

**Memorandum of Understanding between the Department of Labor
Office of Workers' Compensation Programs (OWCP) and the
Department of Health and Human Services, Centers for Disease Control
and Prevention, National Institute for Occupational Safety and Health
(NIOSH) establishing a B reader quality assurance program**

Under the Black Lung Benefits Act (BLBA) and implementing regulations, 30 U.S.C. §§ 901 – 944; 20 C.F.R. Parts 718, 725, the existence of pneumoconiosis may be established based on the appearance of specific pulmonary abnormalities evident on a chest radiograph. The black lung regulations provide that when two or more chest radiograph reports from different physicians conflict, consideration must be given to the readers' respective radiological qualifications. Although a range of professional qualifications may be considered, a particularly important one is B reader certification, which NIOSH grants to physicians who pass a specially-designed examination that tests the reader's proficiency to classify chest radiographs for the presence and severity of radiographic changes using the standardized classification system for pneumoconiosis developed by the International Labour Organization (ILO). This qualification is especially important, because the ILO classification system is used for the reporting of pulmonary abnormalities considered in black lung benefits proceedings. Recognizing the important medical, legal, and societal impacts that B readers may have, NIOSH has had a longstanding commitment to a B reader code of ethics, which encourages B readers to adhere to standards of professionalism, honesty, and objectivity in all professional interactions and to report to appropriate authorities any individuals deficient in character or competence, or any B Readers who are engaging in fraud or deception. As of 2014, prospective B Readers were required to sign statements on their applications to take the B Reader certification or recertification examinations promising to adhere to the B Reader Code of Ethics.

It is expected that B readers' classifications in a case may differ, despite the B Readers' demonstrated proficiency, because the classification of chest radiographs is an inherently subjective process. However, a B reader's classifications should not markedly deviate from mainstream classifications indicating the presence or

severity of abnormalities associated with pneumoconiosis. Such misclassification could undermine a fair evaluation of a miner's entitlement to black lung benefits, particularly when the classifications relate to the presence or absence of "large opacities", which are indicative of severe disease and total disability under the BLBA.

In order to identify B readers who frequently misclassify large opacities associated with pneumoconiosis and to minimize, if not eliminate, their impact on the evaluation of black lung claims, it is the intent of OWCP, as administrator of the BLBA, and NIOSH, as the B reader certifying authority, to enter into this Memorandum of Understanding (MOU) establishing a B reader quality assurance program.

The B reader quality assurance (QA) program will operate as follows:

- OWCP will establish and maintain a QA disputed radiograph repository: a repository of disputed chest radiographs regarding the presence of large opacities consistent with pneumoconiosis submitted in black lung claims. A chest radiograph will be considered disputed when one or more B readers classify a radiograph as depicting large opacities consistent with pneumoconiosis and one or more B readers classify it as not depicting such opacities. OWCP will also establish and maintain a QA disputed readings repository: an electronic repository of scanned images of all B readings (generally submitted on form CM-933, Radiologic Interpretation) dated and signed by each B reader of a disputed radiograph. In addition, OWCP will establish and maintain a QA database: a database containing the names and readings of the B readers interpreting the disputed chest radiographs.
- OWCP will establish and maintain the QA disputed radiograph repository, the QA disputed readings repository and the QA database in accordance with designs, procedures and protocols to be established subsequent to this MOU's effective date. The repositories and associated database will contain no personally identifiable information (PII) concerning black lung claimants, although OWCP will establish procedures to ensure that each B reading can be linked to its respective chest radiograph in the absence of the black lung claimants' PII.

