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**National Institute for Occupational Safety and Health (NIOSH) Quality Assurance Review of B Readers' Classifications Submitted in the Department of Labor (DOL) Black Lung Benefits Program**

draft February 3, 2016

This document implements a Memorandum of Understanding (MOU) between the DOL Office of Workers' Compensation Programs (OWCP) and NIOSH establishing a B Reader quality assurance program.<sup>1</sup> It provides procedures for the NIOSH Respiratory Health Division to follow when conducting quality assurance reviews of B Readers' classifications of coal miners' radiographs submitted in the Black Lung Benefits Program. It also specifies the corrective measures to be taken based on quality assurance reviews.

The B Reader Certification Program was established by NIOSH pursuant to the Federal Mine Safety and Health Act of 1977, 30 U.S.C. § 843. B Readers are physicians certified according to NIOSH regulations in 42 C.F.R. § 37.51 for their abilities to follow the International Labour Office (ILO) system to perform the classifications.<sup>2</sup> B Readers may submit classifications as part of OWCP's process of evaluating claims for compensation under the federal Black Lung Benefits Act, 30 U.S.C. §§ 901 to 944.

This quality assurance review activity focuses on the classification of the presence or absence of large opacities in chest radiographs as described in the ILO classification system, because coal miners with large opacities are irrebuttably presumed to be totally disabled, or to have died, from

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<sup>1</sup> The 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. September 2015. <http://www.dol.gov/owcp/dcmwc/MOUbetweenOWCPandNIOSH.pdf>.

<sup>2</sup> See, ILO. Guidelines for the use of the ILO International Classification of Radiographs of Pneumoconioses, Revised edition 2011. [http://www.ilo.org/safework/info/publications/WCMS\\_168260/lang-en/index.htm](http://www.ilo.org/safework/info/publications/WCMS_168260/lang-en/index.htm).

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pneumoconiosis under 30 U.S.C. § 921(c)(3). Thus, determinations of large opacities have a significant impact on awarding benefits under the Black Lung Benefits Act.

This B Reader quality assurance review includes the following:

1) Prior to undertaking any chest image classifications, NIOSH will establish a Chest Image Evaluation (CIE) panel of at least six B Readers to be potential candidates for evaluating each individual image submitted to NIOSH by OWCP. The CIE panel B readers will be informed that the images they classify come from contested Black Lung Benefits proceedings, and that their classifications will be used by NIOSH Respiratory Health Division (RHD) personnel to determine if a B Reader's classifications submitted in black lung proceedings were within acceptable standards. If the B Reader inaccurately classified images in black lung proceedings, RHD personnel may respond with letters to provide feedback and suggestions for improvement, or to enforce corrective actions, as detailed in items #3e, #4, and #5, below. The B Reader panelists will also periodically be given "quality assurance" chest images to classify and receive feedback from RHD personnel about the quality of their own chest radiographic image classifications of those images. At the discretion of RHD personnel, a B Reader panelist may be removed from the NIOSH CIE panel if the B Reader panelist continues to provide inaccurate classifications despite feedback. The CIE panelists will further be informed that their identities will be permanently unlinked from their individual classifications of black lung chest images in order to maintain their anonymity.

2) B Readers may participate in the NIOSH CIE panel based on scores on their B Reader Certification or Re-Certification examinations and professional qualifications suggesting impartiality

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and excellence. Those who accept invitations will form the CIE panel, which will consist of six or more panelists. The term of service will be 5 years and may be terminated at the discretion of either the B Reader or NIOSH. To remain on the CIE panel, B Readers will need to maintain current B Reader certification.

3) NIOSH will receive from OWCP a written request with supporting materials to conduct a quality assurance review of an individual B Reader, identified by OWCP according to the protocol for referral jointly established by OWCP and NIOSH. Supporting materials provided to NIOSH by OWCP will include five 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. Although NIOSH will be able to link radiographs and classifications with the B Readers who performed the classifications, it will not be able to link this information back to specific Black Lung claimants. Subsequent to receiving OWCP materials, NIOSH will develop a case file for the B Reader under review, which will include the material submitted by OWCP. NIOSH will then proceed as follows:

a. NIOSH will send the B Reader under review a letter noting that he/she is being reviewed, what the quality assurance review process entails, and the B Reader's options to challenge NIOSH's findings as described in item #3f.

