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**RE: COMMENTS OF THE NATIONAL MINING ASSOCIATION ON "A REVIEW OF INFORMATION PUBLISHED SINCE 1995 ON COAL MINE DUST EXPOSURES AND ASSOCIATED HEALTH OUTCOMES "**

The following comments are submitted on behalf of the National Mining Association (NMA) in response to the draft document titled, "A Review of Information Published Since 1995 on Coal Mine Dust Exposures and Associated Health Outcomes" (the Post-1995 Report).

Over many years, NMA and its members have demonstrated their commitment to working with MSHA, CDC and NIOSH to ensure a safe and healthy working environment for all miners. In particular, NMA and its members agree that dust-related diseases in America's coal mines should be eliminated and support the industry and regulatory efforts, grounded in valid science, to accomplish that goal. NMA welcomes the opportunity to participate in this latest effort to evaluate the significance of newly evolving data, to best employ that data to maximize the effectiveness of dust control methodologies and to pursue a course toward the best health outcomes for America's coal miners.

NMA suggests that at this stage, a new approach is called for that will address the scientific controversies that have confounded the dust standards debate and facilitate any comprehensive action that may be needed. That new approach is set forth in the peer review requirements of the Information Quality Act, 44 U.S.C. § 3516, note. (IQA).

The IQA was enacted in 2001, after publication of the Criteria for a Recommended Standard Occupational Exposure to Respirable Coal Mine Dust (1995 Criteria Document), and was inapplicable to the 1995 Criteria Document. The IQA, however, is applicable to the draft and final Post-1995 Report addressed in these

comments. IQA compliance is mandatory for all covered agencies and its application to the Post-1995 Report is not in doubt.

Generally, the IQA requires the Office of Management and Budget (OMB) to publish guidelines applicable to federal agencies "for ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by Federal agencies". 67 Fed. Reg. 8452 (2002). Each covered agency also is required to publish its own guidelines and "establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the [OMB] guidelines." Id.

On Sept. 9, 2010, the U.S. Department of Health and Human Services issued comprehensive agency-wide guidelines to implement the IQA. Part II D contains the sub-agency specific guidelines applicable to the Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry including the National Institute for Occupational Safety and Health, DHHS Guidelines, Part II D(I).

Of equal importance and applicability is OMB's Bulletin for Peer Review, which was adopted to more fully and rigorously implement the language and intent of the IQA. 70 Fed. Reg. 2664-2667 (Jan. 14, 2005) (OMB Bulletin). Because of the high probability that the Post-1995 Report is comprised of highly influential scientific information that may serve as a basis for regulatory action, the Post-1995 Report may also invoke the standards requiring additional peer review in accordance with paragraph III of the OMB Bulletin. 70 Fed. Reg. 2675. The OMB Bulletin also expressly provides that publication for public comment is not a substitute for peer review and does not satisfy the requirements of the bulletin.

For the reasons that follow, NMA believes that careful attention to IQA principles reflected in all applicable guidelines and a comprehensive, unbiased peer review process will provide a better, more useful and more universally acceptable analysis of the health effects that are attributable to coal mine dust exposures in our nation's coal mines.

In the 1995 Criteria Document, the authors favored a recommended exposure level for all coal mines of 1 mg/m<sup>3</sup> as a time-weighted average for up to 10 hr/day during a 40-hour work-week measured according to current MSHA methods. The improvement of other protective strategies was recommended as well. Feasibility and cost were not considered at any length in the 1995 Criteria Document although it was understood that this recommendation would be both costly and difficult to achieve.

The 1995 Criteria Document did not, in the minds of many in the coal mining industry, make a strong or persuasive case that the applicable 2 mg/m<sup>3</sup> permissible exposure limit was inadequately protective or that a reduction would have made a

significant or measurable difference in the elimination or maximum achievable control of dust-related diseases. Much of the research relied upon in the 1995 Criteria Document was based on subject populations that worked for most or all of their careers in much dustier conditions than allowed by the 2 mg/m<sup>3</sup> limit.

At the same time, the Work-Related Lung Disease Surveillance System data showed a dramatic decrease in the incidence of CWP (ILO 1/0 or greater) in the period from 1985-1994. This period also showed a significant decrease in the numbers of miners interested in participating in the surveillance programs, suggesting that the decline in the prevalence of disease in the larger populations of miners was even greater. Also, almost all of the Chronic Obstructive Pulmonary Disease (COPD) data was collected from study participants with little or no exposure to less dusty conditions mandated after 1972, and the COPD studies seemed to do a very poor job controlling for smoking and other non-occupational causes of COPD. This is particularly relevant in that smoking prevalence has been documented to be particularly acute in the Appalachian region. Many have challenged the COPD studies for poor study design and for assumptions that were not justified by known science. In the opinion of some, the 1995 case seeking a more restrictive 1 mg/m<sup>3</sup> standard was more theoretical and aspirational than it was grounded in sound science.

