Dragon, Karen E. (CDC/NIOSH/EID)

From: Mike Kay [mikekay@ocenco.com]
Sent: Friday, June 19, 2009 5:10 PM
To: Szalajda, Jonathan V. (CDC/NIOSH/NPPTL)
Cc: NIOSH Docket Office (CDC)
Subject: Ocenco comments to proposed CCER rulemaking, docket 005
Attachments: Ocenco CCER comments June 19.pdf

Dear Mr. Szalajda,

Please find attached Ocenco comments to the proposed CCER rulemaking.

Sincerely,
Michael Kay
Ocenco Inc

June 19, 2009

Jonathan Szalajda
Branch Chief
CDC/NIOSH/NPPTL
P.O. Box 18070
626 Cochrans Mill Road
Pittsburgh, Pennsylvania 15236

Re: RIN: 0920-AA10: Proposed Rule on Approval Tests and Standards for Closed-Circuit Escape Respirators, Docket #005 Public Comments
42 CFR pt. 84

Dear Mr. Szalajda:

Ocenco, Incorporated is pleased to provide additional comments on the proposed rulemaking for Approval Tests and Standards for Closed-Circuit Escape Respirators published in the December 10, 2008 Federal Register. (73 Fed. Reg. 75027).

Numerous areas of the CCER Proposed Rulemaking are arbitrary and capricious as they are not supported by either data or rationale. These areas include:

1) No data has been presented that supports the need or appropriateness of the proposed high work rates in the Capacity and Performance tests. While NIOSH provides the rationale for not increasing the respiration rate for category 3, they provide no study, data or rationale for increases to categories 1 and 2. As stated in our April 10th comments, these unsupported increases in work rates will force a significant increase in the size and weight of these devices. The proposed capacity 1 work rate represents an 85% increase in oxygen capacity, a 117% increase in carbon dioxide absorbing capacity, and a 83% increase in ventilation rate.

Prior to selecting and purchasing over 400,000 M-20.2 EEBDs, the US Navy conducted shipboard escape trials and concluded that a 10-minute rated SCSR would provide the oxygen necessary to make a shipboard escape (April 23rd, 2009, Aldephi MD, NIOSH CCER meeting transcripts). This US Navy recommendation can also be found at the NAVSEA Damage Control web site http://www.dcfp.navy.mil/library/dcnews/OcencoTip001:

"EGRESS TESTING WAS PERFORMED TO DETERMINE AIR CONSUMPTION AND APPROXIMATE TIME REQUIRED TO EXIT DEEPEST MACHINERY SPACES ONBOARD CARRIERS.

EGRESS TIME FOR ALL TEST SUBJECTS FROM THE MOST REMOTE CORNER OF SPACE TO WEATHER DECK < 4 MINUTES.

THE SOW 10 MINUTE DURATION REQUIREMENTS WAS BASED ON THE RESULTS OF THE EGRESS TESTING."

2) Additionally, US Coast Guards comments to the CCER NIOSH Docket state they have performed extensive inspections and drills to ensure that the tens of thousands of 10-minute

EEBDs they have in service perform to specification, and they are not aware of any problems with this device that warrants the considerable expense to the marine industry of developing new equipment for marine use.

3) Both open and closed circuit devices are certified by NIOSH for escape from IDHL atmospheres, but no data or rational has been provided to explain the difference in performance requirements or levels of safety. Ten and fifteen-minute open-circuit, fixed-flow escape devices are only required to provide a 40 lpm ventilation rate (42CFR, 84.95, 84.88). There are no other flow requirements for these devices. The proposed rulemaking requires 10 and 15 minute closed-circuit escape devices to provide a 65 lpm ventilation rate.

4) The proposed rulemaking requires hard lens eye protection for CCER while allowing open circuit compressed air escape breathing apparatus to provide flexible eye protection. NIOSH provides no study, data or rationale to explain the difference in levels of safety.

5) The proposed rulemaking requires compressed oxygen CCERs to be tested, in violation of the manufacturer's procedure, by exhaling twice into the device at the beginning of the test. While it is true that chemical oxygen CCERs have a history of oxygen starter failure that requires the user to inhale from the toxic mine atmosphere and blow repeatedly into the device, NIOSH provides no study, data or rationale to explain why this extraneous, unnecessary procedure would be imposed on compressed oxygen CCER during the approval testing.

6) NIOSH has not provided data that demonstrates that the breathing simulator provides a human-like response to proposed high work rates. The importance of the breathing simulator having a human-like response is echoed in the NIOSH report *"The Effect Of Dry and Humid Hot Air Inhalation on Expired Relative Humidity During Exercise."* N. Turner et al., 53 AIHA J 256-260 (1992). ***..."this finding is of interest to those involved in respiratory research, particularly those who design and test robotic metabolic simulators. These simulators must accurately mimic the physiological responses of human airways to breathing air of various temperatures and relative humidities."*** NIOSH has not conduct human subject treadmill tests at the work rates proposed in the capacity 1, capacity 2, and performance tests, and verified that the CCER performance on the breathing simulator is consistent with human testing.

Human-like exhaled relative humidity is of particular importance when testing chemical CCERs since oxygen generation is dependent upon the amount of water vapor exhaled through the chemical bed. A nonhuman-like exhaled relative humidity will produce erroneous test results; too much water, and the device overproduces oxygen and duration is shortened, too little water, oxygen products lags behind consumption and the device goes hypoxic.

7) NIOSH has provided no data to support the proposed environmental conditioning. In fact, the proposed environmental conditioning has been proven to be ineffective at ensuring CCER

durability and reliability. As an example; Bureau of Mines report RI9328 shows insignificant performance degradation from a CCER devices that were subjected to the same environmental conditioning proposed in the rulemaking. However, the Long Term Field Evaluation reports over the last decade show that this same device has consistently high levels of performance degradation due to the mining environment.

8) The NIOSH proposed rulemaking states that if the current CCER suppliers, Ocenco and CSE, are forced out of business as a result of this proposed rulemaking, it is economically insignificant. If no suppliers or even one supplier, is willing to develop a CCER for the U. S. mining industry this is an economically significant result and one that will dramatically reduce product availability and reduce safety. While NIOSH has imposed a three year limit on the availability of currently approved CCERs, they have provided no study, data or rationale that would indicate the possibility that CCERs approved to the proposed rulemaking will be available in the time limit imposed.

9) No documentary evidence from CCER users supporting the need for the proposed changes have been supplied. Dr Jeffery Karvitz of the Mine Safety Health Administration, speaking at the International Conference of the International Society of Respiratory Protection in 2008 made the following points;

> There are many cases of successful use of SCSRs for escape from mine emergencies.
> Problem stem from lack of quality training, insufficient training, removal of mouthpiece.
> Problems also stem from lack of proper maintaince and inspection of SCSRs.
> New regulations and provisions have been established to resolve these problems.

Ocenco once again respectfully urges NIOSH to withdraw the proposed rule.

Sincerely,

Michael B. Kay
Engineering Manager
Ocenco, Incorporated