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

From: Mike Kay [mikekay@ocenco.com]
Sent: Friday, April 10, 2009 4:59 PM
To: Szalajda, Jonathan V. (CDC/NIOSH/NPPTL)
Cc: NIOSH Docket Office (CDC)
Subject: RE: Ocenco comments to proposed CCER rulemaking, docket 005
Attachments: Attachment 15.pdf; Attachment 16.pdf; Attachment 17.pdf; Attachment 18.pdf; Attachment 19.pdf; Attachment 20.pdf; Attachment 21.pdf; Attachment 22.pdf

Dear Mr. Szalajda,

Please find attached Attachments 15 -22 (an additional attachment has been included) regarding Ocenco's comments to the Proposed Rule on Approval Test and Standards for Closed-Circuit Escape Respirators, reference NIOSH Docket 005.

Best regards,
Mike Kay

-----Original Message-----
From: Mike Kay [mailto:mikekay@ocenco.com]
Sent: Friday, April 10, 2009 3:51 PM
To: Jon Szalajda (E-mail)
Cc: Niocindocket (E-mail)
Subject: RE: Ocenco comments to proposed CCER rulemaking, docket 005

Dear Mr. Szalajda,

Please find attached Attachments 8 - 14 regarding Ocenco's comments to the Proposed Rule on Approval Test and Standards for Closed-Circuit Escape Respirators, reference NIOSH Docket 005.

Best regards,
Mike Kay

-----Original Message-----
From: Mike Kay [mailto:mikekay@ocenco.com]
Sent: Friday, April 10, 2009 3:47 PM
To: Jon Szalajda (E-mail)
Cc: Niocindocket (E-mail)
Subject: RE: Ocenco comments to proposed CCER rulemaking, docket 005

Dear Mr. Szalajda,

Please find attached Attachments 1 - 7 regarding Ocenco's comments to the Proposed Rule on Approval Test and Standards for Closed-Circuit Escape Respirators, reference NIOSH Docket 005.

Best regards,
Mike Kay

-----Original Message-----
From: Mike Kay [mailto:mikekay@ocenco.com]
Sent: Friday, April 10, 2009 3:42 PM
To: Jon Szalajda (E-mail)
Cc: Niocindocket (E-mail)
Subject: Ocenco comments to proposed CCER rulemaking, docket 005

Dear Mr. Szalajda,

Please find attached Ocenco's comments to the Proposed Rule on Approval Test and Standards for Closed-Circuit Escape Respirators, reference NIOSH Docket 005. Twenty-one attachments will follow under separate emails.
Please contact me if you have any questions.

Best regards,

Michael Kay
Engineering Manager
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April 10, 2009

Mr. 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

Dear Mr. Szalajda:

Ocenco, Incorporated is pleased to provide these 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).

Ocenco is a world leader in internationally-approved respiratory protection equipment, with the mission to manufacture the world's finest safety equipment for hazardous environments.

Because of the importance of this rulemaking and our commitment to worker safety, Ocenco has been involved with this rulemaking from the beginning of the comment period. We participated in public meetings in 2003 and 2006, provided comments in 2006, attended the public hearing on March 23, 2009, and now provide these comments. Additionally, I testified before the Senate Subcommittee on Employment and Workplace Safety on February 15, 2006 regarding coal mine safety and the use and deployment of Self-Contained Self-Rescuers in underground mines.

While we appreciate NIOSH's continuing efforts to develop a sound proposal for improvements to emergency escape respirator requirements, Ocenco continues to believe that the proposal is flawed and will not achieve NIOSH's objective to provide the best possible protective equipment to workers. NIOSH's decision to limit the rulemaking to closed circuit escape respirators is particularly troubling, as the reasons presented for pursuing the rulemaking apply equally to open circuit escape respirators. Further, several specific requirements in the rulemaking proposal are not supported by any evidence in the rulemaking record, in our judgment will not advance worker safety, and instead will impair the effectiveness of CCERs by causing them to be larger and less comfortable for workers to wear. In addition, there is no evidence in the rulemaking record that the critical needs of users in military, maritime, chemical, petrochemical, tunneling, water and sewage and railroad industries have been considered. This is most evident in the agency's disregard for the importance of size and weight in short duration CCERs.

Finally, it is critical to the safety of all users that all test procedures are developed and verified before a new standard is imposed.

For the reasons presented in the attached comments, Ocenco respectfully urges NIOSH to withdraw the proposed rule. NIOSH should issue a new proposal that applies to all emergency escape respirators, and that is supported by sound evidence in the rulemaking record.

Thank you for your consideration of these comments. If you have questions or require further information, please contact Michael Kay, Engineering Manager, at (262) 947-9000 or mikekay@ocenco.com or the writer at droppleman@ocenco.com.

Sincerely,

J. Patrick Droppleman
President and CEO

JPD/mw

COMMENTS TO PROPOSED RULE ON APPROVAL TESTS AND STANDARDS FOR CLOSED-CIRCUIT ESCAPE RESPIRATORS

73 Federal Register 75027, December 10, 2008

RIN: 0920-AA10

42 CFR pt. 84

NIOSH Docket #005

Prepared by Ocenco, Incorporated

April 10, 2009

EXECUTIVE SUMMARY

Ocenco appreciates the opportunity to provide comments in response to NIOSH's proposal to implement new approval tests and standards for Closed Circuit Escape Respirators (CCERs).

Ocenco supports NIOSH's objective to provide the best possible respiratory equipment to workers. Unfortunately, Ocenco concludes the rulemaking proposal does not advance that objective. Given the importance of the rulemaking and the fact that these requirements are reevaluated infrequently, Ocenco believes it is imperative for NIOSH to take the additional time necessary to make substantial changes and improvements to its rulemaking proposal.

