Attachment C

Exponent®

Public Comments on MSHA's Proposed Rule: Lowering Miner's Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors

RIN 1219-AB64

Comments Specific to: Industrial Hygiene and Medical Surveillance Issues

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Comments Specific to: Industrial Hygiene and Medical Surveillance Issues

Prepared for

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Mr. Michael N. Cooper is a Senior Managing Scientist in Exponent's Health Sciences Center for Occupational and Environmental Health. He specializes in occupational health, industrial hygiene, chemical exposure limits, Environmental Health & Safety (EHS) management and program development, EHS regulatory affairs, community communication, and public policy. Mr. Cooper has developed and directed corporate compliance programs and improved corporate culture regarding safety and environmental affairs for a variety of industries, including aerospace, pharmaceuticals, semiconductor, and semiconductor equipment manufacturing in both the United States and internationally. Mr. Cooper has extensive experience in airborne permissible exposure (PEL) development for chemicals within California. He has served or is currently serving on advisory committees for California State OSHA, the American Industrial Hygiene Association (AIHA), and Organizational Resources Counselors. Mr. Cooper is a Certified Industrial Hygienist with graduate degrees in Chemistry and Public Health. During 2008–2009, he served with the forward units of the U.S. Army Rapid Equipping Force from Ft. Belvoir, Virginia. For these assignments, Mr. Cooper was deployed for extensive periods of time in Kuwait, Afghanistan, and Iraq. In this role, he was the lead field engineer supporting technology development and research to provide materiel solutions for deployed tactical units. Mr. Cooper teaches at the University of California Extension Program at Davis.

Sheila McCarthy MHS, CIH

Ms. Sheila McCarthy is a Certified Industrial Hygienist and Managing Scientist in Exponent's Health Sciences Center for Occupational and Environmental Medicine. Ms. McCarthy is experienced in the fields of industrial hygiene and risk assessment involving potential exposures to fibers, pesticides, metals, organic and inorganic chemicals, and to physical agents such as noise, heat, and non-ionizing radiation. Her experience includes performing industrial hygiene studies to evaluate OSHA compliance, illness clusters, and indoor air quality evaluations, and conducting historical and quantitative exposure assessment in support of site-specific risk assessments. As a CIH, Ms. McCarthy has conducted exposure assessments for both occupational and environmental settings. In these settings, she has developed and implemented sampling methodologies and evaluated a number of agents, including fibers, metals, particulate matter, volatile organic compounds, bioareosols, mold, and noise. Ms. McCarthy teaches at the University of California Extension Program at Davis. Her lectures focus on industrial hygiene and physical agents in the workplace, including noise, radiation, heat/cold stress, and ergonomics.

Curricula vitae for Mr. Cooper and Ms. McCarthy are provided in Attachments A and B.

Exponent staff (Mr. Cooper and Ms. McCarthy) were engaged by Murray Energy Corporation (MEC) to conduct a review of the MSHA proposed rule. In particular, we were asked to discuss the industrial hygiene aspects of the proposed rule and investigate the reliability of the continuous personal dust monitors currently in use at Murray and other mines.

Executive Summary

On 19 October 2010, MSHA published a notice of proposed rule-making affecting 30 CFR parts 70, 71, 72, 75, and 90 (Federal Register /Vol 75, No. 201). The stated purpose of the proposed rule is to lower miners' exposure to respirable coal dust by, among other changes, lowering the existing exposure limit, providing for full-shift sampling, providing for single-shift compliance sampling, establishing mine operator requirements for the use of continuous personal dust monitors (CPDMs), and expanding requirements for miners' medical surveillance. While the goal of the proposed rule—reducing miner exposures to respirable dust and thereby reducing incidence of pneumoconiosis and related diseases in coal workers—is laudable and fully supported, there are concerns that implementation of the proposed rule will create some serious difficulties. Three specific areas of concern are addressed: 1) industrial hygiene, 2) reliability of the CPDM based on observations from mine use data and third-party testing, and 3) medical surveillance.

If implemented, the proposed rule will:

- Significantly increase the number of airborne samples that mine operators are required to collect.
- Allow MSHA to issue citations when a single-shift CPDM sampling result is above the new exposure-limit requirement of 1 mg/m^3.
- Implement full-shift sampling that will require some miners to wear the CPDM devices every shift for their entire working career.
- Make undefined changes to the miners' medical surveillance requirements.

Industrial Hygiene Concerns

One of the difficulties with the proposed rule is that, without better design and data linkage, increased workplace monitoring—which will entail a significant effort—is not going to lead to a better understanding of the nature of the dose-response relationship with coal workers' pneumoconiosis (CWP) incidence and will not necessarily improve our understanding of the causative factors leading to CWP, if other factors are not addressed as well, such as silica levels, coal rank, and lifestyle factors (e.g., smoking). Workplace monitoring is typically used to determine worker exposure to levels of contaminants that have been associated with adverse acute or chronic exposures and disease. In general, the more positive the association between a contaminant and an adverse effect or disease, the more effective will be the prevention efforts implemented. In the case of coal dust, many factors have been identified in the literature that could contribute to the development of CWP and allied diseases. These factors include mine size, coal rank and type, silica content, mine region, effect of miner age, and chemical content (e.g., biologically available iron) of the respirable dust.

Consideration should be given to determining whether the large increase in sampling frequency will, in fact, measure the correct indicator(s). Large-scale CPDM data collection is an inefficient way to improve the understanding of causative factors involved in the dose-response relationship with CWP incidence. A smaller, well-designed data set that employs statistical experimental design would be better equipped to differentiate among the many potential causative factors involved.

A primary tenet of industrial hygiene is that engineering controls are the most reliable method of controlling worker exposures, followed by administrative controls and, finally, personal protective equipment (PPE). MSHA and the Federal Mine Safety and Health Act have a history of specifically not relying on respiratory PPE for miner protection. Administrative and PPE control are also not favored by unions, as discussed by union representatives during the public hearing process in February 2011. Although available for miners, it appears that respiratory protection is rarely worn, based on various factors that include comfort and fit. Helmets, which would provide an air curtain and eliminate many of the fit and comfort issues, are also not often used.

For the reasons above, it appears that two of the key tools in the industrial hygienist's tool chest to protect worker exposures—administrative controls and personal protective equipment—have been deemed off limits. Consideration of alternatives that include PPE use and administrative controls available to mine operator safety personnel would likely improve worker health and safety, and their potential use should be addressed more fully in the proposed MSHA rule.

