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Approval Tests and Standards for Closed-Circuit Escape Respirators; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

[Docket NIOSH–005]

RIN 0920–AA10

Approval Tests and Standards for Closed-Circuit Escape Respirators

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: This final rule announces updated requirements that the National Institute for Occupational Safety and Health (NIOSH or Agency), located within the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS or Department), will employ to test and approve closed-circuit respirators used for escaping atmospheres considered to be immediately dangerous to life and health, including such respirators required by the Mine Safety and Health Administration (MSHA) for use in underground coal mines. NIOSH and MSHA jointly review and approve this type of respirator used for mine emergencies under regulations concerning approval of respiratory protective devices. NIOSH also approves these respirators for use in other work environments where escape equipment may be provided to workers, such as on vessels operated by U.S. Navy and Coast Guard personnel. The purpose of these updated requirements is to enable NIOSH and MSHA to more effectively ensure the performance, reliability, and safety of CCERs.

DATES: This final rule is effective April 9, 2012. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of April 9, 2012.

FOR FURTHER INFORMATION CONTACT: Tim Rehak, NIOSH National Personal Protective Technology Laboratory (NPPTL), P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA, 15236; (412) 386–5200 (this is not a toll-free number). Information requests can also be submitted by email to *nioshdocket@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Preamble Table of Contents

I. Background
A. Introduction
B. Approval of CCERs
C. Need for Rulemaking
D. Scope of the Rulemaking
E. Effects of Rulemaking on Federal Agencies
II. Summary of Public Comments
A. Need
B. Size
C. Scope
D. Feasibility
E. State Stakeholders
F. Railroads
G. Training
H. Section 84.300 Closed-Circuit Escape Respirator; Description
I. Section 84.301 Applicability to New and Previously Approved CCERs
J. Section 84.302 Required Components, Attributes, and Instructions
1. Chemical Bed Physical Integrity Iindicator
2. Instructions and Service Life Plan
3. Labeling
K. Section 84.303 General Testing Conditions and Requirements
1. Breathing & Metabolic Simulator
2. Carbon Dioxide
3. Oxygen
4. Peak Breathing Pressures
5. Wet-Bulb Temperature
L. Section 84.304 Capacity Test Requirements
1. Man Test 4
2. Duration Versus Capacity
3. Capacity Ratings
4. Achieved Capacity
M. Section 84.305 Performance Test Requirements
1. Performance Testing
2. Work Rates
3. Hypoxia
N. Section 84.306 Wearability Test Requirements
O. Section 84.307 Environmental Treatments
1. Humidity
2. Temperature
3. Shock
4. Vibration
P. Section 84.308 Additional Testing
Q. Section 84.309 Additional Testing and Requirements for Dockable CCERs
R. Section 84.310 Post-Approval Testing
III. Summary of the Rule
A. Subpart O—Closed-Circuit Escape Respirators
1. Section 84.300 Closed-Circuit Escape Respirator, Description
2. Section 84.301 Applicability to New and Previously Approved CCERs
3. Section 84.302 Required Components, Attributes, and Instructions
4. Section 84.303 General Testing Conditions and Requirements
5. Section 84.304 Capacity Test Requirements
6. Section 84.305 Performance Test Requirements
7. Section 84.306 Wearability Test Requirements
8. Section 84.307 Environmental Treatments
9. Section 84.308 Additional Testing
10. Section 84.309 Additional Testing and Requirements for Dockable CCERs
11. Section 84.310 Post-Approval Testing
12. Section 84.311 Registration of CCER Units Upon Purchase
B. Subpart G—General Construction and Performance Requirements
1. Sections 84.60, 84.63–84.65
C. Subpart H—Self-Contained Breathing Apparatus
1. Section 84.70 Self-Contained Breathing Apparatus; Description
IV. Regulatory Assessment Requirements
A. Executive Order 12866 and 13563
B. Regulatory Flexibility Act
C. Paperwork Reduction Act of 1995
D. Small Business Regulatory Enforcement Fairness Act
E. Unfunded Mandates Reform Act of 1995
F. Executive Order 12988 (Civil Justice)
G. Executive Order 13132 (Federalism)
H. Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)
I. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)
J. Plain Language in Government Writing
V. Final Rule

I. Background

A. Introduction

A closed-circuit escape respirator (CCER) technically defined as a closed-circuit, self-contained breathing apparatus used for escape, is used in certain industrial and other work settings during emergencies to enable users to escape from atmospheres that can be immediately dangerous to life and health. The CCER, known in the mining industry as a self-contained self-rescuer, is used by miners to escape dangerous atmospheres in mines. It is also used by certain Navy and Coast Guard personnel, such as crews working below decks on vessels, where it is referred to as an emergency escape breathing device, and in the railroad industry, where it is known as an emergency escape breathing apparatus. To a lesser extent, it is also used by other workers who work underground or in confined spaces, such as in tunneling operations in the construction industry.

