers confirm NIOSH and MSHA’s 2024 assessment of supply and demand. The ACR requested feedback from current, former, and prospective certified B Readers to determine caseload/capacity, digital capabilities, and program perspectives, and in doing so heard from a sizable portion of that population. Most currently certified B Readers who responded to ACR’s request do not routinely receive cases; some are never contacted for work requiring NIOSH certification. Several former B Readers allowed their certification to lapse due to an apparent lack of demand. ACR heard from a few B Readers with higher case volumes, though these were a minority of respondents, and all were readily able to expand access if needed. Without exception, all radiologist B Readers who responded to ACR have the technological capability to read remotely without regard to geographical location. That being said, there may be benefit in the federal government giving reassurance via guidance on reading across state lines (including reading for states in which the B Reader does not maintain a license) and providing clinical reads alongside B reads. The ACR believes, as NIOSH and MSHA believed in 2024, that any perceived shortage of certified B Readers is inaccurate; the real issue is maldistribution of cases to current B Readers.

While MSHA’s 2024 final rule and prior regulatory and standards changes intuitively seemed likely to increase demand, this may not be the reality. The population of miners employed by the U.S. coal mining industry has declined by over 50 percent over the past 15 years;<sup>3</sup> the B Reader population has had similar reductions by percentage. Moreover, major innovations in radiology information technology, medical imaging data standards/exchange, and teleradiology over that period have enabled radiologist B Readers to increase efficiency and expand capacity. The ACR agrees with MSHA and NIOSH’s perspective in 2024 that any unforeseen real-world increase in demand—distributed effectively and appropriately compensated—would be met by radiologists and other physicians joining or rejoining the program as most current B Readers are not experiencing increased demand for their services at this time.

### **NIOSH Challenges**

NIOSH’s current system of matching demand with B Readers is limited to a static online phone directory. The directory encourages users to filter physicians by state despite the ubiquitous technical ability of radiologist B Readers to read remotely across different geographic locations. B Readers rarely receive unsolicited calls for their services, and many have reported the directory is outdated. Most B reading work is acquired either via established contracts managed by teleradiology companies or via networking/connections with retired/former B Readers. Some current and former B Readers have reported challenges contacting NIOSH to update their directory data. It is difficult for infrequent B Readers to justify maintaining their certifications when they are not routinely receiving cases.

B reading is generally not the primary revenue stream for radiology providers that perform these services, even for those that regularly receive this work. Objectivity is encouraged when a practice does not financially depend on B reading contracts. Nonetheless, it is obviously necessary for

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<sup>2</sup> <https://www.federalregister.gov/d/2024-06920/p-1055>

<sup>3</sup> <https://www.statista.com/topics/5165/coal-mining-in-the-us/#topicOverview>

certified B Readers to recover their investments in the additional training, certification, physician time, and infrastructure to justify obtaining or renewing NIOSH certification. There are perceptions of inadequate, noncompetitive rates in the Coal Workers' Health Surveillance Program (CWHSP) in particular, which may lead to a smaller subset of certified B Readers able to allocate practice time/resources to CWHSP cases.

While the ACR has made tremendous progress with its educational offerings, NIOSH's certification exam is generally regarded as rigorous and challenging for even subspecialized thoracic radiologists. Radiologists, in general, are demonstratively the best performers on the exam compared to other physicians due largely to their primary practice focus on interpreting medical imaging studies. Certification must be maintained on a 5-year cycle regardless of caseload and performance, which may not be necessary for professionally active B Readers. For many participants, exam locations and options can pose travel, cost, and resource challenges.

### **ACR-Recommended Solutions**

The ACR welcomes further dialogue and collaboration with CDC/NIOSH on any or all the below recommendations to improve the program:

- **Modernize Matchmaking and Improve Case Distribution** – Available data does not indicate the B Reader population's inability to meet demand. Thus, the underlying assumptions in NIOSH's RFI are unsupported by real-world practice experiences. Instead of the controversial concept in the RFI, NIOSH should work to modernize and enhance case distribution so it can electronically and dynamically match cases with available B Readers more efficiently. In modernizing this matchmaking system, NIOSH should consider functions such as centralized electronic order entry and capacity tracking. NIOSH can also leverage this software platform to enable quality assurance/quality measurement.
- **Evaluate and Improve Incentives** – NIOSH and other agencies must reevaluate and adjust incentives/compensation in occupational surveillance programs, such as the CWHSP. B Readers and practices that employ physicians with B Reader certification must have the ability to recover their investments in the training, certification, maintenance of certification, compliant workstation/infrastructure, and physician time.
- **Update the Self-Study Syllabus** – The ACR, under contract from NIOSH, previously developed a new digital exam and self-study syllabus, both of which were created in a rigorous, industry-standard method. The current online syllabus, edited and hosted by NIOSH, continues to have errors (wrong images, misclassifications, incorrect facts) despite ACR's feedback. NIOSH should expeditiously update its syllabus pursuant to prior recommendations.
- **Extend Certification to 10 Years** – NIOSH should consider extending certification an additional 5 years to a 10-year cycle. Availability of this extension could depend on whether the physician has read a specified number of cases within the first 5 years. Additionally, NIOSH should consider expanding the available location(s) for recertification, or alternatively, converting entirely to remote testing, which is a reliable process that has been available to academic institutions and medical specialty boards for many years.

- **Fund AI Tools for B Reader Use** – NIOSH should consider a “challenge grant” or other federal funding opportunity for the medical device industry to develop an augmentative CADe/x (computer-aided detection and diagnostic) software device to be optionally implemented and used by radiologist B Readers. The algorithm could provide ILO classification recommendations to the certified B Reader during the read, thereby increasing efficiencies. While there are several Food and Drug Administration (FDA)-authorized CAD-type radiology devices for digital radiography, it is unlikely industry would invest in developing a specialized ILO classification-focused algorithm without training/testing data from NIOSH. Further incentives in the form of CDC funding opportunities and an expedited pathway to market authorization (e.g., FDA’s Breakthrough Devices program) should be considered. CDC/NIOSH could also subsidize adoption or make the tool openly accessible to justify acquisition/implementation by B Readers and practices
- **Promote B Reader Certification** – NIOSH should consider improving advertising/marketing and agency outreach to previously certified B Readers and other interested physicians. NIOSH should prioritize incoming B Reader communications and rapid responses to physician inquiries.
- **Improve Imaging Quality Assurance** – NIOSH should update the 2011 NIOSH guideline, “Application of Digital Radiography for the Detection and Classification of Pneumoconiosis”<sup>4</sup> and institute a rigorous program to monitor image quality from sites certified to obtain chest radiographs for screening programs. Quality assurance should ensure monitoring exposure control, limited post processing, and edge enhancement. NIOSH documents (guidelines and syllabus) should be updated with more relevant content and examples regarding digital image quality issues and artifacts that can mask or mimic pneumoconiosis.

## ACR Responses to NIOSH RFI Questions

### 1) **What is the current demand for B Readers, and would expanding the program to include nurse practitioners and physician assistants help meet this demand?**

As described above, the primary challenge is not overwhelming demand relative to the size of the B Reader population, but instead NIOSH’s passive and outdated approach to matchmaking/case distribution. This problem would not be alleviated by expanding the certified B Reader population to non-physicians and may even exacerbate current challenges justifying recertification of physicians and workstation/infrastructure costs. Few certified B Readers currently receive high volumes of ILO classification cases, and NIOSH does not have modern systems to distribute cases and assess the ongoing ability of B Readers to complete the cases they receive in a timely fashion. The lack of apparent demand—or, more accurately, the inability to distribute and track demand with an organized system—has directly influenced reductions over time in the certified B Reader population. Increasing the certified B Reader pool significantly could also have the unintended consequence of further discouraging existing or formerly certified B Readers from continuing to participate in the program as their relevant case volumes would likely decline.

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<sup>4</sup> <https://www.cdc.gov/niosh/docs/2011-198/pdfs/2011-198.pdf?id=10.26616/NIOSH PUB2011198>

The standard of care in digital radiography is that physicians who meet appropriate qualifications (e.g., radiologists) interpret the images, and that physicians without radiology qualifications are limited to the specific anatomic areas pertinent to their specialties.<sup>5</sup> The ACR strongly opposes the suggestion of expanding certification exam eligibility to non-physician NP and PA professionals. While NIOSH and ILO messages classification work as “noninterpretative,” this is an artificial and arbitrary differentiation, as characterization of disease or disease progression is effectively “interpretative” imaging care. Radiologist B Readers are responsible for all abnormalities or incidental findings on any reviewed image set, and the sample “Chest Radiograph Classification Form” in the appendices of the ILO “Guidelines for the use of the ILO International Classification of Radiographs of Pneumoconioses”<sup>6</sup> calls for documenting other abnormalities, including nearly 30 distinct non-classification-related findings. Non-physician B Readers would be unable to differentiate and report these findings.