CPDM Reliability

Data from multiple mines that are using the latest version of the CPDM show a CPDM fault rate (defined as the number of times the CPDM unit reports an error during use) is approximately 29%, several times higher than the failure rate of 9.8 % reported by the National Institute for Occupational Safety and Health (NIOSH) from their testing of the unit in 2006. Many of the errors reported during mine use require the user to contact Thermo Fisher Scientific (TFS), the manufacturer of the CPDM, for service. Exponent tested three CPDM units in two bituminous mines and encountered multiple faults that interrupted data collection, including pinching of the hose when worn in the close compartment of a shuttle car on the way to the continuous or longwall mining operation.

Side-by-side testing of a gravimetric unit and three CPDM units using talcum dust at elevated temperature and humidity levels was performed by Exponent and Virginia-based E-Labs. Standard tests run for one hour at temperature and humidity conditions likely to be encountered in the mine environment showed differences among the CPDM units and between the CPDM units and gravimetric sampler that varied at times by more than the 1-mg/m^3 criterion that would trigger a citation under the proposed rule. These differences, seen under limited laboratory testing, could be exacerbated due to the significant increase in CPDM sampling required by the proposed rule when subjected to actual mine conditions, and therefore require further evaluation.

The CPDM units are certified by TFS to operate in compliance with EN61326-1 and FCC Part 15 subpart B, in reference to electrical emissions and immunity. Due to the high power requirements of various mining operations, Exponent and E-Labs performed radiated susceptibility testing on a CPDM unit. Based on discussions with mine personnel and using the available equipment at the laboratory, electromagnetic interference tests were conducted to include frequency sweeps between 200 MHz and 1 GHz and measured as 5 Watts and 10 Watts at the receiving CPDM. The lower power level (5 W) is the maximum output at which most hand-held walkie talkie devices operate; tests at higher power level (10 W) were also conducted to mimic the output from the various machines found inside a mine based on discussions with mine personnel. This testing demonstrated that a band of frequencies between 451 MHz and

532 MHz, at power levels between 6 W and 10 W, slowed the CPDM motor, as evidenced by tone changes, and in some cases, the motor stopped completely but did not register a flow fault on the unit. Standard drop and shock tests on a CPDM unit were unremarkable.

Taken together, these data indicate that, while the unit is durable under laboratory drop and shock testing, the high fault rate and variability among CPDM results under similar exposures is a serious concern when collecting samples under actual mining conditions. Fault rates of 29% would significantly impact the collection of required data under the proposed rule. Additionally, limited sample testing of CPDM units in a controlled environment demonstrated that differences among the CPDM units at times spanned more than the 1-mg/m^3 proposed citation level.

The CPDM unit has the potential to improve timely knowledge of the dust levels in coal mines. This potential, however, appears to be offset by the high fault rate and variability under the test conditions we have observed. Based on these data and other considerations, use of the CPDM for compliance purposes based on single-day samples is not advised at this time. Unresolved issues that argue against use of the CPDM for single-shift compliance monitoring include:

- High fault rate of the CPDM
- Variability between the CPDM units and with the gravimetric sampler under elevated temperature and humidity conditions
- Weight, especially as worn during a full shift, along with a miner's other gear
- Potential for unbalanced weight to cause or worsen musculoskeletal disorders
- Potential for distraction (no audible or vibration alarm, display is hard to read in the mine setting), which can reduce the miners' ability to work safely in a challenging environment
- Difficult to wear in a small compartment
- Maintenance, filter changes, and system diagnosis are not possible within the underground mine work environment

- The fact that there is only one manufacturer of the CPDM raises practical concerns about availability and responsiveness to service, maintenance, and training requirements.

Medical Surveillance

Changes to medical surveillance procedures in the proposed rule include the requirement that operators offer spirometry, occupational history, and symptom assessment in addition to the chest radiographic examinations already required. The proposed rule would apply to both underground and surface mines. The medical exam schedule outlined in the proposed rule includes:

- A baseline exam no later than 30 days after hire
- A follow-up exam 3 years after hire
- If the 3 year exam is "abnormal" regarding chest x-ray, evidence of pneumoconiosis, or spirometry changes, a second follow-up exam within 2 years is required.

Historically to date, only a small percentage of miners have participated in the Coal Workers Health Surveillance Program. For more successful disease prevention, it is critical that miner participation in the MSHA medical surveillance program be improved.

The above notwithstanding, the difficulty of implementing a medical surveillance program such as that as described in the proposed rule is difficult to evaluate, because the medical criteria for defining CWP (not a straightforward issue) are not clearly described, nor are the necessary qualifications of medical staff who are administering and interpreting the medical monitoring tests adequately described. The proposed rule states that NIOSH will determine these criteria at a later date. Clearly, various guidelines can be proposed to define abnormal chest x-ray and spirometry changes. Given the controversies around diagnostic criteria and designation of qualified personnel to make decisions regarding the presence of CWP or adverse respiratory health conditions, these aspects of the rule merit full public review and should not be criteria that are added later without the benefit of full discussion and consensus agreement. In addition, the data collected from the medical surveillance program would be of added value from the occupational health research perspective, if the medical status were designed to be linked (even in a small study) to respirable coal-dust exposure, use of respiratory protection data, mine type and size, silica content, and other factors. Such information over time could prove very useful in assisting in the establishment of important causative factors related to CWP prevention.

1 Background

The following comments summarize and expand upon the presentation made by Mr. Michael Cooper at MSHA's public meeting on February 8, 2011, in Washington, Pennsylvania. The focus of that presentation was the observations and results of several studies related to the use of the CPDM in mine settings. The authors went to two bituminous mines in Illinois to collect data, interview personnel, and evaluate both continuous and longwall mining operations. For these efforts, the authors:

- Reviewed the proposed rule from an industrial hygiene viewpoint
- Reviewed National Institute of Safety and Health (NIOSH) CPDM studies and Quantitative Risk Assessment (QRA) literature
- Reviewed conditions in two underground bituminous MEC coal mines
- Reviewed all collected continuous personal dust monitor (CPDM) data for five underground mines
- Interviewed dust managers, miners, and safety and health professionals.

2 Mine Experience with CPDM Sampling

During our mine visits to two underground mines where we observed continuous miner and longwall operations, we discussed several aspects regarding the use of the CPDM at the mines with a variety of mine personnel and safety staff. The following points summarize key concerns of miners, dust operators, and safety and health professionals regarding the CPDM and the proposed rule:

2.1 Miner Concerns

- Frustrated that the unit has a high fault rate
- CPDM is too bulky for seats in equipment compartments; faults occur due to pinched hoses at start of shift
- No alarms—audible, light, or vibration alarm to alert miner of any failures or exceedances
- Difficult to read display using cap lamp
- Hose to cap lamp from the CPDM is too long, catches on equipment
- Connections to remote units are hard to make in the mine, connectors are not as easy to manipulate as those on the standard cap lamp battery
- CPDM does not fit workers' pouches or belt
- Two connector types have to be connected in the mine (Figure 1)—there is a clear preference for the connector type used on current cap lamp battery.