CCERs are commonly worn on workers' belts or stored in close proximity to be accessible in an emergency. They are relatively small respirators, typically the size of a water canteen, which employ either compressed oxygen with a chemical system for removing exhaled carbon dioxide from the breathing circuit, or a chemical that both provides a source of oxygen and removes exhaled carbon dioxide. Users re-breathe their exhalations after the oxygen and carbon dioxide levels have been restored to suitable levels, which distinguishes these ''closed-circuit'' respirators from ''open-circuit'' respirators, which vent each exhalation. The total capacity for oxygen supply and carbon dioxide removal vary by respirator model to address different work and escape needs. The greater the oxygen supply capacity of a respirator, the larger the

respirator size and the less practical or comfortable it might be to wear during work tasks. Current models are encased in hard, water-resistant cases to protect the respirators from damage by impact, puncture, or moisture.

B. Approval of CCERs

NIOSH and MSHA jointly review and approve such respirators for use by miners to escape hazardous atmospheres generated during emergencies in underground coal mines (42 CFR 84.3). NIOSH currently approves or certifies CCERs under 42 CFR Part 84—Approval of Respiratory Protective Devices, Subpart H—Self-Contained Breathing Apparatus, as closed-circuit apparatus for ''escape only.'' Subpart H also specifies requirements for other related, but distinct, types of respirators, including open-circuit escape respirators and respirators (closed- and open-circuit) used by rescuers responding to an emergency (''entry'' and ''entry and escape'' apparatus); none of those other types of respirators are covered by this rulemaking.

C. Need for Rulemaking

This final rule addresses problems that have been identified by NIOSH and users regarding CCERs and is intended to:

- Reduce reliance on human testing of devices, which is difficult to conduct precisely and consistently and to replicate, through the use of a machine-based testing regime that can be accurately and completely calibrated and produces replicable results;
- Establish new performance-based standards for the quality of the breathing supply produced by the CCER, based on the best available physiological research;
- Replace the measurement of the duration of breathing gas supplied with the measurement of the volume of breathing gas supplied (in liters of oxygen) as a principal certification parameter. CCERs are presently approved as providing a specified duration of breathing gas based on the performance of test subjects, but this can be misleading since the actual durations of breathing gas received by users during escapes can differ substantially from those received by test subjects;
- Require design features, as necessary, to allow users to check the material integrity of a deployed unit. This will make it easier for employers and users to detect suspect units through inspection and remove them from service;
- Establish performance-based testing requirements for durability since CCERs are often used in relatively harsh environmental and handling conditions, such as in coal mining; and
- Provide for the approval of new ''dockable'' CCER designs that would allow the user to replenish the breathing gas supply of the CCER safely, reliably, and quickly under escape conditions.

The final rule will result in the approval of CCERs that provide improved protection over those currently approved under the existing regulatory provisions and will facilitate the introduction of new technologies.

D. Scope of the Rulemaking

This rulemaking applies only to closed-circuit escape respirators. It will establish a new Subpart O codifying new testing and approval requirements for these respirators, replacing all testing and approval requirements of 42 CFR Part 84, Subpart H, that are uniquely applicable to closed-circuit escape respirators used only for escape. This rulemaking will not alter the testing and approval requirements applicable to the other types of respirators included under Subpart H.

E. Effects of Rulemaking on Federal Agencies

Federal agencies may wish to harmonize their policies and/or regulations to be consistent with NIOSH's change from the duration-based to capacity-based rating system. Federal agencies that require training as a component of their respirator use regulations may also need to assess and perhaps modify that training in concert with this rule.