First, Ocenco believes the rulemaking should be expanded to include Open Circuit Escape Respirators (OCERs). All of the reasons presented in support of the rulemaking proposal apply equally to OCERs. Failure to address all self-contained respirators in a single rulemaking, just as they are now addressed in a single section of the Code of Federal Regulations, will create confusion and misunderstanding among employers, and will leave users of OCERs with less protection than is provided to users of CCERs.

Second, Ocenco believes many of the proposed requirements are not supported by any evidence in the record, will not improve worker safety, and in some cases will lead to the opposite result by causing CCERs to be larger and therefore too large to store in space-confined applications, and less comfortable for workers in belt-worn applications, and more likely to be set aside rather than worn on the belt. By way of example, NIOSH proposes to implement a new capacity rating system that would establish work rate requirements for Capacity 1 and 2 devices that are not supported by any underlying data, and that can be met only by large increases in the sizes of the units. Every self-contained escape respirator in the world is currently certified under a duration rating system. NIOSH has presented no evidence that this system has not worked well in the field, and thus has presented no compelling justification for abandoning the current duration rating system in favor of a new system that will only cause units to become larger.

Third, the proposal fails to address some serious, known concerns pertaining to existing escape respirators. These include: uncertain reliability of certain indicators (for excessive thermal exposure, moisture damage or chemical bed integrity), the known failure rate of oxygen starters in chemical CCERs, and hazards pertaining to certain chemicals used in chemical CCERs. These are critical omissions in the rulemaking proposal.

Finally, the Federal Mine Safety and Health Act mandates that any new respirator requirements not lead to a reduction in worker protection. Because the proposal would impose new requirements that are not justified by data or experience, and would cause units to be considerably larger than they are now and therefore likely cause workers to be more inclined not to wear them on the belt, Ocenco believes the proposal fails to meet this basic legal requirement.

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Attachment 5: Arthur T. Johnson, *A Review of Self-Contained Self-Rescuer Research*, University of Maryland, Biological Resources Engineering, Human Performance Laboratory

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Attachment 17: Robert Moore, *A Time to Die: The Untold Story of the Kursk Tragedy*, Crown Publishers, 2002, at 240

Attachment 18: Mine Safety Appliances Company Advisory, *Potential for the Quick Start Candle on Mine Safety Appliances Life-Saver 60 Self-Contained Self-Rescuer to Overheat or Catch Fire on Units Manufactured from September 1, 1999 through December 31, 2004* (January 19, 2007)

Attachment 19: E-mail from Nicholas Kyriazi, CDC/NIOSH/NPPTL, to Mike Kay, Engineering Manager, Ocenco, Incorporated (March 10, 2009)

Attachment 20: Statement by Michael Kay, Engineering Manager, Ocenco, Incorporated

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Introduction

Ocenco welcomes the opportunity to provide comment on the proposed rulemaking for Approval Tests and Standards for Closed-Circuit Escape Respirators published in the December 10, 2008 Federal Register.[1] We thank NIOSH for their decision to reopen the comment period for an additional 30 days.[2]

Because of its commitment to worker safety, Ocenco has been involved with this rulemaking from the beginning. The company's goal has always been to provide technical support to assist the Agency in developing a rulemaking proposal that is scientifically sound and protective of worker safety. Ocenco representatives attended the NIOSH Public Meeting to Discuss the Approval of Respiratory Devices Used to Protect Workers in Hazardous Environments on April 10, 2003 in Arlington, VA, as well as the public meeting to continue discussions held in Golden, CO on April 24, 2003. Ocenco also attended the Public Meetings to Discuss Concept Requirements for Certification of Closed Circuit Escape Respirators held in Arlington, VA held on September 19, 2006, and in Golden, CO on September 28, 2006. In addition, Ocenco submitted comments on the NIOSH Closed Circuit Escape Respirator Concept Paper on December 1, 2006. Moreover, Ocenco attended the public meeting concerning the proposed rule in Adelphia, MD held on March 23, 2009. To date Ocenco has not received any comments from NIOSH regarding the serious safety reducing issues raised in our comments.

Ocenco is dedicated to producing the highest quality respirators possible. For over thirty years, Ocenco has focused its engineering expertise on developing reliable equipment for hostile and hazardous environments. Toward that end, we also are committed to supporting NIOSH's efforts through this rulemaking to evaluate the adequacy of current regulatory requirements. Worker safety depends on these regulations and they are modified infrequently. It is therefore critical that changes are based on the best information available, that they address the most pressing safety issues, and that they do so in a comprehensive fashion, addressing worker safety in all effected industries, such as mining, railroads, maritime, industrial, sewer, and off-shore oil.

For the reasons presented in these comments, Ocenco continues to believe the proposed rule fails in its objective to provide the best possible protective equipment to workers. To the contrary, Ocenco respectfully submits that the rule fails to address known safety issues, while proposing new requirements that are not supported by any evidence in the rulemaking record, and that are arbitrary and capricious. The Federal Mine Safety and Health Act (MSHA) mandates that "no mandatory health or safety standard shall reduce the protection afforded miners by an existing mandatory health or safety standard." Respectfully, Ocenco believes this rulemaking, if adopted as proposed, would violate that legal requirement by imposing requirements that reduce worker safety.

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1 73 Fed. Reg. 75027 (Dec. 10, 2008).

2 Ocenco requested an extension of the comment period by a letter dated March 26, 2009. Based on telephone discussion with NIOSH, Ocenco understands that NIOSH considered it impractical to extend the comment deadline at that time, but NIOSH did indicate that it would publish a notice reopening the rulemaking record. We appreciate NIOSH's willingness to provide interested parties with additional time to submit relevant information pertaining to the rulemaking proposal.