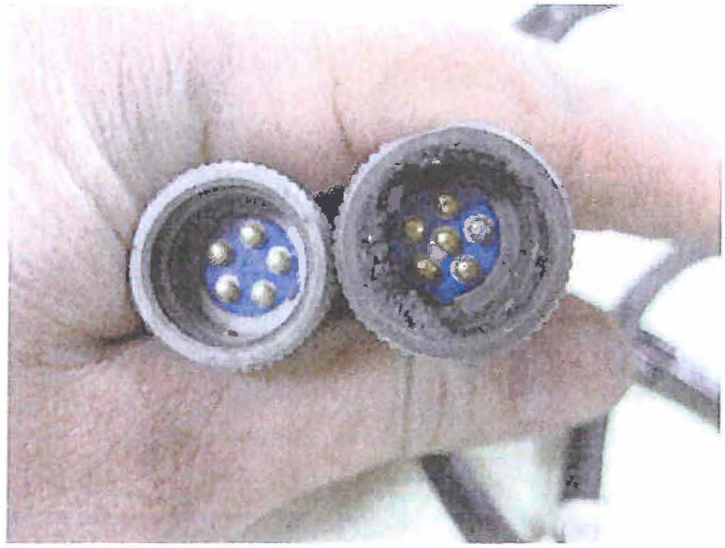


Figure 3. Two connector types that require different cables for the remote

Figure 4. Preference for the standard type of lamp connector – easier to seat and remove in the mine

2.2 Certified Dust Manager Concerns

Dust managers are charged with implementing exposure monitoring programs, maintaining all sampling equipment, and observing and educating workers about the proper care and use of the CPDM monitor. These safety staff had a series of concerns regarding the use of the CPDM on a continual basis for all work shifts:

- The long start time (35 minutes) for the CPDM units, before actual usage by the miner, have routinely made portal-to-portal shift sampling difficult to achieve, and the CPDM unit is more complicated to maintain than the gravimetric sampler
- Maintenance of the CPDM is specialized and requires practiced skill
- Four of five CPDM units had to be sent back to the factory 6 times in 18 months (two were sent twice)
- Significant time (2 weeks) is required to return a unit to the company for repairs
- Concern that one of five units experienced a failed pump during the first year of operation
- Personnel have little experience conducting more detailed maintenance work such as calibration (KO) and tilt audits, cyclone cleaning, and flow audits
- Only one MSHA-approved CPDM unit is on the market at this time.

2.3 Safety and Health Personnel Concerns

- Wearing the CPDM unit may cause unintended worker distraction and decrease the ability for miners to work safely
- Wearing the CPDM may increase the risk for musculoskeletal disorders due to weight added to belt and an unbalanced load
- Difficulty reading the display while working

- CPDM does not provide instantaneous readings to the miner—the unit provides the miner with 30-minute averages and end-of-shift averages; other data can be downloaded but not during the sampling shift
- Misconception that the CPDM is a real-time device. While the CPDM represents a significant improvement as a personal monitoring device over the gravimetric unit, the CPDM does not have the ability to identify specific high-exposure activities that occur within a short time period (<30 minute), which would enable the miner to quickly implement protective measures.

2.4 CPDM Maintenance Issues

Exponent industrial hygienists tested several CPDM units in an office setting prior to mine testing, to become familiar with the instrument's operations and maintenance requirements. During our office testing, we observed that one CPDM unit (S/N 0509055) had several unusual failures despite the ability of the unit to pass diagnostics tests. (This observation was also reported to us by staff at the mines visited.) In our testing, this unit reported end-of-shift (E2 S) results of 1–2 mg/m^3 in an office setting. These concentrations are above the proposed regulatory limit and are unlikely to represent actual levels in a ventilated office environment. The unit repeatedly passed warm-up and software diagnostics that were provided with the unit. Additional tests, including the calibration audits (KO audits), failed once and then subsequently passed. The reason for the failure of the CPDM to accurately report airborne concentrations in an office setting could not be determined, and the unit reported no failures during this sampling.

Based on our experience with the units and our review of information provided about the CPDMs from NIOSH, MSHA, and the manufacturer, we have noticed that key pieces of information are missing. No data concerning mean time between failure (MTBF) of critical parts has been made available. The life of the unit is not defined, and it is unclear when upgrades (hardware, software) for the CPDMs might be available and how long they would take to implement. Such information is critical when these units need to be used for continual sampling in a mine setting.

During testing in the mine, Exponent observed another example of an unusual failure that was observed during CPDM maintenance. The same unit that was tested in the office was brought into the mine during our visit. Prior to entry, the unit was cleaned per daily maintenance requirements outlined in the CPDM manual, and the unit passed all diagnostic tests. While in the mine, however, the unit faulted multiple times during data collection. While performing daily maintenance on the unit immediately after the mine data collection, an odd fibrous carbon material (95% carbon upon laboratory analysis) was found adjacent to the filter, as shown in Figure 3. This was an unexpected finding that has not been fully explained.

Figure 5. Carbon fibrous material found next to Tapered Element during maintenance

NIOSH conducted in-mine testing of pre-commercial CPDM units as reported in their 2006 report (NIOSH 2006). The in-mine testing involved 10 mines across the country, and NIOSH spent 3–10 days at each mine taking full-shift samples. NIOSH evaluated 25 CPDM units with an average operating time of 437 hours per CPDM (equivalent to 44 10-hr shifts). The units were maintained following the daily cleaning procedures outlined in the CPDM manual: removed and cleaned cyclone grit pot, mass transducer module, and inlet tube lines, and installed new filter. Each CPDM was cleaned daily, although the time that the unit operated each day was not specified. No monthly or annual maintenance work was described (KO, flow, tilt audits, and cyclone cleaning).

A total of 1,202 samples were taken, representing approximately 11,000 hours of testing. NIOSH reported that the best units operated for 532 hours without repair. Based on the in-mine testing, NIOSH concluded that the failure rate, defined as the number of invalid samples / total samples, was 9.8% (118 invalid samples / 1,202 samples).