II. Summary of Public Comments

On December 10, 2008, HHS published a notice of proposed rulemaking (73 FR 75027) proposing to update the requirements employed by NIOSH to test and approve closed-circuit respirators used for escaping atmospheres considered to be immediately dangerous to life and health. This class of respirators also includes such respirators required by MSHA for use in underground coal mines. HHS initially solicited public comments from December 10, 2008 to February 9, 2009. On March 4, 2009, HHS reopened the public comment period from March 4, 2009 to April 10, 2009 and announced it would hold two public meetings on the proposed rule on March 16, 2009 and March 23, 2009 (74 FR 9380). HHS again reopened the comment period from May 21, 2009 to June 19, 2009 (74 FR 23814).

HHS received comments from 14 organizations, including one labor union representing coal miners, four respirator manufacturers, one railroad, four trade associations, two federal agencies, one state agency, and one government technology consulting organization. One comment was received after the public comment period was closed and was not considered. In developing this final rule, HHS considered the comments and presentations at the public meetings. Summaries of these comments submitted to the docket and/or made at the public hearings and the corresponding responses from HHS are provided below. The description of the public comments and HHS's responses are followed by Section III, a description of the rule and the changes made in response to the comment received.

A. Need

Comment: HHS received several comments regarding the need for this rulemaking. One commenter suggested that the proposed rule does not sufficiently address the range of problems associated with closed-circuit escape respirators. The commenter's concerns related to matters outside the scope of this rulemaking, such as compliance enforcement.

Response: HHS believes that while the final rule may not resolve every issue involving CCERs, it, along with enhanced training on the proper inspection and use of deployed units, will improve the protection provided by CCERs to the workers who rely on these devices to escape from environments immediately dangerous to life or health. As indicated in the notice of proposed rulemaking preamble, HHS has relied extensively on its investigations of units taken from the field to identify problems that could be addressed through improvements to the current performance standards.

For example, a common problem among units deployed in various industries, including maritime, is that the handling of individual units tends to physically degrade or displace the chemicals necessary for oxygen production and carbon dioxide removal.

This final rule addresses the issue of degradation by establishing improved performance measures to ensure the units are reasonably rugged and the user is able to inspect the unit and readily identify units which fail the manufacturers' inspection criteria.

Comment: Another commenter stated that HHS presents no documentary evidence from device users to support the need for the rulemaking.

Response: HHS has taken this regulatory action in response to decades of reports from the field, from underground coal miners in particular, which have demonstrated that expectations training cannot always prepare a user for the reality of how a CCER will function in an actual escape. It is widely acknowledged that over the course of many coal mine disasters, users have repeatedly reported that (a) units failed to work, (b) units appeared to work but stopped far short of the expected 1-hour duration, or (c) the decision to don a unit was delayed because fresh air was more than 1 hour away.

In NIOSH's judgment, the current certification requirements might be contributing to a risk communication and risk management problem resulting in the situations indicated above. NIOSH is currently required to approve these respirators as providing protection for a specific duration [1] applicable to the particular class of respirator. Durations may be misleading to employers and users, however, because the duration for which a respirator will provide effective protection in the workplace, versus in laboratory testing, will depend on the body weight and physical condition of the user and on the amount of exertion required by the escape. The heavier the user and the greater the exertion, the more rapidly the user will consume the limited oxygen supply and exhale carbon dioxide into the unit; the faster this is done, the greater the likelihood that the exhaled carbon dioxide will accumulate excessively within the user's breathing zone, making breathing intolerable.

Since 1982, NIOSH has received reports of incidents in which users purportedly have not received the duration of protection implied by the approval. While such incidents could have resulted from the respirator failing to perform as approved, they might also reflect limitations of understanding about the testing criteria regarding duration. Accordingly, this rulemaking eliminates the duration-specific approval, replacing it with a capacity rating system based on the quantity of usable oxygen supplied by the model. (See below for a more thorough discussion of the change to a volume-based standard).

In addition to what NIOSH considers a risk communication/management problem, NIOSH field evaluations of approved CCERs conducted systematically and in response to the concerns of users have identified damaged respirators that failed to meet the performance criteria under which they were approved.[2] In some instances, the designs of these respirators did not allow the user or employer to evaluate the condition of a particular respirator prior to its use in either an evacuation drill or an actual emergency. In response to the problems identified, respirator manufacturers have made design improvements to allow persons to check for certain types of damage. However, such checks or indicators are not governed by current regulations and do not exist in some of the respirators currently available. The final rule addresses these indicators which will simplify the inspection of units by employers and users and result in the removal from service of those which show evidence of exposure to conditions that may cause performance problems.