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b. NIOSH will randomly select five B Readers from the CIE panel of six or more B Readers to formally and independently classify each chest image submitted by OWCP using the ILO classification system. NIOSH will choose a separate set of five B Readers (“CIE B Readers”) for each chest radiographic image evaluated. To minimize the potential for conflict of interest, digital chest images sent to the CIE B Readers for classification will be inspected to ensure that they have been de-identified by removing the names of examinees, physicians, and medical institutions. CIE B Readers will be provided with case numbers allowing NIOSH to manage the quality assurance review process, but they will not be provided with the identifiable information specified above. After all independent classifications by each CIE B Reader are verified by RHD as completed, the identifying links to the CIE B Readers who performed the classifications will be removed to ensure that NIOSH cannot identify which of the five CIE B Readers from the CIE panel performed any individual chest image classification.

c. RHD personnel will then evaluate all of the findings, including a comparison between the CIE B Readers’ classifications of the five disputed chest radiographs and those by the B Reader subject to the quality assurance review.

d. A NIOSH B Reader will be considered to be under-reading an individual chest image for the presence of large opacities if he/she records the absence of large opacities and all five of the CIE B Readers note that large opacities are present in the image. A NIOSH B Reader will be considered to be over-reading an individual chest image if he/she records the presence

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of large opacities and all five of the CIE B Readers indicate the absence of large opacities in the image. A NIOSH B Reader will not be deemed as under- or over-reading the presence of large opacities in an individual chest image if his/her classification is in agreement with any of the five CIE B Readers' classifications. The quality assurance review will find a NIOSH B Reader to be inaccurate if he/she under- or over-reads the presence of large opacities in two or more of the five chest radiographs that are reviewed. If he/she under- or over-reads the presence of large opacities in one or less of the five chest radiographs, the B Reader under quality assurance review will not be penalized as described in items #3e, #4, or #5, below.

e. After the evaluation of a B Reader is complete, NIOSH will send him/her an initial written report, via certified mail, to the B Reader's address on record with the NIOSH B Reader Program, notifying him/her of the results of the CIE B Readers' evaluation. If the B Reader is found to be inaccurate, the report will discuss possible technical issues as to why this might have occurred and offer suggestions for addressing these technical issues. Whether specific technical issues are identified or not, if inaccuracy is identified, the report will include a warning to the B Reader that future identification by NIOSH of misclassification of large opacities will result in suspension or revocation of the B Reader's Certification (see steps #4 and #5, below).

f. The initial report to the B Reader described in item #3e will also note that the B Reader may challenge the report's decision in writing if he/she disagrees with NIOSH's finding. The B Reader must submit his/her challenge to NIOSH within 30 days of the date of delivery of

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the report. If NIOSH does not receive a written challenge within 30 days of such date, the initial report will become a final determination. If the B Reader files a written challenge and NIOSH receives it within 30 days of the date of delivery of the report to the B Reader's address, RHD personnel will consider the challenge and respond with a final written determination within 90 days of the date of receiving the challenge. A final determination will be reached by RHD personnel after reviewing all available information, including any new information provided by the B Reader.

g. After a final determination is reached, NIOSH will communicate its findings and final decision in writing to OWCP. If desired by OWCP, NIOSH will explain the findings to OWCP.

4) A second final determination by NIOSH in a subsequent quality assurance review of inaccurate classification of chest radiographs performed by a B reader will result in NIOSH suspending the B Reader's Certification for one year. The suspended B Reader must take and pass the re-certification examination at the end of such year to have his/her Certification reinstated.

5) A third final determination by NIOSH in a third quality assurance review of inaccurate classification of chest radiographs performed by a B reader will result in permanent revocation of the B Reader's Certification.