NIOSH also tracked errors reported by the CPDM and categorized them into two main repair (error) types identified in their 2006 report: 1) remedial— software or hardware modifications, including updates, failed displays, and keypads; and 2) critical—necessary for full-functioning, ultimate instrument reliability. The total number of repairs (errors) identified in their 2006 report ranged from 1.6 to 11 repairs / 1,000 hours, with an average of 4.75 errors per 1,000 hours. If this result is translated to a three-shift operation that uses two CPDM units per day, an error rate of 4.75 / 1,000 hours equates to one repair or error every two weeks, with some of them defined as "critical."

The NIOSH discussion of error rates needs to be considered in terms of several factors. The CPDM units were pre-commercial versions; there are no similar data on the current version of the CPDM sold in 2011. There is no report of monthly or annual maintenance performed by NIOSH; hence, these aspects were not included in their report. The NIOSH (2006) evaluation was a limited study compared to the number of sample hours and units needed to comply with the proposed rule in a given mine operation. It is important to note that some of the faults observed in the NIOSH study may occur with vastly increased frequency if the CPDM sampling frequency is increased as proposed.

No data are provided by NIOSH or the manufacturer that would allow the determination of a mean time between failure (MTBF) for critical parts on the CPDM. Additionally, there are no data provided by NIOSH or the manufacturer to determine the service life of the CPDM. These points underscore that there is not enough industry experience with the CPDM to determine the full range of error conditions, the practical problems that occur during use, or what these conditions will mean for data validity. For these reasons, we conclude that these considerations need to be resolved prior to using the CPDM for compliance purposes.

2.5 Error Rate Comparison between Gravimetric Sampler and CPDM

The error rates or (void rates) of MSHA data from 1995–2004 were reported in Appendix C of the NIOSH (2006) report. Both Inspector void rates and Operator void rates were determined:

Data Type	Void Percentage
Inspector Data	6.1% of the samples were voided (23,399/381,000)
Operator Data	11.7% of the samples were voided (57,000/488,000)

When comparing the gravimetric sample void rates and potential CPDM void rates, NIOSH (2006, p. 36) concluded:

> Based on types of void rates and the expanded capabilities of the PDM, we estimate that about half of the MSHA voided samples could have been valid samples using PDM technology. (p. 36, NIOSH 2006)

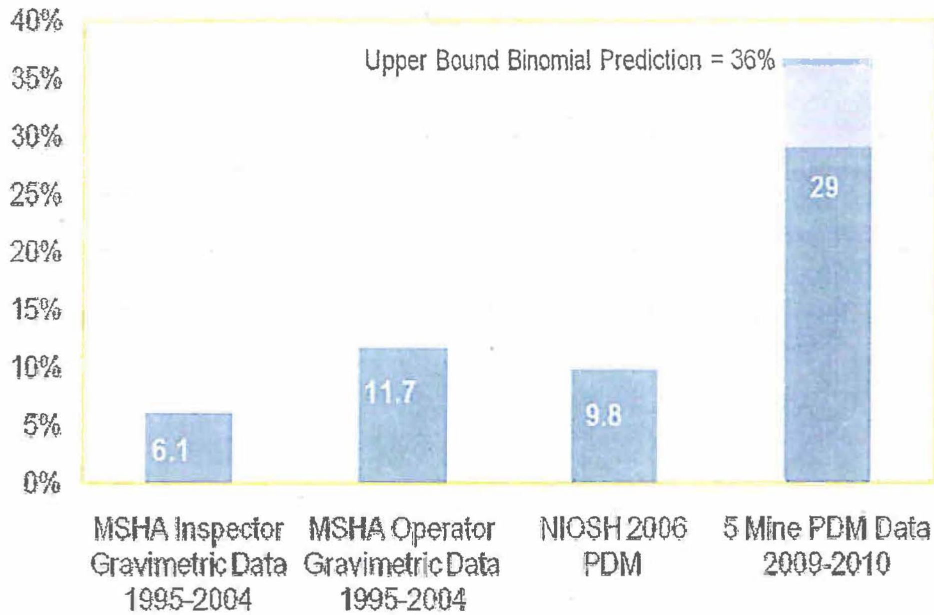
This means that NIOSH expected the void rate to be 6% or lower with the CPDM. Exponent reviewed all records (N=166) from five CPDM units in use during 2009–2010 in five different mines. The percent of invalid samples to valid samples is 48/166 = 29%, almost three times the failure rate of 9.8% (invalid/valid samples) reported by the NIOSH (2006) report.

	Total CPDM Samples	CPDM Error (at least 1)	CPDM Samples Percent Voided	Time Hours	Error per 1,000 Hours
Mine 1	36	10	28	257	39
Mine 2	43	13	30	257	51
Mine 3	28	6	21	208	29
Mine 4	25	5	20	171	29
Mine 5	34	14	41	268	52
Total	**166**	**48**	**29**	**1,161**	

Specific types of errors were identified for these data. Errors were reported on all dust cards from five MEC mines during 2009–2010. Note that errors occurred throughout the sampling period (early and late), contrary to the assumption that fewer errors would occur over time as operators became more familiar with the CPDM. The total number of errors (75) is greater as noted on the prior table (48), because some units reported more than one error per sampling event. Errors fell into the following categories:

Error Type	Number of Errors
Flow out of range	9
High filter load	12
Mass offset error	25
Power low	12
Power low shutdown	11
TE frequency	4
TE not detected	2
Total sample = 166	75

The chart below shows a comparison of the invalid samples to total samples for Gravimetric vs. CPDM results. Gravimetric void rates are based on the MSHA data from 1995–2004. CPDM void rates are based on the NIOSH PDM study (2006) and the MEC five-mine study from 2009–2010. A binomial prediction was estimated at ±7%, and hence, an upper bound for the error rate is noted on the comparison chart.



The NIOSH 2006 study found a pre-commercial PDM void sample rate of 9.8%; however, this is not in agreement with the five-mine study that shows a significantly higher error rate when CPDM units are used under mining conditions. These data suggest that the true error rate of the CPDM in field use is not known. A more comprehensive understanding of the CPDM error rate (types of errors, frequency, maintenance requirements, etc.) should be attained before relying on the instrument for compliance purposes. If the error rate is as high as observed in the five mines, the CPDM is not an acceptable tool on which to rely for compliance purposes.

3 CPDM Testing In a Laboratory Environment—Summary

A concern had been raised about the reliability of the CPDM under normal mine conditions, particularly in underground mining areas with elevated temperature and humidity levels. Although previous in-mine testing had been conducted, temperature and humidity levels were not reported (NIOSH 2006). Based on discussions with mine personnel, a variety of tests were developed to determine whether the CPDM units would perform reliably under a variety of physical and environmental conditions. The purpose of the testing was to determine whether the CPDM units produce reproducible data that are comparable to other monitoring devices under a range of environmental conditions that are typical of underground mines.

