From: Kohler, Jeffery L. (CDC/NIOSH/OMSHR) [mailto:jtk4@cdc.gov]
Sent: Tuesday, May 24, 2011 10:17 AM
To: Wagner, Gregory - MSHA
Cc: Chovanec, Marie I. (CDC/NIOSH/OMSHR)
Subject: RE: CPDM-related comments

2011 MAY 24 A 10:29

Greg,

We were aware of the information presented at the public hearings, and our researchers have analyzed them. Their findings are summarized in the attached document. Please feel free to make them part of the public record.

Thanks, and let me know if you have any questions.

Jeffery L. Kohler, Ph.D.
Associate Director for Mining, and
Director, Office of Mine Safety and Health Research
National Institute for Occupational Safety and Health
Centers for Disease Control
P.O. Box 18070
626 Cochran's Mill Rd.
Pittsburgh, PA 15236

ph: 412-386-5301
fax: 412-386-5300

JKohler@cdc.gov

www.cdc.gov/niosh/mining

From: Wagner, Gregory - MSHA [mailto:wagner.gregory@dol.gov]
Sent: Wednesday, May 18, 2011 11:01 AM
To: Kohler, Jeffery L. (CDC/NIOSH/OMSHR)
Subject: CPDM-related comments

Jeff—

As you know, in the course of the MSHA public hearings on the proposed rule to limit miners' exposure to coal mine dust, there were a number of comments and some data presented relevant to the use of the CPDM. NIOSH personnel were at number of the hearings, and all the comments and the material presented are now posted on the MSHA website.

If you and your staff have had a chance to take a look at these comments, I would be interested in your take on the issues and concerns raised. Since MSHA is in rulemaking, it might be appropriate for you to consider providing comments that will become part of the public record before the public comment period closes at the end of this month.

Thanks.

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AB64-COMM-93

NIOSH Analysis of Comments Questioning the Use of the CPDM

Presenters representing the mining sector introduced data at recent public hearings held by MSHA,[1] which supported use of the NIOSH-developed Continuous Personal Dust Monitor (CPDM) as an "engineering tool," but questioned its readiness for use as a dust sampling device for compliance purposes.[2] Consider the following example to illustrate this distinction.

As an engineering tool, the CPDM could be used to identify dust generation sources and areas of high dust exposures; and then this information could be used to adjust the dust controls to more effectively reduce dust exposures. Importantly, this could be accomplished in near real time, which of course is a key benefit of this innovative device. In contrast, sampling devices such as the CPDM can be used for ***compliance*** purposes only if they meet the specific performance criteria defined in 30 CFR Part 74 and have been approved by the Secretary of Labor and the Secretary of Health and Human Services for use as a compliance sampling device. Accordingly, the issue as raised by the mining sector presenters is whether the CPDM meets the performance criteria specified in 30 CFR Part 74, and therefore could be used for compliance purposes in addition to its use as an engineering tool.

The performance criteria were published in CFR 30, Part 74, in 2010, and they establish the requirements for bias, precision, and reliability that must be met for direct-reading devices such as the CPDM. The results of published NIOSH studies demonstrate that the CPDM meets these performance criteria. At this writing, the CPDM is in the final stages of the approval process, and NIOSH anticipates obtaining approval from the Secretaries of Labor and Health and Human Services to use the CPDM as a sampling device. More detailed descriptions of the NIOSH studies, with explanations to demonstrate that these studies correctly characterize the CPDM's performance, are included in the following sections.

Mining sector representatives also raised concerns that the current CPDM design may cause harm to the musculoskeletal system of the mineworkers. Therefore, this document also includes a description of how the current CPDM design has capitalized on pre-existing technology to ensure that it is an ergonomic device posing no additional risk to the mineworker.

Accuracy

Several presenters provided data suggesting that the sampling performance of the CPDM may not be adequate for this device to be used for compliance. NIOSH questions the interpretation of the presented data given that: 1) the analytical methodology used by some presenters was inappropriate for the conditions to which it was applied; 2) several presenters inappropriately referred to data being presented by using a scientific term that can be interpreted in different

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[1] Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors, 30 CFR Parts 70, 71, 72, 75, and 90.

[2] Compliance devices are used to ensure a mine is operating in accordance to 30 CFR requirements

ways; and 3) none of the datasets presented included statistically representative samples that fully reflect the conditions seen across the U.S. underground coal mine industry.

Several presenters indicated that the CPDM did not meet the NIOSH accuracy criterion.[3] However, the presenters were referencing data collected during field studies; this criterion is designed only for laboratory evaluations, not field evaluations, of a device. Therefore, in those instances where the presenters applied this criterion to data collected in the field, an inappropriate analysis methodology was used, which invalidates the conclusions drawn.