- OWCP will request in writing that NIOSH conduct a quality assurance review of each B reader who falls within the terms of the attached protocol, developed jointly by NIOSH and OWCP, which sets forth objective criteria for referring B readers to the quality assurance program. The quality assurance review request will identify the B reader, and include the disputed chest radiographs, the B reader's classifications of the disputed chest radiographs, the classifications of the disputed chest radiographs by other B readers, and other relevant information.
- After receiving OWCP's request, NIOSH will first determine if the request complies with the protocol for initiating a B reader quality assurance review. If so, NIOSH will then perform a quality assurance investigation.
- NIOSH will conduct the investigation in accordance with procedures to be established by NIOSH subject to OWCP's agreement. These procedures will be developed subsequent to this MOU's effective date. The NIOSH policy will include provisions for (1) informing B readers that a quality assurance investigation has been initiated; (2) developing and evaluating evidence relevant to OWCP's submission; (3) identifying possible actions NIOSH may take at the conclusion of an investigation; (4) allowing B readers an opportunity to challenge the initial investigation findings and notifying them of the final results of the investigation; and (5) informing OWCP whether the investigated B reader's certification remains effective or is suspended or revoked.

OWCP and NIOSH have a long history of working together to administer the BLBA. NIOSH, as OWCP's statutory scientific advisor, continues to provide highly relevant advice that assists OWCP in fulfilling the congressional mandate of awarding benefits to miners who are totally disabled by pneumoconiosis arising out of coal mine employment. The creation of a B reader quality assurance program represents an important effort to meet this mandate. NIOSH and OWCP anticipate that formal publication of these inter-agency activities, MOU, and protocol will help to ensure public trust in the adjudication of black lung claims.

Any modification of this MOU will be valid or binding on the parties only if agreed to by both parties and made in writing and signed by each of the parties. Either party shall provide 30 days written notice to the other party regarding any modification of a provision of this MOU.

Office of Workers' Compensation Programs



Michael A. Chance
Director, Coal Mine Workers' Compensation

September 22, 2015

Date

National Institute for Occupational Safety and Health



David N. Weissman, MD
Director, Division of Respiratory Disease Studies

September 24, 2015

Date

Attachment:
Protocol

Protocol for OWCP Referral of B Reader Classifications to NIOSH for Evaluation

Classifying the presence of “large opacities” in chest images has a very important impact on Black Lung Benefits proceedings, administered by the Office of Workers’ Compensation Programs (OWCP), because coal miners with large opacities are irrebuttably presumed to be totally disabled due to pneumoconiosis as provided by 20 C.F.R. § 718.304(a); 30 U.S.C. § 921(c)(3). Classifications are performed by physicians who are National Institute for Occupational Safety and Health (NIOSH)-certified B Readers. This quality assurance program, to be implemented by OWCP, focuses on OWCP reviewing and reporting classifications to NIOSH by NIOSH-certified B Readers whose findings are frequently inconsistent with other NIOSH-certified B Readers’ classifications of the same chest images for the presence or absence of large opacities.

The quality assurance program involves the following:

If at least one B Reader classifies a large opacity as present on the chest radiograph, OWCP personnel will examine such classification. If the OWCP examiners identify NIOSH-certified B Readers - employed by either the claimants or defendants in such cases - who provide classifications in 5 or more different cases over a 2-year period in which their classifications regarding the presence (or absence) of large opacities differ from **all** other NIOSH-certified B readers employed by the opposing side, then the OWCP examiners will refer such cases to NIOSH for evaluation.

The rationale for referring cases to NIOSH where there are significant variations among classifications provided by the B Readers involved in a case, is to ensure that the B Readers are performing classifications accurately, without bias, and based solely on radiographic findings. We recognize that there may be some subjectivity in the classification of chest radiographs and B Readers may disagree about classification of large opacities - particularly in borderline cases. Thus, this program will not focus on cases where at least one B reader on one side of the case agrees with the B reader of concern on the opposing side. Instead, this program focuses on B readers who frequently disagree with all B Readers on the opposing

side of a proceeding. To provide accurate classification of large opacities in chest radiographs, NIOSH recommends that OWCP refer B Readers to NIOSH for evaluation if the B Reader disagrees with all B Readers employed by the other side of the case about the presence (or absence) of large opacities as described by the ILO classification system in five or more cases within a 2-year timeframe. Materials provided to NIOSH by OWCP for conducting the evaluation will include the name of the B Reader; the 5 chest radiographic images in question; and all classification reports submitted for each of the 5 images within the 2-year time period.