Exponent identified a laboratory in Fredericksburg, Virginia (E-Labs, Inc.), that was available to provide the necessary equipment and technical expertise in testing electronic equipment. This laboratory has extensive experience performing military-specification testing for the government and major industries. Exponent worked with mine personnel and the laboratory to determine the types of tests to be conducted. Five types of tests were identified: 1) settling dust (talcum) tests under controlled temperature and humidity levels, 2) temperature and humidity tests without dust, 3) drop tests, 4) shock tests, and 5) electromagnetic interference tests. These tests were conducted at the laboratory facility under the supervision of Exponent personnel.

Prior to the laboratory tests, a series of ambient air tests were conducted in an office environment. The three CPDM units reported similar airborne concentrations at these normal temperature and humidity levels. At the laboratory, the first series of tests—the settling dust tests—was performed to determine how the three CPDM units would respond to more strenuous environmental conditions typical of a mine and to compare the results from the CPDM units to data from the traditional method of sampling using the gravimetric sampler. Three CPDM units and a gravimetric sampler were placed inside a chamber under controlled elevated temperature and humidity levels with varying dust concentrations. Based on a series of tests, the CPDM units showed considerable differences in airborne concentrations when compared to one another and when compared to the standard gravimetric method analysis. The differences between the CPDM unit and the gravimetric sampler ranged from 0.04 to 4.7 mg/m^3 over one-hour test periods. Airborne concentrations varied among the three CPDM units under the same environmental conditions by as much as 2.7 mg/m^3, but the variations from test to test were not consistent, meaning that one unit did not consistently show higher airborne concentrations compared to the other CPDM units. A consistent trend was not observed regarding the possible association of increased variability between the two sampling devices with increasing temperature or increasing humidity levels, in part because of the limited number of samples, but also because differences between the two methods and among the three CPDM units were considered substantial, particularly considering the new proposed regulatory limit of 1.0 mg/m^3.

The three CPDM units were also placed under additional temperature and humidity chamber tests without the application of dust. Again, variations among CPDM units were seen, with variations up to 0.6 mg/m^3.

The CPDM units were also subjected to a series of other physical tests, including drop tests, shock tests, and electromagnetic interference tests. Following military standard protocols, a CPDM unit performed without error when dropped from a height of 4 feet onto packed dirt. The same CPDM unit underwent a series of shock tests of up to 30 g-forces (or 30 times the acceleration due to gravity). Under these conditions, the unit performed without error.

The CPDM unit, however, experienced problems during electromagnetic interference (EMI) tests. A band of radiofrequency signals ranging from 200 MHz to 1 GHz were directed at a CPDM unit at power levels of 5 W and 10 W. The CPDM unit operated without error during the sweep of signals at a power level of 5 W. When the power level increased to 10 W, the pump continued to operate at lower frequencies, but when a signal at 451 MHz and 10 W was applied, the motor ceased to operate and a flow fault occurred. More focused tests revealed that the motor on the CPDM would cease to operate at power levels above 6 W and 10 W at particular frequencies between 451 MHz and 532 MHz. Interestingly, at these frequencies and power levels, despite the obvious failure of the CPDM motor, no errors were reported by the

CPDM, and it continued to monitor and report airborne concentrations. The failure of the CPDM motor and the lack of reporting by the CPDM unit when EMI is applied are concerning. If a miner wearing this device were to enter an area where these signals are present, even momentarily, the CPDM could fault without reporting an error. These EMI tests evaluated a fraction of the spectrum and potential exposures to electromagnetic signals that exist within the mine. The mining environment should to be monitored to develop a full understanding of the electromagnetic field conditions that exist and to identify those that could potentially affect the operation of the CPDM.

These tests demonstrated that the CPDM does not respond reliably under all controlled conditions that can be typical of an underground mine. Under elevated temperature and humidity conditions, the CPDM units reported airborne dust concentrations that differ, at times considerably, from concentrations determined by the traditional gravimetric sampler. Additionally, under the same test conditions, three CPDM units reported different airborne concentrations at elevated temperature and humidity levels but reported similar concentrations at lower levels of temperature and humidity. The variation among the CPDM units and variation between the CPDM units and the gravimetric sampler method exceeded the proposed regulatory limit of 1.0 mg/m^3. The series of tests also showed that the internal components of the CPDM unit fail when it is surrounded by certain radiofrequency signals, at power levels less than 10 W, and that these failures are often not recorded by the CPDM.

In summary, these tests show that the CPDM is unreliable under certain conditions that can exist within an underground mine. Further evaluation by MSHA and NIOSH of the CPDM under similar conditions should be conducted, and the results of such tests should be disclosed to the public. The purpose of the CPDM unit is to accurately report the airborne dust concentration to which a miner can be exposed. As shown by these tests, the CPDM does not operate reliably under a variety of mining conditions, and the unit reports airborne concentrations that conflict with results from accepted sampling and analytical methods at elevated temperatures and humidity levels. We conclude that more thorough testing of the CPDM unit should have been conducted before the proposed rule was issued. We strongly suggest that MSHA and NIOSH conduct additional testing of the CPDM unit in a mining environment, so that miners do not rely on inaccurate readings to ensure their safety, and so that the Agency does not impose reliance on an unproven device for compliance purposes.

4 Proposed Monitoring Strategy

The proposed rule enforces a new monitoring strategy that is substantially different from the current rule and from other accepted monitoring protocols developed for the protection of workers. Key changes include: 1) decreasing the regulatory limit from 2 mg/m^3 to 1 mg/m^3 2) using single-shift for compliance purposes and 3) dramatically increasing the number of required samples. Each of these changes alone would be considered substantial but the combined effect of these – and other requirements in the proposed rule - make this proposed monitoring strategy questionable not only from a scientific standpoint but also from a feasibility issue.

We agree that full-shift sampling is an appropriate measurement to determine a worker's daily exposure, particularly if the worker's tasks or environment changes throughout the day. However, we disagree with the single-shift sampling for compliance purposes, particularly for chronic diseases that are influenced by long-term average exposures, not a single-shift exceedance.

MSHA has also proposed changing from a bimonthly average of five samples to full-shift, every-shift, sampling for some occupations. The number of required samples at one mine, for example, will increase from approximately 264 samples per year to 7,155 samples per year; nearly a 30 fold increase. Expanded across the entire coal mining industry, this number would be much higher. This is a heavy burden to place on the miner and dust operator who need to work, operate and maintain these units on a daily basis. In addition, as stated previously, large data collection does not necessarily reduce miner exposures nor will it help determine the causative factor(s) associated with CWP. The ability of mines to comply with the proposed regulatory limit, single shift sampling and increased number of required sampling is highly questionable. This area is fully evaluated by Dr. Reiss of Exponent in his report.

