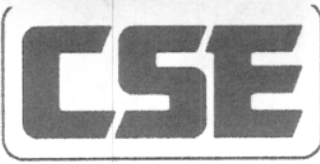


Miller, Diane M. (CDC/NIOSH/EID)

From: Scott Shearer [sas@csecorporation.com]
Sent: Friday, June 19, 2009 4:12 PM
To: NIOSH Docket Office (CDC)
Subject: NIOSH Proposal RIN: 0920-AA10 42 CFR pt. 84
Attachments: CSE Response to NIOSH Proposal Final.pdf; Cover Letter Response to NIOSH
Proposal CCER.pdf

Please accept CSE Corporation Comments to RIN: 0920-AA10 Approval Tests and Standards for



Friday, June 19, 2009

NIOSH Docket Office
Robert A. Taft Laboratories, M/S C 34
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Cincinnati, Ohio 45226
Telephone 513-533-8303
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Reference: RIN: 0920-AA10
Approval Tests and Standards for Closed-Circuit Escape
Respirators; Notice of Proposed Rulemaking-42 CFR Part 84

Dear Sirs / Madam:

CSE commends NIOSH on its continuing efforts to promote research and development of Closed Circuit Escape Respirator (CCER) technology through its field evaluation and testing programs. We welcome this opportunity to offer comments, and discuss the proposed rulemaking-42 CFR Part 84 program. It is our hope that this will lead to a continuing dialogue that will result in enhanced evaluation, and testing programs, which directly result in advancements in Closed Circuit Escape Respirator technology for this nation's miners. Pursuit of innovation can only occur by challenging current technologies, and establishing new objectives. CSE is committed to working with all stakeholders during this process and future projects with an open mind and open dialog.

As requested CSE has provided the following response to the Federal Register Notice that posted on December 10, 2008 regarding the Notice of Proposed Rulemaking for Closed-Circuit Escape Respirators.

Thank you for your consideration regarding our recommendations for the Proposed Rulemaking for Closed-Circuit Escape Respirators. I look forward to further dialog on these issues, please contact me any time, at 412-856-9200, or E-mail at sas@csecorporation.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'S.A. Shearer', followed by a horizontal line.

Scott A. Shearer
President and CEO



**CSE Corporation Comments to
RIN: 0920-AA10
Approval Tests and Standards for Closed-Circuit Escape
Respirators; Notice of Proposed Rulemaking-42 CFR Part 84**

June 19, 2009

Condition Indicators:

CSE supports the proposed rule's requirements in section 84.302 for means to be provided for users to be able to assess the current condition of a CCER. The end-user must be able to readily identify the status of a CCER upon inspection. It is vital that the end-user have indicators or warning systems capable of providing the means for the end-user to evaluate the CCER with minimal effort and to have the greatest assurance that the CCER is in good operating condition.

Periodic Testing of Deployed Units:

NIOSH has developed a database regarding field deployed Self-Contained Self-Rescuers or Closed Circuit Escape Respirators (CCER) through its Long Term Field Evaluation (LTFE) program. The issuance of the LTFE report provides a general overview to the industry as to the condition of fielded CCERs, including some of the very worst examples of units, but offers very little value to the manufacturer as to the specific data. Inviting the manufacturer to participate in the process by opening this database specific to that manufacturer would further innovation and development of CCERs. Allowing the manufacturer to analyze the data, along with physical inspection of the CCER would greatly assist future innovation and design.

In order for the data obtained in the LTFE to be valid and of value to the regulatory agencies, manufacturers and users, the rule should specify that only units that pass the approved user inspection criteria issued by the manufacturer will be used for LTFE testing. CCER manufacturers are required under existing certification approvals and will be required under this proposed rule to provide users with procedures and criteria for inspection of the CCER to be used in determining whether the CCER is in condition appropriate for use. Only CCERs that pass this inspection criteria are permitted to be used in the field and only such CCERs should be used for the LTFE testing. Otherwise, the testing will not serve its intended purpose, which, as stated in the preamble, is to determine the ability of fielded CCERs to perform in accordance with their certification.