Example: 1 – The case of B Reader Z

- a. Case 1
 - i. Defendant: B Reader Z, reading for the coal mine operator, finds no evidence of a large opacity.
 - ii. Claimant: B Readers S and T, reading for the miner, find evidence of a large opacity.
 - iii. Case assessment: This would count as one of the 5 cases of disagreement for B Readers Z, S, and T.
- b. Case 2
 - i. Defendant: B Reader Z, reading for the coal mine operator, finds no evidence of a large opacity.
 - ii. Claimant: B Readers U and V, reading for the miner, find evidence of a large opacity.
 - iii. Case assessment: This would count as one of the 5 cases of disagreement for B Readers Z, U, and V.
- c. Case 3
 - i. Defendant: B Reader Z, reading for the coal mine operator, finds a confluence of small opacities but no large opacity.
 - ii. Claimant: B Readers W and X, reading for the miner, find evidence of a large opacity.
 - iii. Case assessment: This would count as one of the 5 cases of disagreement for B Readers Z, W, and X.
- d. Case 4

- i. Defendant: B Reader Z, reading for the coal mine operator, finds no evidence of a large opacity.
 - ii. Defendant: B Reader S, reading for coal mine operator, finds evidence of a large opacity.
 - iii. Claimant: B Readers C, D and G, reading for the miner, find evidence of a large opacity.
 - iv. Case assessment: This would count as one of the 5 cases of disagreement for B Reader Z, but not for B Readers S, C, D, and G.
- e. Case 5
- i. Defendant: B Reader Z, reading for the coal mine operator, finds no evidence of a large opacity.
 - ii. Defendant: B Reader T, reading for the coal mine operator, finds evidence of a large opacity.
 - iii. Claimant: B Readers C, D and F, reading for the miner, find evidence of a large opacity.
 - iv. Case assessment: This would count as one of the 5 cases of disagreement for B Reader Z, but not for B Readers T, C, D, and F.

If these 5 cases occurred within a 2-year period, OWCP would refer B Reader Z to NIOSH for evaluation, because B Reader Z did not find evidence of large opacities in each case and his conclusions were inconsistent with all the B Readers' findings who read the same x-rays for claimants.

Example: 2 – The case of B Reader A

- f. Case 1
 - i. Claimant: B Reader A, reading for the miner, finds evidence of a large opacity.
 - ii. Defendant: B Readers B and C, reading for the coal mine operator, find no evidence of a large opacity.

- iii. Case assessment: This would count as one of the 5 cases of disagreement for B Readers A, B, and C.
- g. Case 2
 - i. Claimant: B Reader A, reading for the miner, finds evidence of a large opacity.
 - ii. Defendant: B Readers D and E, reading for the coal mine operator, find no evidence of a large opacity.
 - iii. Case assessment: This would count as one of the 5 cases of disagreement for B Readers A, D, and E.
- h. Case 3
 - i. Claimant: B Reader A, reading for the miner, finds evidence of a large opacity in the upper zone.
 - ii. Defendant: B Readers F and B, reading for the coal mine operator, find the presence of small opacities with a confluence of opacities in the upper zone.
 - iii. Case assessment: This would count as one of the 5 cases of disagreement for B Readers A, F, and B.
- i. Case 4
 - i. Claimant: B Reader A, reading for the miner, finds evidence of a large opacity.
 - ii. Claimant: B Reader H, reading for the miner, finds a confluence of small opacities but no large opacity (in this example, the miner employs 2 B Readers).
 - iii. Defendant: B Readers C, D and G, reading for the coal mine operator, find no evidence of a large opacity.
 - iv. Case assessment: This would count as one of the 5 cases of disagreement for B Reader A, but not for B Readers H, C, D, and G.
- j. Case 5
 - i. Claimant: B Reader A, reading for the miner, finds evidence of a large opacity.
 - ii. Claimant: B Reader I, reading for the miner, finds no evidence of a large opacity (in this example, the miner employs 2 B Readers).