Ocenco respectfully urges NIOSH to withdraw the rulemaking proposal. A new rule should be issued that: addresses all escape respirators, not just closed-circuit escape respirators (CCERs); addresses known hazards pertaining to chemical CCERs that field studies have shown have a 16% failure rate of their oxygen starters; and does not impose requirements on CCERs that are not supported by evidence and will cause the units to be considerably larger.

These comments are supported by a statement submitted by Michael Kay, Ocenco's engineer manager. Mr. Kay has 25 years of experience in the design, use and performance of escape respirators, and has observed their use in escape trials onboard ships, in mines, and other industrial applications (see attachment 20). Ocenco remains committed to working with NIOSH to develop a rulemaking proposal that meets NIOSH's objective of promoting worker safety through the use of the best possible respiratory equipment.

Item 1: Scope of The Rulemaking

Comment: The Rulemaking Should Apply Equally to Open Circuit and Closed Circuit Respirators.

NIOSH states several reasons in the proposal to explain the need for changes to the standards. These reasons include storage in harsh environmental conditions, non-uniform testing devices, and duration specific certifications.[3] The reasons cited apply equally to open-circuit escape respirators (OCERs). Excluding open circuit escape respirators from the rule is arbitrary and does not support the goal of improving the effectiveness of protective equipment for workers.

NIOSH states that the storage of closed circuit escape respirators (CCERs) in harsh environmental conditions necessitates the proposed rule. However, OCERs are used in the same hazardous environments as closed circuit escape respirators. They are used for escape in underground mines, onboard ships, and in numerous industrial applications. Product literature from manufactures such as ISI, Drager, Interspiro, and North show that their open circuit escape respirators are used in mining, industrial, shipboard, and railroad applications.[4] Both types of respirators are utilized by identical populations, traveling identical escape routes. The damage caused by temperature extremes, humidity, shock, and vibration, is not limited to closed circuit escape respirators; all breathing apparatus that are exposed to these hazardous conditions are susceptible to damage and performance degradation. Therefore, if NIOSH is to achieve its proposed objective to provide the best respirators possible, the rulemaking proposal must be expanded to include open circuit escape apparatus.

NIOSH also states that current performance testing requirements for CCERs rely on a non-uniform testing regime, and asserts that the "proposed improvements would establish a consistent testing regimen for evaluating the life support capability of CCERs".[5] The rulemaking fails to address the fact that all self-contained breathing apparatus – open and closed circuit- are currently tested by NIOSH using a non-uniform test regime which does not control for differences between human subjects involved in the testing. If the current testing is

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3 73 Fed. Reg. 75028.
4 *See* attachments 1-3, 21
5 73 Fed. Reg. 75028.

problematic and uniform testing is an important objective, then OCERs will equally benefit from a consistent test regime. As stated above, open and closed circuit escape respirators are used in identical applications. NIOSH recommends either OCER or CCER devices for escape from IDHL atmospheres. The persons responsible for selecting self-contained escape respirators—industrial hygienists, safety directors, damage control personnel—have a choice between open or closed circuit escape respirators. For these safety professionals to make an informed decision, they must be assured that the life saving devices available to them have been tested and certified to the *same* performance standards. Therefore, the consistent testing regime proposed in the rulemaking must apply to open circuit escape apparatus. The reality is that under the proposed approach, while purporting to require a consistent testing regime for CCERs, NIOSH would be requiring *inconsistent* testing regimes for open versus closed circuit, with no technical or scientific basis for doing so.

Finally, NIOSH asserts the rulemaking is needed because duration ratings may be misleading to employers and users.[6] *Every* self contained breathing apparatus in the world, open and closed circuit, is certified by duration and not by oxygen capacity. Each device is marked with a rated duration. While the proposed rulemaking suggests that there is confusion over duration-specific certifications, a great deal more confusion will result when safety professionals must chose between an OCER rated by duration or a CCER rated by capacity. As discussed further below, in order to achieve the objectives of maximizing worker safety and saving lives, the concept of certifying respirators by oxygen capacity should be removed from the rulemaking. The point here is that NIOSH's asserted justification for the rule applies equally to OCERs and CCERs, and implementing a change in the rating system for one type of respirator and not the other does not make sense and will lead to even greater confusion than NIOSH asserts exists now.

The rulemaking should not be finalized in its current form. Rather, NIOSH should withdraw the proposal and reissue it in a comprehensive form that applies to all escape respirators. Such an approach would be consistent with the current regulatory framework, which addresses all escape respirators in the same regulation.[7] Piecemeal rulemaking addressing discrete types of self-contained breathing apparatus' will only lead to increased confusion and danger, rather than achieving the goal of ensuring the best possible respirators are supplied. Moreover, because these rulemakings are undertaken infrequently and take many years to complete, failure to take a comprehensive approach in this rulemaking is inefficient and will likely result in OCERs not being addressed for many years, leaving workers who rely on those devices with less protection than workers using CCERs. There is no rational basis for accepting such an outcome that reduces safety. Further still, addressing all escape respirators in a single rulemaking will bring all interested parties into the proceeding, which can only serve to improve the technical input for the rulemaking, and improve the final product.

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6 *Id.*

7 42 C.F.R. pt. 84, Subpart H.

Item 2: Duration Versus Capacity Rating Systems and Proposed Work Rate Requirements

Comment: The current duration regime should not be changed to a capacity rating regime; the proposal is at odds with all existing rating systems worldwide and will only lead to confusion and misunderstanding among employers and employees.

Comment: The proposed work rates for Capacity 1 and 2 devices are not supported by evidence in the record and would cause an increase in the size of CCERs. The proposed ventilation rate for Capacity 1 devices is contradicted by experience with OCERs that function in similar circumstances with lower NIOSH-approved ventilation rates.

NIOSH proposes changing the current duration testing regime to a new capacity testing regime.[8] As already stated, e*very* self contained breathing apparatus in the world, open and closed circuit, is currently certified by duration and not by oxygen capacity. NIOSH has not presented any valid reason for imposing a new rating system. Further, the specific work rates and ventilation rates in some cases are not appropriate. We address the latter point first.