The draft Post-1995 Report, like its predecessor, seems to NMA to raise more questions than it answers and again shows less concern for documented confounding factors than NMA believes is warranted.

The centerpiece for the 2010 draft is a reported increase in the prevalence of pneumoconiosis among underground coal miners in the periods from 2000-2004 and 2005-2009 over the percentage of miners showing some level of CWP in the periods from 1990-1994 and 1995-1999. The 2005-2009 data showed a slight overall decline from the 2000-2004 period even though the more recent period reflects a targeted study. The study itself states: "the recent CWXSP findings may be upwardly biased, with the implication that the apparent rise in prevalence may be an artifact". The data reported do not show the degree of severity or advancement of CWP in these study groups, or compare severity with prior study groups.

The Post-1995 Report also reports that miners are developing CWP at earlier ages; that there has been an increase in years of potential life lost (YPLL) for currently exposed miners; and that new research confirms earlier findings that coal mine dust may produce clinically significant levels of chronic airways obstruction in miners independent of and perhaps additive to the effects of cigarette smoking. Perhaps, most troubling is a reported significant increase in prevalence of progressive massive fibrosis (PMF) in populations of longer term miners in the 2005-2009 period.

When the 1995 Criteria Document was publicly disseminated, it generated controversy in the mining and scientific community. The Post-1995 Report will do little to quell the ongoing controversy. Instead, it raises many questions that seem to be glossed over or deemed irrelevant in the pursuit of the Post-1995 Report's principal recommendation for a reduction in the PEL to 1 mg/m<sup>3</sup> of coal mine dust and the development of a new separate PEL for crystalline silica.

For example, the conclusion that the periods from 2000-2004 and 2005-2009 show a meaningful and permanent increase in prevalence compared to earlier periods is a difficult claim to prove given the changing populations of miners examined; the likelihood that recent exposures would not significantly alter surveillance results for subjects whose work history occurred principally before the 2000-2004 and 2005-2009 time frames; and the lack of any longitudinal consistency in the self-selecting miner population. It does not seem that these confounding factors can easily be ironed out by standard statistical conventions, even though the draft claims to have largely eliminated serious bias. That claim is not convincing and questions of reproducibility and transparency remain unanswered.

The same concerns are present in the reported increases in PMF. After very steep declines in the prevalence of PMF, the reported uptick, especially in the 2005-2009 period, merits much more critical investigation and verification than it gets in the Post-1995 Report. PMF often is misdiagnosed even by B readers and the causes are still not well understood. Because the numbers of cases are few, even considering an increase in prevalence, and because typically the less healthy miners select into the surveillance programs and that effect is magnified by a targeted surveillance program, any conclusion that there is a PMF epidemic is premature and perhaps mistaken. It seems highly unlikely that PMF prevalence would so rapidly start creeping up to 1975-1985 levels when the subject populations had much more significant exposures to respirable dust for most of their mining careers. A more rigorous peer reviewed investigation certainly is warranted in this connection.

In the same regard, the YPLL data is, in our opinion, entirely unreliable. In many coal mining communities, and certainly in eastern Appalachia, death certificates of former coal miners very frequently include a reference to pneumoconiosis or COPD as an "underlying" or even principal cause of death in order to help with a black lung claim. Indeed, in the litigation of black lung claims, the law has evolved to give little or no weight to death certificates in determining the cause of a miner's death.

The COPD analysis in the report is also quite controversial. Almost all of the principal research cited in the original 1995 Criteria Document involve miners with exposure histories pre-dating the 2 mg/m<sup>3</sup> federal dust standard or foreign studies that are often difficult to evaluate or compare with U.S. data. In many of these studies, both from the U.S. and elsewhere, cigarette smoking histories are not very well documented, other causes of chronic airways obstruction, like asthma, are ignored and study design is subject to question in important respects.

The Post-1995 Report does not suggest that there is an increase in chronic obstructive lung disease or that the prediction of researchers cited in the original 1995 Criteria Document that the 2 mg/m<sup>3</sup> standard would substantially reduce the risk of dust related COPD was incorrect. The post-1995 studies cited are very difficult to evaluate, have not all been peer-reviewed, and in many ways, seem to reflect the conviction of many of the pre-1995 researchers that they were correct in the first place -- broadly implicating coal mine dust in severe COPD, notwithstanding the views of critics.