This rulemaking also upgrades testing standards by more stringently verifying the quantity and quality of breathing gas supplied by approved CCERs. In certain circumstances, particularly during a prolonged or highly energetic escape, this type of respirator may provide the user with a constrained supply of oxygen and permit levels of carbon dioxide that can feel uncomfortable. The upgraded testing standards provide improved assurance that the levels of oxygen and carbon dioxide will be maintained consistently within tolerable limits throughout their use during an escape. Together with effective training to ensure that users are familiar with the particular breathing experience to be expected of this type of respirator, these improvements should help to ensure that workers can make full use of the respirators during an escape.

HHS is also improving on the existing standard by avoiding human test subject variability in defining capacity and limiting its use in testing performance characteristics. Use of the breathing and metabolic simulator will ensure that neither the capacity nor the performance test criteria are wholly dependent on human subjects, which will establish a consistent and hence more reliable testing regimen.

Comment: Finally, a commenter from the maritime sector expressed concern that the rulemaking and expenses associated with the replacement of currently-deployed units were unwarranted because HHS has not demonstrated that CCERs used on ships are problematic.

Response: HHS does not expect the promulgation of this final rule to be a hardship on the maritime sector. The 6-year grandfather clause in the proposed rule has been omitted from this final rule, allowing units currently deployed on ships to remain in service until the end of their service life. To ensure no disruption in the supply of CCERS, currently-approved devices may not be manufactured and labeled as NIOSH-approved and sold after April 9, 2015.

B. Size

Comment: Seven commenters expressed concern that the improved standards might result in the production of larger, heavier CCERs.

Response: HHS does not expect that a manufacturer would increase the size or weight of a CCER design in response to the new standards. It is possible that manufacturers could enlarge certain individual respirator designs or increase their weight in order to meet the new capacity rating standards and the more effective eye protection requirements. However, because most current CCER designs include eye protection, HHS does not expect an increase in either size or weight solely for this reason. Further, NIOSH bench testing on currently-approved units demonstrates that they can provide the same amount of oxygen as required by the capacity standards in this final rule. For example, current 1-hour units provide 80 liters (L) of oxygen, comparable to a Cap 3 device; 10-minute units provide approximately 25 liters of oxygen, comparable to a Cap 1. The new standards afford greater latitude regarding potential variety in the capacity of individual respirator designs, given that each capacity rating encompasses a range of oxygen volumes (e.g. Cap 1 units can contain from 20 L to 59 L of oxygen). This latitude should promote designs that more closely meet the varied capacity, size, weight, and other requirements of different users, occupational settings, and emergency provisions and contingencies.

C. Scope

Comment: HHS received three comments indicating that the scope of the rulemaking should be expanded to also include technical standards for open-circuit escape respirators. Another commenter concurred with the Agency's approach, stating that limiting this rulemaking to CCERs is warranted because of the clear distinctions between the two types of technology.

HHS also received a comment demanding that the scope of the

[1] 42 CFR 84.53.

[2] See, e.g., Kyriazi N, Shubilla JP. *Self-contained self-rescuer field evaluation: seventh-phase results.* Pittsburgh, PA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; March 2002. DHHS (NIOSH) Publication No. 2002–127, RI 9656.

proposed rule address all aspects of development, purchase, deployment, tracking, and use of CCERs in coal mines.

Response: NIOSH is updating all of its standards under 42 CFR Part 84 using an incremental or modular approach. The updating of CCER standards was a high priority to the Agency and to users and employers because of the extensive concerns raised regarding this technology. Open-circuit escape respirators employ distinct technology that is likely to require different changes to the current standards. HHS intends to address open-circuit escape respirators in a future rulemaking.

Under 42 CFR Part 84, HHS establishes applicable construction, performance and respiratory protection requirements for respirators. Section 84.3 describes MSHA's authority to co-approve respirators determined to be suitable for use in mines. HHS does not have authority to regulate the deployment and use of CCERs in coal mining or other industries.

D. Feasibility

Comment: HHS received one comment stating that HHS has not provided data indicating that it would be feasible for CCER manufacturers to produce designs capable of meeting the new certification standards before the 3-year cut-off date for sales of currently approved models.

Response: CCER manufacturers have provided extensive comments during the development of this rule and have not indicated this concern. As discussed below, this final rule omits the proposed 6-year grandfather clause limiting the duration over which currently approved CCERs may continue to be used within their prescribed service lives; as discussed below under § 84.301, the final rule does not discontinue the approvals of CCERs currently deployed or sold within 3 years of the effective date of this rule. Moreover, while the rule provides incentive for innovation, it does not specify new performance parameters that cannot be met by existing technology.