Other international agencies have different exposure limits and sampling strategies. One potentially important example is the Australian coal mine experience in New South Wales (NSW). The Australia Coal Mine Health and Safety regulation sets a limit of respirable coal dust without silica at 2.5 mg/m^3 and a limit of 0.12 mg/m^3 for respirable coal dust with silica. The limit for respirable dust without silica is higher than the current MSHA exposure limit and the monitoring requirements are significantly less than those stated in the MSHA's proposed rule. Under this approach Australia, as reflected in the experience in Coal Services in NSW, has achieved a significantly lower incidence of CWP.

5 Medical Surveillance

Although some medical surveillance requirements have changed with the proposed rule, critical medical surveillance program elements that will significantly affect the program have yet to be defined by MSHA. A public comment period should be provided for these key program elements to ensure that recommendations are supported by sound science and that implementation will not exert undue impact on potential stakeholders.

These program elements, which remain to be defined, include the following:

- 72.100 Paragraph (a) (1). This section deals with the overall qualifications and approval of persons who will provide medical surveillance testing pursuant to the proposed MSHA standard. The proposed regulation states that operators will be required to provide medical examinations at "facilities approved by National Institute of Occupational Safety and Health." However, the criteria for determining qualification and approval are not defined. These should be subject to review to ensure that all qualified medical providers have the opportunity to provide such services.

- 72.100 Paragraph (a) (1). The professional qualifications of professionals who will interpret the results of the medical surveillance examinations are not defined. The proposed regulation does not specify whether the term "facilities" encompasses health-care professionals who will be responsible for interpreting the medical surveillance examination test findings. The interpretation of medical surveillance examination findings requires integration of several key examination components, including occupational history, symptom questionnaire, spirometry, and chest x-ray data. The qualification criteria and approval process for professionals who will provide these assessments should be defined to ensure that all qualified medical providers have the opportunity to provide such services.

- 72.100 Paragraph (c) (1). The medical criteria that will be used to determine that an adverse health effect has occurred from coal dust exposure are not defined. The proposed regulation states that "evidential criteria" will be identified by NIOSH, but the process for this is not defined. Several different standards could be used to define what represents an adverse change, which differ in sensitivity and specificity for determining adverse effects. Final criteria developed by NIOSH should be subject to public comment. At this point, the MSHA proposed rule has not provided for such public comment, because specific criteria have not been adequately described.

- MSHA indicates that miners who demonstrate a loss of lung function or disease on a five-year follow up medical examination, which is performed because the initial three-year evaluation showed abnormal findings, will require more frequent testing "to detect and prevent further progression" of disease (Page 64445 regarding proposed paragraph (c) (3)). However, MSHA provides no guidance regarding the nature or frequency of such testing. The process, content, and frequency for more frequent medical evaluations for at-risk workers should be defined and subject to public comment.

6 Questions for Consideration

Based on this review of industrial hygiene aspects of the proposed rule, the following questions should be addressed when considering the proposed rule or alternatives.

1. Why do the five mine error rates differ from the NIOSH (2006) error rates?
2. Why do some units perform more poorly than others?
3. What is the true fault rate for PDM units taking full-shift samples, every day?
4. What are the known or suspected interferences with the unit?
5. How does the unit fault rate increase over time; i.e., as the CPDM unit ages?
6. What is the useful life of the PDM units?
7. What are the MTBF rates for the critical components of the PDM?
8. How long will it take to implement approved changes to software and/or hardware of the CPDM?
9. What happens when the CPDM unit faults?
   - No effect?
   - Is a resample required on a smaller portion of the shift?
   - If a resample is required, how does this affect the time to clean, restart, and possibly recharge the unit?
   - Is another sample required on another shift?
   - Are the fault dust data uploaded to MSHA?
   - How are these counted?
   - Is this a citation event?
10. Has the Australia approach to reducing miner incidence of CWP been reviewed by NIOSH and MSHA in determining the sampling approach and respirable coal dust exposure limits?
11. Has MSHA and NIOSH estimated the reduction in exposure and the impact on CPW incidence for miners wearing air helmets?
12. Has MSHA estimated the reduction in exposure and the impact on CPW incidence for miners if Administration controls are utilized including miner rotations from high respirable dust areas?

7 Conclusions

Based on this discussion, the proposed rule poses a number of unanswered questions. These concerns center on the lack of standard industrial hygiene practices to reduce worker exposures, the reliability of the CPDM, and missing elements of the medical surveillance program. These issues, identified in this report, have not been adequately addressed, but they represent critical issues that should be resolved. A successful industrial hygiene monitoring program that reduces the incidence of miner's respiratory disease and, at the same time, does not introduce other health and safety risks requires further consideration of the issues described in these comments regarding CPDM reliability and medical monitoring.

Based on our experience working with the CPDM, our evaluation of mine data, and the independent laboratory testing of the unit, we have concluded that the CPDM does offer promise as an advancement for monitoring underground coal-mine dust levels; however, at present, it is not reliable for continuous monitoring in underground mining environments. For these reason, although the CPDM is valuable for research and general monitoring purposes, it should not be used for single-sample compliance purposes. Data from multiple mines show an error rate almost three times higher than the failure rate that NIOSH reported from their testing of the unit. Laboratory testing, particularly at elevated temperature and humidity levels, has shown considerable differences among the CPDM units, at times by more than 1 mg/m^3, the regulatory limit under the proposed rule. Differences between the CPDM and the traditional gravimetric method were also observed under more strenuous environmental conditions. These differences, now observed only under limited laboratory testing, would likely be exacerbated due to the significant increase in CPDM sampling required by the proposed rule. These points underscore that there is not enough industry experience with the CPDM to determine the full range of error conditions, practical problems during use, or the implications of these conditions on data validity. Therefore, we conclude that these considerations need to be resolved prior to instituting the use of the CPDM for compliance purposes.

Large-scale data collection, as mandated by the proposed rule, is an inefficient way to improve the understanding of the causative factors involved in the dose-response relationship with CWP incidence. Smaller, well-designed surveys that employ carefully thought out survey designs and statistically meaningful sampling procedures would be much more cost effective at identifying situations that lead to high miner exposures, and therefore, to which targeted prevention efforts can be implemented, rather than simple expending all available resources to collect exposure, resulting in inability to effectively put these data to use at disease prevention.