NIOSH would establish a three capacity ratings system: Capacity 1, Capacity 2, and Capacity 3. The proposed rulemaking justifies the Capacity 1 work rate by claiming that "low capacity devices are likely to be used for short, very challenging escapes that would induce exceptionally high work rates",[9] yet provides no evidence to support this claim. In addition, there is no evidence to support the selection of the Capacity 1 work rate.[10]

The proposed rulemaking cites to the 1975 Kamon study as support for the capacity test work rates.[11] This is not true. The table below compares the oxygen consumption reported by Kamon, and those proposed in the rulemaking.

Oxygen Consumption (VO2) STPD

CCER	1975 Kamon Report	Proposed Rulemaking
Capacity 1	1.43 LPM (43 liters O2/30 minutes)	2.5 LPM
Capacity 2	1.42 LPM (64 liters O2/45 minutes)	2.0 LPM
Capacity 3	1.35 LPM (81 liters O2/60 minutes)	1.35 LPM

The proposed rulemaking justifies testing Capacity 3 devices at the 1.35 liters per minute (LPM) oxygen consumption rate as this represents the oxygen requirements of the 50th percentile coal miner performing the NIOSH #4 Man Test. The rulemaking argues against using the 95th

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8 73 Fed. Reg. 75032.

9 73 Fed. Reg. 75033.

10 Note: In the proposed rulemaking, respiratory work rates are defined by four factors: ventilation rate (VE), oxygen consumption (VO2), carbon dioxide production (VCO2), and the respiratory frequency (RF). An increase in work rate results in an increase in VE, VO2, and VCO2. For simplicity, this discussion will use VO2 as the indicator of work rate.

11 E. Kamon et al., *Steady state respiratory responses to tasks used in Federal testing of self-contained breathing apparatus*. 36 AIHA J 886-896 (1975). (Attachment 4).

percentile miner (220 pounds) as this would be a more stringent test, requiring the Capacity 3 device to increase in size. The rulemaking states that:

> This is of concern because the larger that a CCER is designed to be (to supply a greater minimum capacity of breathing gas), the less practical the CCER becomes to be worn on a belt (for availability in case of an emergency) during routine work activities. Limiting the size of CCERs has been a consistent concern of miners. NIOSH is proposing an oxygen consumption rate based on the 50th percentile miner as a reasonable balance between establishing an adequate minimum breathing gas supply for demanding escape scenarios and ensuring that available devices can be worn safely, practically, and without excessive discomfort for the duration of a work shift.[12]

While the proposed rulemaking logically endorses a reasonable balance between gas supply and wearability for Capacity 3 devices, it abandons this logic when it comes to Capacity 1 and Capacity 2 CCERs.

By design, Capacity 1 and Capacity 2 CCERs are smaller, lighter, and more comfortable to wear than Capacity 3 CCERs. In some confined space applications, such as low coal seams, small compartments on ships, and railroad locomotives, these smaller escape respirators are the only workable option. The proposed capacity work rates for these CCERs will require that they increase in size and weight. An indication as to how much larger a Capacity 1 CCER will need to be can be found in the 2005 University of Maryland study.[13] This study found that a currently approved 60 minute device (Capacity 3) cannot pass the Capacity 1 test. At the NIOSH proposed 2.5 LPM work rate for Capacity 1 CCERs, the device performed for 6.5 minutes before the test subject quit the test. The device provided 16 liters of oxygen, short of the minimum 20 liters required for a Capacity 1 device. It can be concluded from this that for a CCER to meet the Capacity 1 requirements, it may have to be larger than a current 60 minute device. However, some would argue that the current 60 minute devices are already too big to be worn safely, practically, and without excessive discomfort for the duration of a work shift. Ocenco has witnessed and been told by mine operators that shuttle car and battery-powered scope operators routinely remove their 60-minute CCER from their belt and store the device on the machine because they are considered too bulky and uncomfortable. The arbitrary work rates assigned to the proposed Capacity 1 and 2 test requirements will cause these devices to increase in size and weight, reducing safety to the mine, ship, locomotive, and industrial personnel, defeating the purpose of the rule.

The proposed capacity test regime also requires a Capacity 1 CCER to provide a ventilation rate of 55 LPM, yet NIOSH-approved 5 and 10 minute OCERs are only required to provide a ventilation rate of approximately 35 liters/minute STPD.[14] There are eighteen models of open

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12 73 Fed. Reg. 75034.

13 Arthur T. Johnson, *A Review of Self-Contained Self-Rescuer Research*, University of Maryland, Biological Resources Engineering, Human Performance Laboratory. (Attachment 5).

14 42 C.F.R. 84.95 establishes the service time of open circuit respirators using a breathing machine ventilating at 40 LPM ATP- ambient temperature, pressure, and water vapor. The gas conditions in the proposed rulemaking are expressed as STPD - standard temperature (0°C), pressure (760 mmHg), dry, (0

circuit escape respirators currently approved by NIOSH that deliver air to the user at a fixed flow rate of approximately 35 LPM or less. If a user's ventilation rate were to exceed 35 LPM while wearing one of these devices, the hood/gas reservoir would collapse against his face and he would be forced to remove the respirator.

If short escapes produce extremely high work rates as proposed in the rulemaking, there would be reports of 5 and 10-minute OCERs failing to provide enough air to the user. The lack of reported failures provides strong evidence that the 35 LPM flow rate does in fact provide the ventilation rate needed for short duration escapes; therefore, the proposed Capacity 1 ventilation rate of 55 LPM is arbitrary and not supported by evidence.