E. State Stakeholders

Comment: One commenter indicated that the Department's efforts to reach out to state mine safety agencies on the development of this rule were inadequate.

Response: HHS reached out to all stakeholders by providing numerous opportunities to comment throughout this rulemaking process. HHS announced all public meetings and opportunities to provide written comment in the **Federal Register** during both the concept and rulemaking stages. During the concept development work carried out by the Agency preceding this rulemaking, public meetings were held to solicit input from all stakeholders. These meetings included participation from representatives of labor and industry, other federal and state agencies, as well as manufacturers and academia. Subsequently, during this rulemaking, the docket and public comment meetings were open to all interested parties and included participation by a consultant to the mine safety agency of West Virginia.

F. Railroads

Comment: Two commenters advised HHS to consider the use of CCER by railroads.

Response: HHS acknowledges the use of escape respirators by the railroad industry, and specifically recognizes the respirator requirements codified by the Rail Safety Improvement Act (RSIA) of 2008 (49 U.S.C. 20166; Pub. L. 110–432, sec. 413). While no final rule concerning escape respirators have yet been promulgated under the RSIA, HHS has considered the RSIA requirements in drafting this final rule. This final rule does not conflict with the RSIA respirator requirements, which address the supply of CCERs on railways but do not include design or performance specifications. The omission from the final rule of the proposed 6-year grandfather provision regarding the continued use of already deployed CCER units should eliminate any feasibility concern of the railroads.

G. Training

Comment: HHS received two comments questioning whether the new rule will affect the training given to coal miners.

Response: Such training is governed by MSHA, Department of Labor, pursuant to its authority under the Federal Mine Safety and Health Act (30 U.S.C. 952, 811), and codified under 30 CFR 75.1504. The Agency has worked with MSHA throughout the course of this rulemaking to ensure that MSHA policies will be consistent with the amendments to Part 84.

H. Section 84.300 Closed-Circuit Escape Respirator; Description

Comment: HHS received three comments objecting to the use of the term ''closed-circuit escape respirator'' to identify the subject of this rulemaking. These commenters would prefer to classify these devices as ''self-contained self-rescuer,'' the term commonly used by the mining industry. One of these commenters suggested that the use of a terminology not recognized by the mining industry resulted in that community not understanding the rule's potential impact.

Response: While the mining industry categorizes these devices under one term, they are referred to as ''emergency escape breathing apparatus'' on railroads, and as ''emergency escape breathing devices'' onboard ships. CCER is the classification of this type of respirator under any of these designations. HHS will retain the classification ''closed-circuit escape respirator'' because it is the technically correct name of the devices to be considered for approval and because HHS does not intend to impose one industry's designation on other industries that have their own. The use of the term ''closed-circuit escape respirator'' in this rulemaking does not in any way proscribe the use of the term ''self-contained self-rescuer'' by manufacturers or the mining industry, or other terms used by other industries. This is consistent with the current standard (42 CFR Part 84, Subpart H), which does not refer to the devices as ''self-contained self-rescuers,'' but rather ''closed-circuit self-contained breathing apparatus.''

I. Section 84.301 Applicability to New and Previously Approved CCERs

Comment: HHS received various comments on the proposed 3-year certification phase-in period for new devices and the proposed 6-year grandfather clause for units purchased prior to the effective date of the final rule. One commenter supported both the 3-year phase-in and the grandfather clause, and opposed the option discussed in the notice of proposed rulemaking of omitting the grandfather clause, which could result in currently approved CCER units remaining in the field for 13–18 years (their potential service life) following promulgation of this final rule. One commenter requested that HHS include no phase-in period, and that instead manufacturers should be prepared to supply new units, approved under the final rule, immediately upon promulgation. The same commenter suggested that HHS would otherwise exceed its authority under the Mine Improvement and New Emergency Response (MINER) Act of 2006 (29 U.S.C. 671(h), Pub. L. 109–236, sec. 6) by delaying the deployment of new technologies. Two other commenters concurred with HHS regarding the exemption of the Department of Defense (DOD) from the 6-year grandfather provision of the proposed rule, as proposed therein. Finally, four commenters opposed the 6-

year grandfather clause for units approved under the current standards. They argued that the discarding of CCERs with remaining service life would be financially costly and potentially infeasible, considering the difficulties experienced by manufacturers in producing sufficient CCER supplies for the mining industry under the expanded deployment requirements promulgated by MSHA under the MINER Act (30 U.S.C. 876 (E)(iii)).[3]