Secondly, presenters described data that pertained to "accuracy." However, this term was not defined in the presentations, and should have been defined by referencing two statistically independent and fundamental parameters known as "bias" and "precision." Bias is defined as the uncorrectable relative discrepancy between the mean of the distribution of measurements from a method and the true concentration being estimated, expressed as a fraction.[3] Although precision can be expressed in various ways such as repeatability or reproducibility, NIOSH defines precision, with no loss of generality, as the relative variability of measurements on replicate samples about the mean of the population of measurements, divided by the mean at a given concentration.[3]

Further, bias and precision can be estimated by different methods, including regression analysis. Regression analysis is a statistical methodology that uses the relation between two or more quantitative variables so that one variable can be predicted from the other, or others.[4] This methodology is widely used in business, the social and behavioral sciences, the biological sciences, and many more disciplines.[4] NIOSH's experimental design was developed such that the bias and precision of the CPDM could be estimated by regression analysis of data obtained in field environments. CPDM performance was compared to the defined and accepted reference standard within the U.S. mining industry, which uses the gravimetric method.[5,6]

Thirdly, in its evaluations of CPDM performance, NIOSH collected and analyzed samples that were statistically representative of the U.S. underground bituminous coal mining industry.[7] The sample set was selected using the Survey Select procedure from the SAS statistical analysis

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[3] Kennedy, E. R., Fischbach, T. J., Song, R., Eller, P. M., and Shulman, S. A., 1995. "Guidelines For Air Sampling And Analytical Method Development And Evaluation," U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 95-117.

[4] Neter, J., M. H. Kutner, C. Nachtsheim, and W. Wasserman, in *Applied Linear Statistical Models,* WBC-McGraw-Hill, Boston, 4th ed., 1996.

[5] Page, S. J., J. C. Volkwein, R. P. Vinson, G.J. Joy, S. E. Mischler, D. P. Tuchman, and L. J. McWilliams, 2008. Equivalency of a personal dust Monitor to the current United States coal mine respirable dust sampler. *J. of Environ. Monit.* **10**(96-101). Available at http://pubs.rsc.org/en/Content/ArticleLanding/2008/EM/b714381h.

[6] Coal Mine Dust Personal Sampling Unit, CFR 30 Part 74.

[7] *Sampling of Populations: Methods and Applications*, Third Edition, Paul S. Levy & Stanley Lemeshow, 1999, John Wiley & Sons, Inc.

software package.[8] The samples were collected at approximately 20% of the active mechanized mining units. Statistically representative samples are critical for correct estimation of the bias of the CPDM relative to the gravimetric method, in that the bias will not necessarily be properly estimated from studies conducted in a limited number of mines or regions, regardless of the number of samples obtained at these locations.[6,7] The methodology used by NIOSH was reviewed and approved by various members of the mining sector[9] prior to data collection and prior to publishing the final results.

To further illustrate the disparity in available data, it is noted that none of the datasets presented at the hearings were statistically representative of the entire U.S. underground coal mining industry. The largest dataset was presented by Alliance Coal during the Arlington, VA, hearing. Alliance collected 955 samples from within six of its mines (located in two MSHA districts) by having personnel wear a CPDM and a gravimetric sampler concurrently. However, the Alliance samples were not representative of all U.S. underground coal mines. The NIOSH data was collected from over 100 mines (located across 10 MSHA districts)[4] and represents the entire U.S. underground bituminous coal mining industry. Therefore, the NIOSH data is the most appropriate dataset available to reference when evaluating the CPDM as a compliance device for the industry as a whole.

In terms of bias, the results presented by Alliance Coal supported those published by NIOSH, demonstrating that the average concentration measured by the gravimetric method (0.83 mg/m^3) was virtually identical to the CPDM average value of 0.82 mg/m^3.[10] The conclusion that should be drawn from both the Alliance and NIOSH datasets is that there is no statistically significant difference and that the bias between the CPDM and gravimetric sampler used is zero. As noted above, bias cannot necessarily be estimated correctly from studies conducted in a limited number of mines or regions regardless of the number of samples obtained at these locations. Although not obtained through a rigorous mine selection, Alliance Coal has presented a dataset which appears suitable in terms of bias only.

Considering the next important statistical parameter—precision—Alliance Coal expanded upon its results by claiming that the CPDM variability was too large to be used as a compliance device. The relevant facts are these: 1) given total control of all parameters in any given test, there will be no imprecision or variability in the regression analysis, and 2) imprecision in a regression is a direct estimate of the degree to which there are unknown and uncontrolled parameters at work during the test.[3] The variability reported by Alliance Coal was primarily due

[8] SAS Institute, Inc., Cary, NC.

[9] Representatives from the mining sector included member companies of the Bituminous Coal Operators' Association, the National Mining Association, and the United Mine Workers of America.