Further, the lack of reported failures of OCERs provides strong evidence that the 40 LPM NIOSH test regime for these devices is effective at providing safe, reliable respirators that satisfy the work rates of the intended application. As a result, NIOSH should test and certify CCERs under the same work rate they test OCERs. This test and certification approach represents the lowest risk to the end user as it relies on a proven test regime.

The foregoing demonstrates specific flaws in the proposed capacity rating system. We turn now to the more general question – whether NIOSH has presented any compelling reason to abandon the duration rating system that has been used effectively for decades in favor of an approach that is not used anywhere else in the world. Respectfully, Ocenco submits that NIOSH has not presented any valid reason for changing from a duration to a capacity rating system, and thus has not demonstrated any benefit that would offset the confusion that is certainly to occur when employers and employees attempt to adapt to the new system, while duration rating systems continue to be used worldwide.

NIOSH's principal rationale is that a duration rating system is predicated on certain assumptions about the physical attributes of the average user and the circumstances of use, which may not always apply.[15] While that is true, NIOSH has not demonstrated that this has led to any problems *in the field* when it comes to *respirator selection*. The rating system is designed to aid in the proper selection of respirator equipment for particular work environments. The selection of the appropriate equipment typically is made by trained personnel who understand the rating system, are fully aware of the circumstances presented by each work environment, and thus are able in each case to make appropriate respirator selections. There is no evidence in the record that the current duration rating system has posed problems to professionals when selecting the proper equipment for workers in mines, on ships, or in other work environments. Indeed, one suspects that if the duration rating system were problematic, the problems would have become apparent long ago.

Ironically, NIOSH proposes that a table should be provided by a CCER manufacturer in the CCER user instructions that would relate capacity ratings back to an expected duration.[16] It states that this would enable employers to readily compare differences in respirator capacity

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mm Hg water vapor). Converting from ATP to STPD conditions will reduce gas volume. All gas volumes in this discussion are at STPD conditions.

15 73 Fed. Reg. 75032.

16 73 Fed. Reg. 75033.

within a given rating to choose a respirator model that best serves their employees. However, NIOSH does not explain how the table would be any more effective at helping an employer chose an appropriate device as opposed to the current duration system. The concerns NIOSH has expressed regarding the current duration rating system would seem to apply equally to the proposed table. Stated differently, if the table would be effective, then there is no reason to believe the duration rating system is not effective, which it is.

Instead of retaining a proven effective system, that is accepted worldwide, NIOSH would completely change the systems between OCERs and CCERs, which would lead to much greater misunderstandings for employers and employees. Employers would have to invest time and training to re-educate their employees as to what the capacity system means.

NIOSH also acknowledges that changing the standard from duration to capacity legally requires the agency to demonstrate the use of capacity to approve equipment in mines will not constitute a reduction in protection or duration of the breathing supply regulated currently under the one-hour requirement.[17] While NIOSH proposes that using the Man test 4 would accomplish the required demonstration, it does not effectively address the legal requirement. The proposed rulemaking use of Man test 4 also contradicts NIOSH's argument that a duration standard is inadequate, as it will continue to rely on the one-hour Man test 4 test, which of course involves an evaluation of duration.

Finally, NIOSH recognizes the importance of the small size of CCERs. The larger a CCER is designed to be, the less practical it will be to be worn on a belt by a worker during routine activities.[18] As already described, NIOSH proposes that the recommended capacity rating for Capacity 3 devices is "a reasonable balance between establishing an adequate minimum breathing gas supply for demanding escape scenarios and ensuring that available devices can be worn safely, practically, and without excessive discomfort for the duration of a work shift." Hence, NIOSH effectively acknowledges that any change to a capacity rating system that would increase the size of the devices, such as would occur here because of the inappropriate work rates being proposed for Capacity 1 and 2 devices, would *reduce* worker safety because of the greater likelihood that workers will not wear the CCERs. Consequently, absent concrete evidence that the capacity rating system will lead to demonstrable offsetting safety benefits, NIOSH by definition cannot make the required legal showing that the proposed change in rating system will not lead to a reduction in worker protection and worker safety.

Item 3: Performance Test Requirements

Comment: No data is provided to support the proposed performance test requirements. Work rates of firefighters are not relevant.

NIOSH proposes a performance test regime to ensure an adequate breathing supply for the user immediately upon donning and under varied work rate.[19] However, no data has been provided to

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17 This point is discussed further under Item 10.

18 73 Fed. Reg. 75034.

19 73 Fed. Reg. 75034.

support the 3.0 LPM performance test requirements, which would be used for all capacities. The proposed rulemaking references three reports as supporting documentation for the performance work rates.[20] While these reports discuss the work rates associated with fire fighting and working in hazardous environments, they provide no information as to the metabolic costs of an escape from a hazardous atmosphere.

A review of the referenced reports shows that the only citation of the 3.0 LPM work rate is in the 1995 NIOSH study.[21] This report states that for fire fighting activities, "the mean metabolic cost for the 95th percentile firefighter is 3.0 LPM, and therefore work intensities of 3.0 LPM should be included in a multiple work rate protocol."[22] The report concludes by saying, "**further research is needed before recommendations can be made for updating the present human testing protocols and methods for SCBA performance evaluation.**"[23] To Ocenco's knowledge, this research has not been done. Thus, none of the reports cited by NIOSH in the proposed rule provide any support for this aspect of the rulemaking proposal. The only report that even addresses the topic expressly reserves judgment on the question for workers other than firefighters, stating that further work is needed *before* changes are made to existing requirements. Therefore, the cited 1995 NIOSH study in fact contradicts NIOSH's claim that current evidence is sufficient to support the proposal.