For these and other reasons, many pulmonary scientists and others remain unconvinced that the CDC/NIOSH publications and research conclusions on coal mine dust are sufficiently reliable and scientifically rigorous to be considered authoritative.

The forward to the draft Post-1995 Report states:

A principal intent [of the Report] is to determine whether the 1995 recommendations remain valid in light of the new findings and whether they need to be updated or supplemented . . .

NMA does not conduct medical research, but many of its members are understandably concerned whether decision makers, whose research has a significant impact on them, are basing their analyses on the best possible science that is untainted by bias and outcome-driven studies and whether such science has been subjected to peer-review.

The IQA should have a significant role to play in addressing those concerns and testing the validity of the scientific conclusions reached. NMA believes also that OMB's Final Information Quality Bulletin for Peer Review should be employed to ensure that the data and new research relied upon in the Post-1995 Report are appropriately disseminated to the public and regulators in keeping with the new requirements imposed by the IQA and the Bulletin for Peer Review.

NMA understands that CDC and NIOSH are very familiar with the requirements of the IQA and OMB's Bulletin for Peer Review. Because the 1995 Criteria Document was not subject to IQA requirements, it would be appropriate that the Post-1995 Report now should be subject to a full peer review exercise. The Post-1995 Report presents new data and analysis and assumes the correctness of the analyses disseminated in the original 1995 Criteria Document without having also subjected it to peer review. There is no doubt that the Post-1995 Report proposes to disseminate influential scientific information as defined in Part II of the Peer Review Bulletin and it may well satisfy the requirements of Part III of the bulletin pertaining to Highly Influential Scientific Assessments.

Several peer review requirements stand out as being particularly noteworthy in this setting. First, NMA believes that special attention should be paid to the requirements of "independence" of reviewers and "rotation" of reviewers. NMA is concerned that the failure to include critics of the most controversial conclusions noted here suggests that the authors and researchers are not totally independent and unbiased. Following OMB's Peer Review Bulletin will help to gain industry acceptance of the final Post-1995 Report and better cooperation as the dust standard debate continues.

It is noted further that a certification of the administrative record of the peer review proceeding is required if there is an intent to use the Post-1995 Report in support of regulatory action.

Independent of the peer review process, NMA urges the drafters of the final report to pay special attention to IQA quality criteria. The essential principles of information quality according to the IQA statute, OMB and CDC guidelines are "utility," "objectivity" and "integrity." CDC Guidelines V.A. OMB and CDC guidelines further provide: "With regard to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (SDWA) (42 U.S.C. 3009-1(b)(3)(A) and (D))." Id. § VII. The exacting risk assessment principles of the SDWA are set forth in § VII of CDC's guidelines.

Looking at the key elements of the information quality assessment, the objectivity standard is most directly implicated in an IQA review of the Post-1995 Report.

Under OMB and CDC guidelines, "objectivity" requires that covered information be "accurate, clear, complete and unbiased . . ." and include the disclosure of "errors sources, affecting data quality . . ." 67 Fed. Reg. 8459. The agency may ensure that the information reported is "accurate, reliable and unbiased" and that the "original and supporting data shall be generated and the analytic results shall be developed using sound statistical and research methods." Id. Agency compliance and the IQA are satisfied by "1) clearly identifying the limitations inherent in the information dissemination product (e.g., possibility of errors, degree of reliability and validity) so users are fully aware of the quality and integrity of the information . . ., 2) taking reasonable steps to remove the limitations inherent in the information, and 3) reconsidering [the delivery of] the information . . . ." Memorandum M-05-04 for the Heads of Executive Departments and Agencies (Dec. 17, 2004)  
<http://whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-04.pdf>.

The COPD and chronic obstructive airways analyses, the meaning of new prevalence data and statistical relevance and validity of that data, viewed in light of study design and study populations; the relevance of any conclusion across all segments of the coal mining industry, including surface and Western mining

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operations; and the significance properly accorded to market data cited will all be better understood and accepted following rigorous peer review according to the OMB criteria, and the overall application of IQA quality standards where, as here, influential scientific information has been submitted for public dissemination and regulatory action. Federal science authorities have an obligation to satisfy the new requirements discussed in these comments.

For the reasons noted in this letter and, in particular, in light of the considerable controversy that has persisted for decades in the dissemination and utilization of information concerning the health hazards of coal mine dust, it is time to subject the research data to the best possible analysis to seek a consensus among all stakeholders for the future.

Thank you for this opportunity to comment and your consideration of these views.

Sincerely,

A handwritten signature in cursive script, appearing to read "Bruce Watzman".

Bruce Watzman