Response: HHS recognizes that recent amendments to the statutory schemes governing two of the three main users of CCERs—mining and railroads—require the deployment of substantially increased numbers of units of escape respirators. For example, the Rail Safety Improvement Act of 2008 requires that the Federal Railroad Administration in the Department of Transportation enact regulations mandating respirators on certain locomotives for all crewmembers (49 U.S.C. 20166; Pub. L. 110–432, sec. 413). Similarly, the MINER Act requires mine operators to make additional caches of respirators available to workers, a provision which has been implemented by MSHA and mine operators. HHS also recognizes that the relevant, industry-specific regulatory agencies and DOD are authorized to govern respirator use within their specific industry domains and that their authorizations differ.

Within 3 years of the effective date of this final rule, NIOSH will continue to recognize respirators manufactured and labeled as NIOSH-approved devices and sold by manufacturers under the current approvals as long as they continue to be maintained and used in accordance with the conditions of approval. It is not appropriate for HHS, which is not authorized to govern respirator use in particular industries, to consider requirements or limitations on the continued use of approved CCERs that are deployed currently or may be deployed within the 3-year manufacturing/labeling and selling limitation of this final rule. Such consideration would involve matters outside of HHS's purview, including the varying service life ranges of different CCER designs currently approved by NIOSH; the different storage, maintenance, and use conditions; differing feasibility concerns regarding maintenance of an adequate supply of CCERs; and the agencies' different statutory and regulatory requirements.

Eliminating the 6-year grandfather period in the final rule removes potential economic costs[4] to employers that could result from replacing or retrofitting any respirator designs that remain in use at their worksite but are not submitted to NIOSH for retesting under the new approval tests. This change also fully addresses the feasibility concerns raised in the public comments. On the other hand, it allows that some currently-approved CCERs may remain in service for their entire service life, unless the relevant regulatory or purchasing agencies determine otherwise. Designations of service life for currently-approved CCERs range from 10 to 15 years.[5] As noted in the notice of proposed rulemaking, these designations do not account for the highly varied conditions of storage and handling of CCERs across different work environments. Through extensive field studies evaluating the condition of CCERs deployed in coal mines, NIOSH and MSHA have found that the actual deployment duration of current CCERs in coal mines tends to be substantially less than designated, due to wear and tear and damaging environmental conditions.[6] In other industries involving less physically degrading conditions, CCERs may be more likely to remain available for deployment for their full service life.

With respect to the 3-year phase in period, HHS recognizes the difficulty experienced by some manufacturers in meeting the current demand for respirators and the potential need for design development and related production line changes. The Department finds that it would not be feasible to require manufacturers to redesign products and change their production processes immediately upon promulgation of the final rule. Therefore, HHS has retained in the final rule the proposed allowance for CCER manufacturers to continue the sale of manufactured and NIOSH-labeled currently-approved CCERs for 3 years, upon this rule's effective date. The final rule has been changed slightly from the language that was originally proposed, to indicate that respirators must be manufactured and labeled NIOSH-approved within the 3-year deadline, as well as sold by manufacturers within that deadline, to ensure that respirators approved under the new standard are integrated into the field as quickly as possible.

As of the effective date of this rule, NIOSH will only accept applications for approval of CCERs under these new standards. NIOSH believes there are manufacturers who will be ready to submit applications to meet the new standards at that time and will do so to enhance the marketability of their products. In addition, the new rule permits the introduction of new technology, such as the dockable unit.

J. Section 84.302 Required Components, Attributes, and Instructions

Comment: HHS received various comments regarding components required to indicate specific types of damage that might reduce the effectiveness of the CCER unit. Two commenters supported the provision in its entirety; one supported the objective but proposed that the indicators be designed to minimize false positives (when the indicator falsely indicates there is a problem) and false negatives (when the indicator falsely indicates there is not a problem). One commenter requested that all indicators be failsafe (100 percent accurate in indicating problems) and that indicators should become permanently altered to indicate material or functional degradation. Another commenter suggested that the rule should require an additional indicator, specific to CCERs that use compressed oxygen or chlorate candles, which would allow the user to verify that the oxygen starter will activate. Another commenter requested that oxygen starters employed in CCERs be required to include a pressure gauge.