Requiring a CCER to meet the oxygen consumption rate of the 95th percentile firefighter will necessitate a substantial increase in the size of the CCER. This is inconsistent with the proposed rulemaking objective, already described, of establishing a balance between adequate minimum breathing gas supply and ensuring a device is small enough so that a worker will keep it on his/her belt for the duration of a work shift.[24] Respiratory protection professionals recognize that firefighting activities demand higher work rates than escape activities; as an example, the US National Fire Protection Association standard requires that self-contained breathing apparatus designed for fire-fighting provide for ventilation rates of 102 LPM.[25]

The proposed performance test work rates are inappropriate for escape respirators, and no evidence has been provided to support the selection of these work rates. Ocenco agrees with the conclusion from the 1995 NIOSH report that further research is needed before legislating new test protocols. The rule should focus on the objective of providing the best respirator possible. By establishing a performance test regime that is unsupported by any evidence, the proposed rulemaking does not achieve this goal.

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20 Nina Turner et al, *Evaluation of Proposed Methods to Update Human Testing of SCBA*, 56 AIHA J 1195 (1995) (Attachment 6); V. Louhevaara et al, *Cardiorespiratory strain in jobs that require respiratory protection*, 55 Int. Arch. Occup. Environ. Health 195 (1985) (Attachment 7); P.W. Lemon & T.T. Hermiston, *The human energy cost of firefighting*, 19 J. Occup. Med. 558 (1977) (Attachment 8).

21 Turner, *supra* note 21.

22 *Id.* at 1196.

23 *Id.* at 1200.

24 73 Fed. Reg. 75034.

25 National Fire Protection Association 1981, Standard on Open-Circuit Self-Contained Breathing Apparatus for Fire and Emergency Services, 2002 Edition. (Attachment 9).

Item 4: Proposed Indicator Requirements

Comment: The proposed requirement fails to address the need to improve the performance of the indicators.

NIOSH is proposing to require the manufacturer to include indicators for excessive thermal exposure, moisture damage, and chemical bed integrity.[26] The stated purpose of these indicators is to help decrease the possibility of the respirators becoming damaged yet staying in use. Ocenco certainly supports the objective. However, for an indicator to be effective it must demonstrate correlation to the intended performance attribute by minimizing false positives and false negatives. NIOSH has not provided a means to demonstrate this correlation, and has not provide a minimum required correlation. For example, NIOSH LTFE reports, phases 7-10, demonstrate that the accuracy and reliability of the chemical bed integrity indicator currently in use has poor correlation between decibel levels and CO_2 performance.[27] Further, the chemical bed integrity indicator currently used in the coal mines is not as accurate as those used in the NIOSH laboratory, and is more susceptible to false negative readings.

Additionally, despite the reasoning that temperature, moisture, and chemical bed integrity indicators are necessary to detect degradation, CCERs that are currently equipped with these three proposed indicators actually continue to show increasing levels of degradation that are not being detected by the miner.[28] The proposed rule does not explain how it plans on addressing and improving the effectiveness of the indicators. As a result, the current proposal is not based on evidence, and fails to deal with the real problem. Rather than require all CCERs to incorporate potentially ineffective indicators, NIOSH should do the work necessary to establish correlation between indicator response and CCER performance degradation.

Item 5: Proposed Environmental Treatments

Comment: NIOSH's proposal to test units with environmental treatments is incomplete (humidity is not included) and does not include the correct test protocols.

NIOSH proposes administering various environmental treatments to the CCER to ensure it is reasonably durable and resistant to performance-degrading environmental factors.[29] Despite this, even though humidity was mentioned as a factor that degrades CCER performance, it is not part of the proposed environmental conditioning. In order for this rulemaking to be as effective as possible, Ocenco recommends including a 48 hour 100% Relative Humidity treatment be conducted after the drop and vibration tests.

Ocenco supports ensuring that CCERs are durable and resistant to environmental factors. However, no data has been presented that demonstrates the proposed environmental treatments in the rulemaking are effective at duplicating and accelerating the conditions of use in the field. Further, the rulemaking does not address the environmental conditions seen onboard ships, in

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26 73 Fed. Reg. 75029.

27 NIOSH Self- Contained Self-Rescuer Long Term Field Evaluations, Phases 7-10. *See* Phase 7, pages 5 and 12; Combined Phase 8-9, pages 12 and 26; and Phase 10, pages 7 and 15. (Attachments 10-12).

28 *Id.*

29 73 Fed. Reg. 75036.

locomotives, or other industrial applications. Nevertheless, there is data that supports the environmental conditioning required by the US Navy for shipboard CCERs. As stated in the rulemaking, the Navy is by far the largest user of CCERs.[30] The Navy Commercial Item Description for these devices requires that they undergo MIL-S-901D, Grade A Shock tests, MIL-STD-167-1, Type 1 Vibration tests, Salt Fog Corrosion tests, and Flame Resistance tests.[31] The Navy also requires that the device continue to provide air if the breathing bag collapses, a ten second donning time, and a 0.999 oxygen starting reliability. Given the success that the Navy has had with CCERs that meet these requirements, the performance and environmental requirements detailed in the US Navy Commercial Item Description should be required for all CCERs in order for the rulemaking to effectively achieve its objectives.

Item 6: Hypoxia

Comment: It is inappropriate and unfounded to address hypoxia by violating the manufacturer's approved donning procedures.

Comment: The Rulemaking should address the known oxygen starter failure rate in chemical CCERs. The failure to address this concern is a critical omission of the proposed rule.

NIOSH proposes a test to evaluate the potential for a user to experience hypoxia upon donning a CCER.[32] The stated reason behind the proposal is that hypoxia could occur with a CCER using compressed oxygen if a CCER user is not adequately trained in its use. NIOSH states that some users will exhale into the CCER regardless of its design, rather than exhaling to activate the device. However, the proposed rulemaking singles out compressed oxygen as a hypoxia risk without evidence, and ignores other known risks of hypoxia arbitrarily.[33] NIOSH's assumptions are arbitrary. NIOSH states in its justification that the performance testing "assumes" some users of CCERs will not comply with instructions and exhale regardless of design. However, NIOSH has not provided any evidence stating why it is making such an assumption, nor why it is "likely" that some users will exhale. The proposed rule arbitrarily ignores other assumptions that can be argued to be more likely, such as a chemical CCER user not exhaling sufficient into a device that requires cold-starting.