Nurses and PAs are essential supportive personnel on physician-led health care teams. Their education, training, and experience levels are no substitute for the intensive and specialized training physicians receive. For radiologists, this training includes at least 13 years of education, including approximately 12,000-16,000 hours of clinical patient care during internship and residency. The postgraduate 4-year medical school requirement is foundational to the practice of medicine in that it entails a comprehensive understanding of the human body, its systems, functions and disease processes. While in medical school, radiologists study anatomy, physiology, pathology, pharmacology, and pathophysiology as is required of all graduating physicians. Medical school is followed by a 1-year clinical internship, and then a 4-year residency program interpreting tens of thousands of imaging studies under the supervision of a practicing radiologist. Most radiologists elect to continue their training with an additional 1-2-year post-residency fellowship program to hone their diagnostic skills in a particular subspecialty. Near the end of residency and again after beginning practice, radiology residents must pass multiple sets of board-certifying examinations. Further, ongoing maintenance of certification requirements ensure radiologists commit to continuing medical education, practice quality improvement, and ongoing professional development to ensure continued proficiency and expertise in the rapidly advancing field of medical imaging.

By contrast, NP and PA training programs include little specialized education in medical imaging. Training to become an advanced practice registered nurse (APRN) generally consists of a 2-3-year postgraduate masters or doctoral degree program, and 500-720 hours of nursing-relevant clinical training. A survey of family NP program directors reported that, within their programs, 25 percent of NPs had no radiologic training, 40 percent had less than 10 hours, 33 percent had 1-2 days, and 2 percent had a few weeks.<sup>7</sup> Roughly 85 percent of Doctor of Nursing Programs have a nonclinical focus on leadership-related skill tracks.<sup>8</sup> As for PAs, their postgraduate training typically consists of 1-year healthcare experience and a 2-year accredited PA program with a total of 2,000 clinical hours with no residency requirement or dedicated training in radiology.

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<sup>5</sup><https://gravitas.acr.org/PPTS/GetDocumentView?docId=135+&releaseId=2>

<sup>6</sup>[https://www.ilo.org/sites/default/files/wcmsp5/groups/public/@ed\\_dialogue/@lab\\_admin/documents/publication/wcms\\_867859.pdf](https://www.ilo.org/sites/default/files/wcmsp5/groups/public/@ed_dialogue/@lab_admin/documents/publication/wcms_867859.pdf)

<sup>7</sup>[https://www.npjjournal.org/article/S1555-4155\(17\)30969-8/abstract](https://www.npjjournal.org/article/S1555-4155(17)30969-8/abstract)

<sup>8</sup><https://pubmed.ncbi.nlm.nih.gov/30943837/>

Critically, B Reader training/certification assumes a foundation of pulmonary and diagnostic radiology interpretive expertise that NPs and PAs do not possess. The related surveillance programs require consistent and reliable classifications which would be impossible to attain for non-physicians who are not held to the same strict standards and codes of ethics. Medical licensure laws vary by state, and non-physician review of these cases can create legal and ethical challenges. The presumption of even the most basic adequacy in reviewing cases for pneumoconiosis overlooks the clinical fact that every case review is, effectively, image interpretation, with an inherent medical responsibility to interpret every finding visible on the examination. Providing the ILO classification while overlooking subtle abnormalities, such as early imaging findings of malignancy, can have tragic implications for patients as many occupational exposures also increase cancer risk, specifically lung cancer and mesothelioma.

If NIOSH were to hypothetically implement this ill-advised policy, NPs and PAs would inevitably encounter myriad real-world barriers in establishing B reading practices. All the above-mentioned challenges experienced by the physician B Reader population would also apply to non-physician B Readers. The NIOSH certification exam is resource intensive and rigorous even for diagnostic radiologists, and it is unlikely NP/PAs would pass the exam barring substantial reductions in rigor and quality. Occupational surveillance/screening is comparatively highly litigious, and healthcare practices that employ or provide physician supervision of non-physician B Readers may not be as willing to accept their expanded liability exposures. Compliant radiology workstations, effectively routinely available to all radiologists, are sophisticated, expensive, and require ongoing resources, updates, quality assessment, and cybersecurity risk mitigations. Moreover, per NIOSH's website, the primary overseers of ethical practice by B Readers are state medical boards; this physician-specific oversight mechanism would be nominal or nonexistent for NP/PA B Readers, thereby raising further questions of ethics, accuracy, and consistency.