General Testing Conditions and Requirements:

Since the Rulemaking Proposal-42 CFR Part 84 intends on utilizing Automated Breathing Machine Simulator (ABMS) for the approval certification process and data collection, it is incumbent upon NIOSH to provide verification of the performance and accuracy for each ABMS simulator managed by the NIOSH laboratory responsible for testing to ensure that tests are reproducible and the data collected will be valid. In order to provide for complete transparency of the ABMS testing process and to enable others to conduct their own scientifically valid tests to reproduce the test results, CCER equipment manufacturers should be provided with the design specifications and configuration for the ABMS including Bills of Material, Drawings, System Operating Software, ABMS Software. Such things as the status of each of these ABMS with regard to hardware and software configurations and whether there are any variations in hardware or



software configuration are critical. We cannot emphasize enough that having access to this information is essential to our ability to properly analyze and interpret each of the ABMS test results for design purposes. CSE would also advocate that until all manufacturers are provided with uniform disclosure as to the design and performance parameters of the NIOSH ABMS, NIOSH should provide the opportunity for each manufacturer to visit the ABMS laboratory to review the ABMS hardware and software.

Specifically, we request that each manufacturer be provided with the following data for each of its CCERs evaluated on the ABMS or Human Subject:

- a) Expired carbon dioxide concentrations, both peak and average.
- b) Inspired carbon dioxide concentrations, both peak and minimum.
- c) Expired and inspired oxygen concentrations.
- d) Pressures, including expired and inspired peak and expired and inspired average pressures.
- e) All protocol parameters, including inspired and expired tidal volumes, breathing frequency, volume of carbon dioxide introduced (VCO_2), volume of oxygen removed (VO_2), and total minute exhalation volumes (Ve).
- f) All relevant temperature data, including inspired wet and dry bulb temperatures; expired wet bulb temperatures at the mouthpiece; dry bulb temperatures at the water bath, lung and mouthpiece.
- g) Water vapor content of the inspired and expired gas.
- h) Room Temperature of ABMS laboratory.
- i) Raw data of the test run.
- j) ABMS parameter settings at start of each test run.

We would like to have this data for each test at as frequent an interval as possible, preferably the raw data collected by your data acquisition system. Further, we are requesting additional information regarding your testing and data collection. Specifically we would like to know the sampling rate for the raw data, and the algorithm used by the ABMS software for generating the data reported by the software from the raw data. Finally, we would like to know how the data shown in the final report were obtained from the ABMS data.

Of particular importance when testing a chemical-based oxygen-generation breathing apparatus, such as the SR-100 on the ABMS, is the ABMS lung configuration, lung temperature, and water vapor content of the exhaled gas that is utilized in the testing. There are numerous potential variables within the ABMS that can influence the water vapor content during the ABMS exhalation cycle but the aforementioned have the greatest influence in water vapor content of the ABMS exhalation cycle. Variation in the water vapor content affects all breathing apparatus under testing as water vapor is a critical component of the exhalation gases which react to generate the oxygen and scrub carbon dioxide in the chemical-based oxygen-generation breathing apparatus.

If wet bulb and dry bulb temperatures are to continue to be the indicator of water vapor content of the inhalation/exhalation gas, then the wet bulb thermometer device must be subjected to scrutiny as to its capability, accuracy, and precision. CSE feels that wet bulb response is not a fundamental property, but, rather, is specific to the system in which it exists. For example, wet bulb response will vary with different flow rates, different amounts of water on the thermocouple or different size thermocouples. Because of this, we expect that it will be difficult to standardize humidity responses between simulators using such a device. Please consider that manufacturers in the industry may wish to correlate their simulators to those used by NIOSH. The design used by NIOSH must therefore take into account the need for other simulators to be able to replicate NIOSH's results. For example, are these parts available for purchase or are they specialized components? Consideration should be given to a fast response sensor that may be a suitable substitute for determining relative humidity of simulator systems that can be mass-produced to industry specifications. We would be happy to provide you with information on alternative designs.



Temperature control must also be examined when considering the water vapor content inside the simulator. Temperature of the lung section is currently monitored but is not currently temperature controlled. Data from NIOSH Long Term Field Evaluation 8 and 9 indicate there may be as much as a 15° F variance in the laboratory room temperature depending on the time of year and as much as 5° F over a single day. Consider also the temperature variation within the system. It is critical that temperature be accurately controlled during the testing, as this will affect water vapor content inside the breathing circuit, which in turn will affect performance of the breathing apparatus. A human test subject starts the test with an approximate core temperature of 98.6° F (37.0° C) and an exhalation temperature of approximately 91.4° F (33.0° C) at the mouth which should be the temperature at the mouthpiece of the ABMS during the exhalation cycle. Results from the Long Term Field Evaluation 9 indicate starting temperatures as low as 79.8° F (26.6° C).