The proposed rulemaking states that hypoxia could occur with compressed oxygen escape respirators if an inexperienced user fills the breathing bag with nitrogen, although no evidence is given to support this claim. To the contrary, in June of 2006 NIOSH performed thirty #4 Man Tests on compressed oxygen devices manufactured by Ocenco.[34] The test subjects had little to

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30 73 Fed. Reg. 75033.

31 Naval Sea Systems Command, Commercial Item Description: Emergency Escape Breathing Device (EEBD). (Attachment 13).

32 73 Fed. Reg. 75034.

33 For example, two known risks of hypoxia include falling on a chemical CCER and losing the air in a breathing bag, and having the chemical bed solidify because the miner removed his mouthpiece for a few minutes to talk or help start a friend's CCER. Kathleen M. Kowalski-Trakofler et al., *Expectations Training for Miners Using Self-Contained Self-Rescuers in Escapes from Underground Coal Mines*, 5 J. Occup. Environ. Hyg. 671 (2008). (Attachment 14).

34 NIOSH Task Number TN14366.

no experience in wearing CCERs, and none had worn the Ocenco device before. Despite their inexperience, none of the test subjects began the test by exhaling into the device. Exhaling potentially toxic air into a closed circuit escape device is an unnatural act.

NIOSH states that "many CCER users are trained to exhale into a CCER upon donning it."[35] However, the only time miners are taught to exhale into a CCER is when the oxygen starter fails on a chemical device. According to the NIOSH Long Term Field Evaluation (LTFE) Phase 10 report, such failure requiring exhalation occurred in sixteen percent of one model of chemical CCER tested.[36] When this failure occurs, the approved procedure is to then exhale 4 to 7 times into the device to manually activate oxygen generation. The NIOSH report shows that inhaled oxygen levels can drop to 12% when a chemical CCER is cold-started. According to a NIOSH report, it may take as long as 7 minutes for the device to build up to 19.5% oxygen.[37]

Based on the foregoing NIOSH evidence, a hypoxia risk exists only with chemical CCERs that have failed oxygen starters. Therefore, the proposed rulemaking should test CCERs in accordance with the manufactures approved donning procedures, including cold start procedures without the use of oxygen starters. Additionally, the rulemaking should require that CCERs that use an oxygen starter (compressed oxygen or chlorate candle) are equipped with an indicator that allows the user to verify that the oxygen starter will activate. This would recognize this system failure and eliminate the inherent dangers in permitting cold-start procedures to be used.

The 30-second maximum donning time requirement must apply to all CCERs, including those that may require a cold start. This cold-start maneuver becomes impossible if the user needs to transition to a second device. The surrounding atmosphere is toxic and the user does not have sufficient volume in the device he is wearing. This is a known, current risk that continues to go unresolved. Because these rules are changed infrequently, any proposed changes should be as comprehensive as possible to achieve the objectives of maximum worker protection.

The survivor of the Sago mine tragedy reported that failure of chemical devices to start properly was a critical factor in the loss of life in that incident. He reported that several miners were unable to start their devices by exhaling into the equipment. Moreover, at least one miner removed his respirator to assist a co-worker who was having difficulty, and then was unable to restart his own. Thus, tragically, we have real-world experience pointing to the need to address this concern with chemical devices, and yet the proposed rulemaking does not address this deficiency.[38]

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35 73 Fed. Reg. 75034.

36 NIOSH, Self-Contained Self-Rescuer Long Term Field Evaluation: Tenth Phase Results, RI 9675, 2008. (Attachment 12).

37 Kowalski-Trakofler, *supra* note 34.

38 *Id. See also* Statement of Randal L. McCloy, Jr. of June 19, 2006, Report of Investigation: Sago Mine Explosion, at 30-31, 33, 35, and 37. (Attachment 15).

Item 7: Inhaled Gas Temperature

Comment: The proposed inhaled gas temperature is not supported by any evidence.

As part of the proposed general testing conditions and requirements for the certification of CCERs, the rulemaking states that the acceptable ranges for wet-bulb temperature:

> "Are based on physiological research at Pennsylvania State University. Researchers found the highest tolerable wet-bulb temperature of inhaled air was approximately 50 degrees Celsius. Based on such research and NIOSH findings from testing escape respirators, NIOSH proposes 50 degrees Celsius as an excursion limit and 43 degrees Celsius as an average operating requirement. Test subjects have found this temperature to be tolerable during the one-hour certification tests."[39]

This is anecdotal. Further, the referenced 50 degree Celsius limit was based on a sixty-minute exposure. The current NIOSH temperature limits allow higher inhaled gas temperatures for short duration SCBAs, and allows an additional 5 degrees Celsius increase for escape devices.[40]

Ocenco supports rule changes that will achieve the objective of improving the quality of respirators. However, the proposed inhaled gas temperature is arbitrary and would not accomplish that goal. NIOSH has presented no evidence that supports the 43 degree Celsius limit proposed. International Standard ISO23269-1, Emergency *Escape Breathing Devices for Shipboard Use,* sets the maximum inhaled gas temperature at 50 degrees Celsius.[41] In order to maximize the effectiveness of the rule, Ocenco recommends the adoption of the ISO23269-1 temperature limits instead of the arbitrary and irrelevant limits proposed.

Item 8: Eye Protection

Comment: The proposal to require impact resistance eye protection is not supported by customers and would increase the size of units.