**2) *Are there specific geographic areas or populations that might benefit from having nurse practitioners and physician assistants certified as B Readers?***

Advances in digital radiography and teleradiology have eliminated geography as a consideration when evaluating B Reader access within the United States. All current radiologist B Readers have the technological capability to expand beyond their geographical areas to any patient population in need. Expanding certification eligibility to non-physicians would not increase access but may exacerbate the widespread matchmaking/case distribution problems and deter radiologists and other physicians from becoming certified and reading for surveillance programs.

NIOSH and other federal agencies could explore issuing guidance on providing these services across state lines. It remains unclear whether a physician in the state of where the study is performed needs to provide a clinical read in addition to an ILO classification provided by a physician physically located in another state. Ideally, a classification form and a clinical report would be generated anywhere in the country by a board-certified radiologist without the cost of a separate, additional clinical chest x-ray interpretation by a physician certified by the in-state medical board. Federal guidance should unambiguously cover these and other nontechnical considerations of remote B reading services, including consideration of multi-state licensing compacts.<sup>9</sup>

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<sup>9</sup> <https://telehealth.hhs.gov/licensure>

**3) Are there any potential risks associated with expanding the B Reader certification to nurse practitioners and physician assistants and, if so, how can those risks be mitigated?**

The current B Reader certification exam was created with the assumption of prior physician-level training and experience in the interpretation of chest x-ray studies. Non-radiologists/non-physicians are not familiar with the differences of conventional and digital radiography. They are not formally trained to recognize image noise, under/overpenetration, edge enhancement, or dose creep. Even non-radiologist physician B Readers have generally struggled with radiology fundamentals; this is in part why the non-radiologist failure rate on the quality component of the NIOSH certification exam is problematic.

Adding NPs and PAs would eliminate state medical boards from overseeing accurate and ethical practice by B Readers. NIOSH and the surveillance programs have historically struggled to monitor and address outlying performers even in the physician B Reader population and could not possibly have confidence that non-physician B Readers would be accurate, consistent, and sufficiently monitored. Employers/patients may also not have recourse against substandard/unethical practice. Physicians supervising NPs and PAs in their clinics/offices are unlikely to have the radiography expertise to serve in those supervisory roles effectively. Moreover, non-physicians are simply not adequately trained and board-certified to expertly identify, differentiate, report, and manage other radiology findings common to ILO classification services, including a myriad of infectious, inflammatory, traumatic, and neoplastic pathologies.

To be clear, the NIOSH RFI suggests an objectively substandard model of care. It is impossible for the agency to mitigate all the risks of non-physicians providing specialist-level physician services. B reading cannot be safely and effectively incorporated into traditional NP/PA practice models in a manner that provides confidence to public or government stakeholders, and we believe the CWHSP would be particularly vulnerable to a resultant decline in quality and consistency.

**4) ILO classification of chest radiographs is not the same as clinical interpretation. Are there states where scope of practice and standards of care allow nurse practitioners and physician assistants to perform clinical interpretation of chest radiographs without physician oversight? In states where physician oversight is required for clinical interpretation, is it also required for ILO classification? What would be the best approach to ensuring that appropriate clinical interpretations are obtained for all contemporary chest radiographs undergoing ILO classification by nurse practitioners and physician assistants?**

The description of ILO classifications as distinct from interpretive care has historically been useful for separating A reads from B reads and justifying the involvement of non-radiologist physicians such as pulmonologists. However, this is generally an artificial, and potentially dangerous distinction. ACR's standing policies and practice guidelines disapproving non-physician involvement in the interpretation of imaging do not exempt ILO classifications, and it is unlikely this distinction would be supportable in liability cases. Moreover, interpretation and reporting of abnormalities in the imaging are integral parts of these services, as evidenced by ILO guidelines.

As noted above, NIOSH has generally struggled to help distribute cases throughout the certified B Reader population, and many B Readers do not have ample opportunities to use their NIOSH

certifications. Therefore, with respect to Question 4, it is unclear how NIOSH could ensure “appropriate clinical interpretations” are obtained in situations in which ILO classifications are performed by non-physician B Readers, as this would necessitate electronic ordering/referral processes that are not part of the program. NP/PAs may also be unable to order follow-up care in states where they practice. A more efficient and clinically safe approach would be to create a system where a board-certified radiologist provided the clinical narrative and an ILO classification for one fee; in many situations, this is done by one physician providing the clinical interpretation and billing and the B Reader providing the ILO classification and billing separately.