Key components that are recognized as part of an established hierarchy of controls to protect workers in an industrial environment are lacking in the proposed rule. The use of administrative controls and personal protective equipment is not mandatory, and MSHA should reconsider this omission, to fully protect workers and help avoid adverse health effects.

With respect to medical surveillance, the proposed rule is incomplete and not ready to be evaluated, because the critical criteria for defining CWP are not clearly described, nor are the necessary qualifications of medical staff who are administering and interpreting the medical monitoring tests adequately described. A public comment period should be provided for these key program elements to ensure that recommendations are supported by sound science and that implementation will not exert an undue impact on all potential stakeholders.

8 References

NIOSH. 2006. Laboratory and field performance of a continuously measuring personal respirable dust monitor. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2006-145, RI 9669.

Volkwein JC, Vinson RP, McWilliams LJ, Tuchman DP, Mischler SE. 2004. Performance of a new personal respirable dust monitor for mine use. Pittsburgh, PA: DHHS (NIOSH) Publication No. 2004– 151, RI 9663.

E-Labs. 2011. Settling dust, temperature/humidity, drop, shock and radiated susceptibility testing applied to Four (4) Personal Dust Monitors P/N 42-009904 in accordance with MIL-STD-810F Environmental Engineering Considerations and Laboratory Tests, Dated 1 January 2000 and Customers Verbal Instructions. E-Labs Environmental Test Report No. 2341-B., dated April 20, 2011. Fredericksburg, VA.

TFS. 2009. PDM Manual. Model 3600 PCM. Personal Dust Monitor Part No. 42-009904, Thermo Fisher Scientific. June 19.

Attachment A

Curriculum Vitae for
Michael N. Cooper

Michael N. Cooper, M.P.H., CIH
Senior Managing Scientist

Professional Profile

Mr. Michael N. Cooper is a Senior Managing Scientist in Exponent's Health Sciences Center for Occupational and Environmental Health. He specializes in occupational health, industrial hygiene, chemical exposure limits, Environmental Health & Safety (EHS) management and program development, EHS regulatory affairs, community communication, and public policy. Mr. Cooper has developed and directed corporate compliance programs and improved corporate culture regarding safety and environmental affairs for a variety of industries, including: aerospace, pharmaceuticals, semiconductor, and semiconductor equipment manufacturing in both the United States and International settings. He has created and implemented corporate compliance and auditing programs, clean-up strategies for groundwater contamination, site closure and site development planning, due diligence for real estate transactions, occupational health functions, and has hosted local community forums regarding industry chemical usage. Mr. Cooper has built strong relationships with state regulators within various departments in California including Radiological Health, OSHA, and various Fire Departments. He has served as the corporate radiation safety officer and the biosafety officer for several industries.

Mr. Cooper has extensive experience in permissible exposure (PEL) development for chemicals within California. He has served or is currently serving on advisory committees for California State OSHA, the American Industrial Hygiene Association (AIHA), Organizational Resources Counselors, the American Electronics Association, and other voluntary and advocacy groups. Mr. Cooper has taught college courses in chemistry, physics, hazardous materials management, and industrial hygiene at the University of California (UC) Davis, UC Extension, San Jose State University, and De Anza College. He has developed and taught AIHA accredited continuing education courses in radiation safety and industrial hygiene.

Prior to joining Exponent, Mr. Cooper was the Director of Corporate Environmental, Health & Safety at Vishay Intertechnology, a semiconductor and electronics component manufacturer. At Vishay he was responsible for EHS programs in California, Israel, China, Germany and Taiwan. He was also Senior Manager for EHS programs at Novellus Systems, a semiconductor equipment manufacturer, and EHS manager at Behring Diagnostics, a medical device manufacturer.

While at Exponent, Mr. Cooper has worked on diverse projects including mitigation of a Q-fever outbreak and assisting with a NIOSH Health Hazard Evaluation, litigation support for industrial hygiene cases, and assessment of radiological issues for a 100-year-old chemical plant in California, working with various State agencies and community action groups. During 2008–2009, he served as an Exponent Department of Defense contractor with the forward units of the US Army Rapid Equipping Force from Ft. Belvoir, Virginia. For these assignments, Mr. Cooper was deployed with military personnel for extensive periods of time in Kuwait, Afghanistan, and

Iraq. In this role, Mr. Cooper was the lead field engineer supporting technology development and research to provide materiel solutions for deployed tactical units. Mr. Cooper worked with various Army task forces, units, and core personnel in the areas of overheadwire mitigation, intelligence/surveillance/ reconnaissance, and counter IED efforts.

Academic Credentials and Professional Honors

M.S., Chemistry, San Jose State University, 1989
M.P.H., Public Health, San Jose State University, 1984
B.S., Chemistry, University of California, Berkeley, 1980

Licenses and Certifications

Certified Industrial Hygienist, Comprehensive Practice, American Board of Industrial Hygiene, 1994

California Community College Teaching Credential, lifetime, 1989

Publications

Cohen R, Steinmaus C, Quinlan P, Roberts T, Cooper M. Keeping up with science: Developing PELs in California. The Synergist, March 2007; 32–35.

Cohen R, Steinmaus C, Quinlan P, Ku R, Cooper M, Roberts T. Development of permissible exposure limits. International Journal of Occupational and Environmental Health July/September 2006; 12(3):242–247.

Presentations

Cooper M. A perspective on safety and health in Afghanistan—Images of Operation Enduring Freedom. Organizational Resources Counselors (ORC) quarterly meeting, September 2008.

Cooper M. Setting permissible exposure limits—Viewpoint from a Cal OSHA State Health Expert Advisory committee member. Organizational Resources Counselors (ORC) quarterly meeting, June 2008.

Cooper M. Radiation safety for the industrial hygienist. Peninsula Industry Business Association, April 2007.

Cooper M. Are permissible exposure limits dead or alive. Panel discussion, Organizational Resources Counselors, March 2005.