- iii. Defendant: B Readers C, D and F, reading for the coal mine operator, find no evidence of a large opacity.
- iv. Case assessment: This would count as one of the 5 cases of disagreement for B Reader A, but not for B Readers I, C, D, and F.

If these 5 cases occurred within a 2-year period, OWCP would refer B Reader A to NIOSH for evaluation, because B Reader A discovered evidence of large opacities in each case and his conclusions were inconsistent with all the B Readers' findings who read the same x-rays for coal mine operators.

Example: 3 – The case of B Reader K

k. Case 1

- i. Defendant: B Reader K, reading for the coal mine operator, finds no evidence of a large opacity.
- ii. Claimant: B Reader AA, reading for the miner, finds evidence of a large opacity
- iii. Claimant: B Reader BB, reading for the miner, finds no evidence of a large opacity.
- iv. Case assessment: This would not count as one of the 5 cases of disagreement for B Readers K or BB, but would count as a case for B Reader AA.

l. Case 2

- i. Defendant: B Reader K, reading for the coal mine operator, finds no evidence of a large opacity.
- ii. Claimant: B Readers CC and DD, reading for the miner, find evidence of a large opacity.
- iii. Case assessment: This would count as one of the 5 cases of disagreement for B Readers K, CC, and DD.

m. Case 3

- i. Defendant: B Reader K, reading for the coal mine operator, finds a confluence of small opacities but no large opacity.
- ii. Claimant: B Reader EE, reading for the miner, finds evidence of a large opacity
- iii. Claimant: B Reader FF, reading for the miner, finds no evidence of a large opacity.
- iv. Case assessment: This not would count as one of the 5 cases of disagreement for B Readers K or FF, but would for B Reader EE.

n. Case 4

- i. Defendant: B Reader K, reading for the coal mine operator, finds no evidence of a large opacity.
- ii. Defendant: B Reader GG, reading for coal mine operator, finds evidence of a large opacity.
- iii. Claimant: B Readers FF, HH and II, reading for the miner, find evidence of a large opacity.
- iv. Case assessment: This would count as one of the 5 cases of disagreement for B Reader K, but not for B Readers GG, FF, HH, and II.

o. Case 5

- i. Defendant: B Reader K, reading for the coal mine operator, finds evidence of a large opacity.
- ii. Defendant: B Reader JJ, reading for the coal mine operator, finds no evidence of a large opacity.
- iii. Claimant: B Readers LL, MM and NN, reading for the miner, find evidence of a large opacity.

- iv. Case assessment: This would not count as one of the 5 cases of disagreement for B Reader K, LL, MM, and NN, but would for B Reader JJ.

OWCP would not refer B Reader K to NIOSH for evaluation based on these 5 cases within a 2-year period because only 2 “cases of disagreement” occur within the five cases. If OWCP identified 3 additional cases of disagreement within the same 2-year period where B Reader K provided classifications of large opacities that were in disagreement with all B Readers employed by the opposing side, then B Reader K would be referred to NIOSH for evaluation.

The quality assurance program also involves the following:

If the OWCP examiners identify NIOSH-certified B Readers - employed by OWCP - who provide classifications in 5 or more different cases over a 2-year period in which their classifications regarding the presence (or absence) of large opacities differ from **all** other NIOSH-certified B readers employed by the claimant or differ from **all** other NIOSH-certified B readers employed by the employer, then the OWCP examiners will refer such readings by the OWCP-employed B Reader to NIOSH for evaluation.