In several states, some APRNs are legally allowed to “interpret” radiographs (e.g., for suspected pneumonia), but these states may require additional education, training, and certification for APRNs to perform such tasks. Several of these states require a licensed practitioner/physician to order imaging procedures such as following up on abnormalities via additional imaging studies read by board-certified radiologists. Our understanding is that in states that controversially allow nurse-level interpretation, physician oversight is required for ILO classifications. Importantly, real-world radiography practice by non-physicians is limited by myriad other factors such as payer/reimbursement requirements, on-label medical device use considerations, facility credentialing and privileging, availability and cost of malpractice insurance, and a patient’s willingness to utilize a non-physician for medical care, among others.

**5) *How do you anticipate different interested parties (e.g., physicians, nurse practitioners and physician assistants, industry representatives, workers, health profession boards) would view the potential expansion of the B Reader program to include non-physicians?***

The ACR received feedback from certified thoracic radiologists that the identification of interstitial lung disease threshold on chest radiographs is one of the most challenging tasks they are asked to perform. NIOSH’s consideration of non-physician expansion fails to take into account all the ancillary knowledge needed to rate the quality of a study and identify potential sources of technique/post processing errors in addition to primary and secondary diagnoses. NIOSH must not underestimate B reading as simple pattern recognition and matching with ILO standards rather than a physician-level service requiring specialized radiology training, as this perspective can have a critical impact on surveilled workers and their employers.

There has been a resounding medical community backlash against NIOSH’s RFI, as evidenced by many comments from individual physicians on the public docket. The ACR’s official position, as established by the ACR Council, strongly opposes non-physician involvement in radiology image interpretations. This established position does not exempt ILO classifications by B Readers, which involves characterizations of disease/disease progression and routinely calls for abnormality identification in these imaging studies.

If NIOSH were to ignore medical community feedback and implement this type of expansion, non-physician B Readers are realistically unlikely to thrive providing ILO classification services. In addition to the training discrepancy and lack of fundamental radiology expertise, reading workstations are sophisticated and expensive, occupational surveillance/screening is comparatively litigious, NIOSH’s matchmaking is inefficient and reliant on network/teleradiology contacts that NP/PAs do not possess, and medical licensure laws and rules largely restrict non-



physician B reading services even in states that nominally allow certain APRNs to interpret radiographs.

Moreover, prior to establishing a self-sustaining B reading practice, the act of passing the certification exam would be prohibitive for non-physicians (even more so than it is currently for non-radiologist physicians). NIOSH would likely need to reduce the rigor of training and the exam, which would call into question the value of certification, the competence of future B Readers, and the availability and adequacy of training programs for non-physician B Readers.

**6) What challenges might arise during the implementation of this expansion, and how could they be effectively managed?**

In addition to the previously mentioned practical considerations for NP/PAs, NIOSH would also need to work across the federal government and state agencies to change relevant laws and regulations (beyond just 42 CFR Part 37) to allow certified B Reader NP/PAs to use their certifications. This would take many years to implement, while disincentivizing more physicians from entering the program and replacing former/retired B Readers. NIOSH should instead invest its time and resources into program modernization and case distribution to support current and future physician B Readers.

**7) Do you have any other information or comments relevant to whether nurse practitioners and physician assistants should be able to become B Readers and, if so, the best way to implement that expansion?**

Despite a gradual reduction in the B Reader population commensurate with the percentage reduction of relevant miner populations, it is unclear from data or professional experiences of B Readers that the current population is unable to meet demand. In real-world practice, many/most B Readers who provided ACR with feedback are not routinely receiving work requests requiring their NIOSH certifications. Finding a way to better engage the existing B Reader population via modernized matchmaking and incentives should be NIOSH's topmost priority. Expanding eligibility for certification to NPs and PAs should not be considered, as this would result in substandard and inconsistent quality of care, new ethics/oversight concerns, medicolegal questions and uncertainties, and decreased physician involvement in related surveillance programs.

Thank you for your consideration of these comments. The ACR invites continued dialogue and collaboration with CDC/NIOSH staff to modernize and improve the current program. Please contact Michael Peters, Senior Director, Government Affairs, at [mpeters@acr.org](mailto:mpeters@acr.org), with questions.

Sincerely,



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