Prior Experience

Director of Corporate Environmental, Health & Safety, Vishay Siliconix, 2003–2007
Senior Manager of Corporate EHS, Novellus Systems, 1999–2003
Manager of EHS, Behring Diagnostics (Syntex/Syva), 1994–1999
Senior Safety Engineer, Amdahl Corporation, 1991–1994
Various positions including Contamination Control Engineer, Senior Material and Process Engineer, and EHS coordinator for the central chemistry laboratories, Lockheed Corporation, 1982–1991

Academic Appointments

- Instructor, Health & Safety Management and Program Development, University of California, Davis, 2007–present
- Instructor, chemistry and hazardous materials management, De Anza College, Cupertino, 1989–2005
- Developed and co-presented industrial course for Biosafety and Radiation Safety Officers working in Biotechnology, 1996–1999 (Course received approval for continuing education credits with the American Industrial Hygiene Association)
- Lecturer (hazardous materials management certificate coursework), University of California, Santa Cruz, 1993–1996
- Lecturer (chemistry and physics), San Jose State University, 1981–1988

Research Experience

- Thesis work in audiometry at the Santa Clara County Juvenile Detention Facility, San Jose State University, 1984
- Thesis work studying biological phosphate anhydrides using 31P nuclear magnetic resonance spectroscopy, San Jose State University, 1987–1989

Science Advisory Boards/Panels

- California State OSHA Health Expert Advisory Committee, committee sets health-based regulatory permissible exposure limits for airborne contaminants, appointed 2007–2009
- American Industrial Hygiene Association Workplace Environmental Exposure Limit Committee, committee sets voluntary occupational exposure limits for airborne contaminants, 2005–present
- Steering Committee, Western Occupational Safety & Health Group, Occupational Resources Counselors, committee of industry EHS professionals, 1998–2006

Professional Affiliations

- Health Expert Advisory Committee , California State OSHA Permissible Exposure Limit Advisory Committee on Airborne Contaminants (appointed for 2001–2004, re-appointed 2007–present) (member)
- Workplace Environmental Exposure Level (WEEL) Committee, American Industrial Hygiene Association, 2005–present
- Steering Committee, Western Occupational Safety and Health Group, Organization Resources Counselors, 1998–2006, 2009–present
- Phylmar Group—Occupational Health and Safety Forum, 2004–2007 (member)
- American Chemical Society, 1990–present (member)
- American Industrial Hygiene Association, 1994–present (member)
- American Board of Industrial Hygiene, 1994–present (member)

Attachment B

Curriculum Vitae for
Sheila McCarthy

Sheila A. McCarthy, CIH
Managing Scientist

Professional Profile

Ms. Sheila McCarthy is a Certified Industrial Hygienist and Managing Scientist in Exponent's Health Sciences Center Occupational and Environmental Medicine. Ms. McCarthy is experienced in the fields of industrial hygiene and risk assessment involving potential exposures to fibers, pesticides, metals, organic, and inorganic chemicals, as well as physical agents such as noise, heat, and sources of ionizing and non-ionizing radiation. Her experience includes performing industrial hygiene studies to evaluate OSHA compliance, illness clusters, and indoor air quality evaluations, and conducting historical and quantitative exposure assessment in support of site-specific risk assessments.

As a CIH, Ms. McCarthy has conducted exposure assessments for both occupational and environmental settings. In these settings, she has developed and implemented sampling methodologies and evaluated a number of agents including fibers, metals, particulate matter, volatile organic compounds, bioareosols, mold, and noise. Examples of her work include a historical exposure assessment that required the evaluation of thousands of industrial hygiene sampling reports, for the purpose of developing a job exposure matrix (JEM) that provided 8-hr time-weighted average (TWA) exposures for various occupations involving asbestos-containing products. Her work has also included assessments of indoor air quality within concentrated animal feeding operations (CAFOs) and measurements of emissions from these types of facilities. Ms. McCarthy recently conducted a comprehensive analysis of exposure data related to metal fumes, including hexavalent chromium, from common welding activities in light of new OSHA regulations related to hexavalent chromium.

Ms. McCarthy teaches at the University of California Extension Program at Davis. Her lectures focus on industrial hygiene and physical agents in the workplace (noise, radiation, heat/cold stress, and ergonomics).

Prior to her work in public health, Ms. McCarthy has over 10 years experience in the engineering and computer science fields.

Academic Credentials and Professional Honors

M.H.S., Johns Hopkins Bloomberg School of Public Health, 2004
B.E.E., The Catholic University of America, 1991

Recipient of two-year NIOSH Training Grant Fellowship, Johns Hopkins Bloomberg School of Public Health, 2002–2004

Publications and Presentations

McCarthy SA, Hicks JB. Reaction to California's heat illness and prevention regulation. American Industrial Hygiene Annual Conference (AIHce), May 26, 2010.

Hicks J, McCarthy SA. Hexavalent chromium air sampling data from welding and steel cutting. Electric Power Research Institute, report no. 1016821, October 2009.

McCarthy SA, Suen M, Rey P, Hicks JB. Fungal concentrations during typical household activities. American Industrial Hygiene Annual Conference (AIHce), June 2, 2009.

Hicks J. Program on technology innovation: Nanoparticles at coal and gas fired power plants. Electric Power Research Institute (EPRI), Report No. 1016820, December 2008.

Rule AM, Chapin AR, McCarthy SA, Gibson KE, Schwab KJ, Buckley TJ. Assessment of an aerosol treatment to improve air quality in a swine Concentrated Animal Feeding Operation (CAFO). Environ Sci Technol 2005; 39(24):9649–9655.

Centeno JA, Kolker A, Gibb HJ, McCarthy SA. Potential health risks from long-term mercury exposure, a medical geology opportunity. 9th International Symposium on Metal Ions in Biology and Medicine, Lisboa, Portugal, May 21–24, 2006.

Chapin AR, McCarthy SA, Rule AM, Gibson KE, Buckley TJ, Schwab KJ. Antibiotic-resistant bacteria in air and water associated with chicken and hog facilities. 104th General Meeting of the American Society for Microbiology, New Orleans, LA, May 23–27, 2004.

Prior Experience

Project Manager, Sciences International Inc., 2006
Senior Associate, Sciences International Inc., 2004–2006
Research Coordinator, Johns Hopkins Bloomberg School of Public Health, March–August 2002; January–April 2004
Intern, General Electric, Aircraft Engine Division, 2003
Instructor, K Computing, 1999–2001
System Support Engineer, Silicon Graphics Inc. (SGI), 1997–1999
System Administrator, HT Medical, 1995–1997
Electronics Engineer, Naval Surface Warfare Center, Department of Defense, U.S. Navy, 1991–1995

Ex

Professional Affiliations

- American Industrial Hygiene Association, 2002–present
- Local chapters for the AIHA
  - Northern California Section of the American Industrial Hygiene Association, 2009–present
  - Potomac Section of the American Industrial Hygiene Association, 2004–2007; Treasurer-Elect, 2007–2008
  - Chesapeake Section of the American Industrial Hygiene Association, 2002–2004
- Society of Risk Analysis, 2006–present
- Deputy Managing Editor, *Risk Analysis: An International Journal*, 2007–2008