NIOSH proposes to require each CCER to include eye protection capable of enduring rough handling in mines.[42] This proposal would require a rigid plastic hood or rigid plastics goggles to be attached to the device. However, the proposed rulemaking requirement to include impact resistance eye protection is not supported by the end users. In addition, the US Navy, the largest user of these devices, only requires in their EEBD Commercial Item Description that a loose hood be attached to the device to provide for eye protection against smoke. The hood shall not restrict the use from wearing corrective lenses.[43] It does not require a rigid plastic hood or goggles. In addition to the lack of necessity for such impact protection, the size of CCERs will

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39 73 Fed. Reg. 75032.

40 42 C.F.R. 84.103

41 ISO 23269-1:2007, Ships and marine technology—Breathing apparatus for ships—Part 1: Emergency escape breathing devices (EEBD) for shipboard use. (Attachment 16).

42 73 Fed. Reg. 75036

43 Navy CID, *supra* note 36.

increase in order to accommodate the inclusion of certified impact-resistant eyewear. Additionally, NIOSH-approved OCERs do not require equivalent eye protection. Ocenco recommends the proposed rulemaking drop the requirement for ISO certified eye protection.

Item 9: Failure to Address Other Known Hazards

Comment: The additional testing in the proposed rulemaking fails to address known chemical hazards.

As stated previously, Ocenco is committed to changes in the existing rule that will lead to increased worker safety. However, the additional testing that would be required by the rulemaking wholly fails to address known hazards, and instead focuses on making changes that will not lead to a better performing or safer respirator. The potassium superoxide (KO_2) used in chemical CCERs is a known fire risk. It reacts violently with water and hydrocarbons, both of which are in abundance in an underground coal mine. The instruction manuals for these CCERs warn of a risk of fire if KO_2 comes into contact with combustible substances. It has been reported that men trapped onboard the Russian submarine Kursk, died in a fire caused by a KO_2 cartridge being dropped into the water.[44] Ocenco recommends NIOSH conducts extensive safety hazard tests on CCERs that contain KO_2. As water and petroleum are known hazards, there should be induced ignition tests to insure the devices containing KO_2 are safe.

In addition, Chlorate candels are a known fire risk.[45] These devices have caused fires onboard aircraft (Value Jet 592), submarines (HMS Tireless) and surface vessels (Navy OBA replacement). Ocenco recommends the proposed rulemaking include extensive safety hazard testing on CCERs that contain chlorate candels.

Item 10: Violation of the Federal Mine Safety and Health Act

Comment: The proposed rulemaking will reduce miner safety in violation of the Federal Mine Safety and Health Act.

The Federal Mine Safety and Health Act (MSHA) require that "no mandatory health or safety standard shall reduce the protection afforded miners by an existing mandatory health or safety standard."[46] Respectfully, Ocenco believes the proposed rule fails to meet this basic legal requirement.

Under the law, NIOSH is required to show that the certification test procedures for all Capacity CCERs used in underground mines do not cause a reduction in protection, or reduction in duration of breathing supply regulated under the MSHA requirement.

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44 Robert Moore, *A Time to Die: The Untold Story of the Kursk Tragedy*, Crown Publishers, 2002, at 240. (Attachment 17).

45 Mine Safety Appliances Company Advisory, *Potential for the Quick Start Candle on Mine Safety Appliances Life-Saver 60 Self-Contained Self-Rescuer to Overheat or Catch Fire on Units Manufactured from September 1, 1999 through December 31, 2004* (January 19, 2007). (Attachment 18).

46 30 U.S.C. 811(a)(9).

Not only would the proposed rule changes fail to increase the protection to workers using CCERs, it would in fact reduce the protection afforded workers provided under existing health and safety standards, in violation of the MSHA. The proposed rules will reduce miner protection by:

- Needlessly increasing the size of CCERs, particularly Capacity 1 and 2 devices, making them less likely to be worn on the belt and available when needed.
- No longer conducting the #4 Man test on Capacity 1 and 2 CCERs approved for use in coal mines in accordance with 30 C.F.R. 75.1714, which permits the use of CCERs of all durations not less than 10 minutes.
- Requiring all CCERs, regardless of their history of service, to be equipped with humidity, temperature, and bed integrity indicators of undetermined correlation and accuracy would decrease safety. False-negative indicator readings will result in increased numbers of damaged CCERs to remain in service.

NIOSH has not yet demonstrated their claim that the proposed capacity concept is a substantial improvement to the current Man testing. In fact, NIOSH believes the continued use of Man testing as a supplement to the new testing requirements is the most practical way of accomplishing this demonstration. It is reckless to push through sweeping changes as to how life-saving breathing apparatus are tested and approved based on assumptions and not research. As an example, the only Capacity 1 tests NIOSH conducted on the Ocenco M-20 were performed three months after the proposed rulemaking was published on December 10, 2008.[47] Further, we have been told by NIOSH personnel that the Environmental Treatments in the proposed rulemaking have not been performed on any of the currently certified devices.

NIOSH has not developed test protocols for their proposed requirements. It has no way of knowing if any respirator existing is able to pass these proposed standards. Thus, NIOSH cannot state what the impact of the rule will be, positive or negative, because it has not developed procedures to determine which respirators will pass or fail. In addition, manufacturers have no way of developing CCERs that will gain approval, because there are no test procedures to determine if the criteria will be met. The pass/fail protocols will be technically complicated, and they will have a significant impact on design. However, because they have not been written, the impact on safety is unknown. This failure to provide standards that can be measured with current test procedures will in fact decrease safety. Under the proposed rulemaking, there is no evidence that the changes in requirements will promulgate a better, more reliable, belt-wearable device.

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[47] E-mail from Nicholas Kyriazi, CDC/NIOSH/NPPTL, to Mike Kay, Engineering Manager, Ocenco, Incorporated (March 10, 2009). (Attachment 19).