[10] To be strictly correct, it should be pointed out that dust concentration data are lognormally distributed. Because of this, a simple arithmetic average cannot be performed on the datasets and the appropriate method is to average the logarithms of the numbers, followed by un-transformation of the logarithmic averages. This method results in true average concentrations that are typically lower than simple arithmetic averages. However, the relative difference between the averages will remain the same in either case.

to uncontrolled variables known to exist in field samples.[11] Because the experimental design did not control for the variability resulting from the samples themselves, it was not an appropriate estimate of the CPDM's precision. Instead, the data presented by Alliance Coal included variability potentially caused by significant dust gradients known to exist, sampler inlet location differences, and the nature of mine ventilation. Ventilation currents found in mines can produce widely varying results or seemingly poor precision between two identical side-by-side instruments, even though their inlets may be separated by only a few inches. To appropriately estimate the precision of the CPDM, the experimental design must minimize the uncontrolled variables in the sampling. NIOSH has conducted such experiments with the CPDM and has demonstrated that the precision of the CPDM is, at a minimum, equivalent to that of the gravimetric method.[12]

In sum, based upon the flawed experimental design and data analysis methods presented at the public hearings, NIOSH firmly asserts that these data should not be considered when assessing the readiness of the CPDM as a compliance device. NIOSH reasserts that because its experimental design included a dataset that was representative of the entire U.S. underground bituminous coal mining industry, and because the CPDM was compared to the defined and accepted reference standard under well-controlled conditions, it is the appropriate dataset to reference when evaluating the readiness of the CPDM as a compliance device for the industry.

Reliability

Presenters also raised concerns regarding the reliability of the CPDM for long-term compliance use in mines. NIOSH recognizes two problems with their interpretation: 1) The retrospective nature of their experimental designs, and 2) the misinterpretation of the CPDM error messages.

First, those individuals who presented at the public hearings assessed reliability using experimental designs that were retrospective analyses inadequate for drawing conclusions about CPDM reliability. These retrospective studies relied on the analysis of data collected by the CPDM at multiple mines without an appropriate experimental protocol to control for data quality. Given that these data did not control critical variables (e.g., operator training, sampling methodology, and sample size and distribution across mines), they do not provide an appropriate estimate of the CPDM's reliability.

Second, presenters misrepresented the number of failures of the CPDM observed during their experiments by including those devices that produced error messages relative to sample validity.

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[11] Kissell, F.N. and H.K. Sacks, 2002. Inaccuracy of Area Sampling for Measuring the Dust Exposure of Mining Machine Operators in Coal Mines, *Min Eng* **54**(2):33-39. Available at http://www.cdc.gov/Niosh/mining/pubs/pdfs/ioasf.pdf.

[12] Volkwein, J. C. Vinson, R.P. S. J Page, L.J. McWilliams, G.J. Joy., S.E. Mischler, and D.P. Tuchman. Laboratory and field performance of a continuously measuring personal respirable dust monitor. CDC RI 9669. Sept. 2006. 47 pp. Available at http://www.cdc.gov/niosh/mining/pubs/pdfs/2006-145.pdf.

The CPDM measures a mineworker's exposure to dust in real-time and provides feedback to the user if the sample is not valid. This real-time feedback is critical, as invalid samples are identified immediately and the CPDM provides the mineworker with a message indicating potential causes for the invalid sample. This is a significant improvement upon the currently defined and accepted reference standard, which is unable to inform the mineworker in real-time if the sample is invalid. Unfortunately, this novel error-tracking feature was misrepresented at the public hearings; i.e., presenters raised concerns regarding the number of "errors" reported by the CPDM when used in their mines. However, the "errors" reported by the device were indicative of the potential for or the existence of an actual invalid sample. Thus, these error messages are not a failure of the CPDM—rather they provide the user with valuable constructive feedback in real-time concerning sample validity.

To demonstrate further, the frequency of error messages resulting from invalid samples is directly linked to the validation criteria defined in the CPDM's software. NIOSH has identified several parameters currently being used as these validation criteria. These parameters are based upon the extensive list of sample validation criteria for the gravimetric method previously developed by MSHA.[11] However, previous experience with the first implementation of the gravimetric method for compliance sampling in 1969 demonstrated that defining the final validation criteria would require routine use of the sampler as a compliance device. Furthermore, it is expected that these validation criteria might need to change or be modified as mining conditions and practices advance, indicating the true iterative nature associated with defining validation criteria for this purpose. A limited dataset including error messages from five mines was introduced at the hearings, and the presenter incorrectly interpreted sample validity error messages as evidence that the CPDM had failed. Consequently, the conclusions drawn from these data (i.e., a failure rate of 41 errors per 1000 hours) were not valid. Again, the NIOSH published data remains the most appropriate dataset to assess the failure rate of the CPDM.[11]