CSE recommends the following for consideration when utilizing a wet bulb thermocouple to determine water vapor content with the ABMS circuit. Producing humidities of 5 to 95 % can involve all the usual techniques of dynamic gas mixture production. Mechanical pump feed, evaporation, and saturation of air streams are all techniques used to introduce water vapor to a gas stream. However, potential problems exist with each technique.

A wet bulb psychrometer consists of two thermometers placed in close proximity. The bulb of one is housed in a wick saturated with water (the wet bulb), while the other (the dry bulb) is left completely open to the gas of interest. The gas, usually flowing past at a velocity of at least 1,000 feet/minute, cools the wet bulb thermometer to a new equilibrium temperature. The relative humidity can then be obtained by knowing the dry bulb temperature and the difference between the dry and wet bulb temperatures.¹

Although this method seems simple enough, there are several disadvantages. In dynamic systems, water must be continually supplied to the wet bulb to maintain wick saturation. Also, the measuring unit must be placed in a separate gas stream, since water evaporating from the wick further adds to the moisture of the gas stream, especially at lower humidities. Additional errors occur from inadequate flow rate, radiant heating effects, contaminated wick, contaminated water, and an improperly fitted wick.²⁻⁴ For these reasons, it is often desirable to use calibrated electronic measurement devices.⁵

Electronic methods have the advantage of direct measurement of both temperature and a variety of humidity outputs. Currently, relative humidity detectors often rely on bulk polymer resistance, thin-film capacitance,⁶ and strain-gauge sensors.⁷ The response time is usually less than 2 minutes with an accuracy of better than ±5% full scale.

The preamble to the proposed rule states: "The advantage of the simulators, as discussed in II.C. of the preamble, is that their performance for all metabolic parameters can be calibrated and replicated, whereas each human test subject performs uniquely, making the testing less repeatable." CSE agrees that the ABMS is a valuable diagnostic tool and provides a level of analysis difficult to attain from a human subject wearing a CCER while involved in exercise. However, CSE considers the human subject in all its variations to be the ultimate qualifier in defining acceptable performance. CSE has utilized its own ABM Systems for years but would not consider replacing the human subject for final verification. In CSE's experience with product certification testing, NIOSH has sought out this variability in its test subjects (50th percentile to the 99th percentile coal miner) to verify product performance which provides a broad representation of the mining population. Limiting the testing to a smaller representation of the mining population would not benefit the industry or the end-user. NIOSH appears to have the same opinion regarding the human subject, as indicated in the preamble which states, "The purpose of this human test is to provide assurance that the simulator is reasonably measuring the capacity of the respirator as it would be expended in actual use."



CSE agrees that the NIOSH recommended Excursions outside of existing operating parameters during product certification testing as defined in the proposed rule would not be harmful to humans. However, CSE is opposed to lowering the Excursion limits to these levels. CSE recommends further study before implementing these excursions to certification and operating parameters.

Classification by Capacity Testing:

CSE respectfully requests further clarification as to how a certification test representing the 50th percentile miner is consistent with established certification test practices, which represents the 95th and even 99th percentile miner. Previous opinion expressed by NIOSH indicates that the 50th percentile ABMS test is not equivalent to the current certification test. The LTFE 10 Report stated: The BMS test consisted of the average metabolic work rate exhibited by the 50th percentile miner weighing 87kg while performing the 1-hour man-test 4 as described in 42 CFR 84. However, even though the average work rate is the same, LTFE testing is not equivalent to certification testing. The certification testing imposes high and low work rates that the average work rate, used in the LTFE does not.⁸

Unlawful Reduction of Miner Safety:

For all the reasons stated in these comments, this rulemaking will unlawfully result in a lowering of the mandatory safety standards for CCERs in mines. The Federal Mine Safety and Health Act mandates that “[n]o mandatory health or safety standard promulgated under this title shall reduce the protection afforded miners by an existing mandatory health or safety standard.”⁹ Manufacturers like CSE, who already manufacture a product that meets existing and proposed rule make requirements are being placed between a rock and a hard place. While CSE will continue to provide CCERs that outperform the minimum standards mandated by NIOSH, it must confront the general lowering of safety standards that the proposed ruling making offers to miners. If the rule making is adopted, it must be accompanied by curative legislation that protects manufacturers who placed NIOSH on notice of concerns from product liability claims, if forced to manufacture to a reduced standard.

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6. Lafarie, J.P. Humidity Sensors Based on Dielectric Polymers,” *Sensor Expo West Proceedings*, 303c-1 (1989).
7. Brownawell, M. *Sensors* 23:33 (1989)
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