In addition to proper interpretation of the error messages, NIOSH used an experimental design that controlled critical variables needed to ensure the quality of data collected. Two factors relative to reliability—critical repairs and remedial repairs—were evaluated.[11] Critical repairs were considered those that required factory service while remedial repairs were those capable of being performed in the field. Using this experimental design with critical variables controlled, the critical repair rate of the pre-commercial devices was calculated to be 1.24 repairs per 1000 hours, with a total rate of 4.75 repairs per 1000 hours. These repair rates are an order of magnitude less than the suggested failure rates presented at the public hearings due to the presenter's inappropriate analysis of the CPDM's error messages as described above. Furthermore, these repair rates are expected to improve with quality control systems required for certification under 30 CFR§74.

Ergonomic Considerations

Mineworkers wear various types of equipment on their mining belt. Concerns were raised at the public hearings regarding the potential impact that the additional weight and volume of the CPDM may have on mineworkers. When the CPDM was conceived in 1999, mineworkers typically wore both a self-contained self-rescuer (SCSR) on their belt along with a battery to power their cap lamp. Through the PDM Partnership,[13] extensive discussions took place between NIOSH, labor, and mining operators regarding the design of the CPDM given the necessity of these items. This group unanimously agreed that the CPDM must be integrated with the cap lamp battery to capitalize on the existence of currently available technology. As such, the current CPDM integrates the dust sampler and cap lamp battery, with a total weight that is within 8 ounces of the traditional cap lamp battery alone.

Any statement of the influence of the CPDM on biomechanical loading and balance needs to be considered within the proper context of the addition of the CPDM to the miner's ensemble, as well as the removal of redundant equipment such as the cap lamp battery or other pertinent pieces. Traditional lead acid cap lamp batteries weigh over 5pounds (and are still in use) and the SR-100 self-rescuer weighs 5.7 pounds. The additional weight added by the CPDM needs to be considered relative to these weights as well as the miner's belt, possible tools, and the continuous mining machine remote control unit. The total relative increase in weight of the miner's belt is low given that only 8 ounces is added by combining the CPDM with the cap lamp battery. Not only is the marginal weight change of the miner's ensemble key with respect to biomechanical loading, but the resultant weight distribution characteristics (especially height and anterior-posterior position of center of mass) are important with respect to balance issues. Studies by Lin et al.[14] and Dempsey et al.[15] show that user preferences and biomechanics of different loading configurations are complex, but, as their research identified, the least problematic configuration studied was placing two symmetric loads below hip level with two shoulder straps and a waist belt. Although this configuration used criss-crossed straps, it is otherwise similar to a typical miner's belt configuration. In fact, it can be argued that a miner's belt may be more effective than the bag studied at reducing shoulder loads by transferring loading to the hips, which reduces injury risk to the shoulders and back.

Finally, recent advances in cap lamp technology have allowed the battery to be reduced in size and weight. As a result, representatives from the mining industry suggested that the CPDM should not be used as a compliance device until it accommodates this new technology. This stance fails to embrace the reality that technology is continuously progressing and advancing. Technological advances are ubiquitous and provide tremendous benefit to society as they transform industry practices. A simple example of a transformative technology would be the

[13] The PDM Partnership included member companies of the Bituminous Coal Operators' Association, the National Mining Association, and the United Mine Workers of America.

[14] Lin, C.J., Dempsey, P.G., Smith, J.L., Ayoub, M.M., and Bernard, T.M. (1996). Ergonomic investigation of letter-carrier satchels: Part II. Biomechanical laboratory study. *Applied Ergonomics* **27**(5):315-320.

[15] Dempsey P.G., Ayoub M.M., Bernard T.M., Endsley M.K., Karwowski W., Lin C.J., and Smith J.L. (1995). Ergonomic investigation of letter-carrier satchels: Part I: Field study. *Applied Ergonomics* **27**:303-313.

personal computer. Industry shows a level of acceptance in purchasing and using current computer technology despite the realization that advances in this technology are continuous. Acceptance occurs because industry has recognized the benefits offered by the current version of the technology and therefore refuses to wait until the next generation is made available. The same principle applies to mining technology. Ultimately, the current design of the CPDM will be modified to accommodate the change in cap lamp technology. However, in its current form, the CPDM offers the proven capability to reduce dust exposures in the mining industry.

Concluding Remarks

Scientific studies conducted by NIOSH and detailed in this response demonstrate the suitability of the CPDM to perform as a compliance device. The critical characteristics that define the CPDM's readiness such as bias, precision, reliability, and mine-worthiness have been supported in peer review documentation. None of the evidence presented at the public hearings changes these findings.