Response: HHS has retained requirements for indicators in certain circumstances. These requirements are intended to codify what has become standard equipment on currently-approved respirators. Some types of damage are obvious, but the purpose of the indicators is to reveal critical damage or unacceptable environmental exposures that would not be otherwise evident to users. Such indicators are required only to address susceptibilities of the particular CCER design and are required only for those components or attributes critical to the life-preserving functions of the respirator. While it may not be possible to build a device that

[3] U.S. Government Accountability Office. *Additional guidance and oversight of mines' emergency response plans would improve the safety of underground coal miners.* April 2008; GAO–08–424 at 24. *http://www.gao.gov/new.items/d08424.pdf.* Accessed October 7, 2010.

[4] See Section IV.A of this preamble for a discussion of potential economic costs.

[5] One product has a service life of 15 years, but to achieve this service life, it must be reconditioned by the manufacturer at 10 years if stored and at 5 years if carried.

[6] NIOSH evaluations of the physical condition and performance of deployed CCERs are conducted routinely as a quality assurance measure and in response to complaints, concerns, and emergency incidents. The findings of these evaluations are documented in published Long-Term Field Evaluations and NIOSH internal reports; actionable findings provide the basis for remedies addressed by NIOSH and the applicant.

cannot be broken, it is possible to build a device that clearly indicates when it should no longer be relied upon to protect the wearer. HHS will require manufacturers to include indicators that unambiguously alert users to the detection of damage or degradation. These indicators will permit employers and users to inspect units, and remove from service those units that demonstrate exposure to conditions that may cause performance problems.

NIOSH will examine the accuracy and reliability of indicators on a case-by-case basis, as this is an important element of ensuring that they are effective. A substantial potential for false negatives would be of particular concern since it might mislead employers and users regarding CCER units that should be removed from service. A high potential for false positives would also be problematic because the employer might remove undamaged units from service based on the false indications, which has cost implications but also could impact the credibility of the indicators, potentially discouraging compliance. However, in NIOSH's experience—which includes Long-Term Field Evaluations, manufacturer audits, and investigated field complaints—true false positives are rare, as indicators are designed to minimize their occurrence. CCER units are known to experience performance degradation after exposure to extreme (as defined by the manufacturer) heat and moisture; temperature and heat indicators on currently-approved units reliably alert users to exposures that have the potential to cause a unit to be unable to supply oxygen or scrub carbon dioxide at sufficient levels to effect an escape. The standard, as written, does not require that an indicator alert the user that the unit has sustained damage, but that the unit has been subjected to environmental conditions that could cause damage to the unit. NIOSH will validate indicators during the certification process and through post-approval testing under its Long Term Field Evaluation program discussed in the notice of proposed rulemaking (73 FR 75027 at 75037, December 10, 2008) and its Certified Product Investigation Program. HHS agrees that manufacturers should attempt to design indicators to minimize false positives and negatives, but will not require that standard in the final rule. To enable NIOSH to effectively evaluate the indicators, the final rule text requires manufacturers to provide NIOSH with information about each indicator, including an explanation of how the indicator works, any relevant data that will enable the evaluation, and any tools used by the manufacturer to evaluate indicator function.

In this final rule, HHS has added a provision requiring an oxygen starter indicator or other component to detect certain damage or deficiencies to the starter if it is a critical component to the effective use of the CCER. For compressed air starters, this may mean a pressure gauge; for a chemical starter, it could mean a color change chemical indicator observable through a port/window; for any unit, it could mean instructions to observe conditions that may prevent intended activation and release of the starter oxygen (i.e., denting or damage or a pulled or broken starter pin) or an indicator of the starter assembly's exposure to moisture, excessive temperature, g-force, or other physical damage.

1. Chemical Bed Physical Integrity Indicator

Comment: Two commenters addressed the issue of chemical bed physical integrity indicators for carbon dioxide scrubbers: One believed such an indicator is unwarranted since quality control during manufacturing will ensure that the scrubber will work when required, and post-approval testing will verify continuing effectiveness after deployment; the other commenter requested specific requirements for these indicators.

Response: The chemical bed physical integrity indicator will not be required if the chemical oxygen supply or chemical carbon dioxide scrubber cannot be altered by impact, vibration, or any other environmental factor. This indicator would only be required when the design of the CCER would allow for the degradation of chemical oxygen supply or the carbon dioxide scrubber. The text of this provision has been revised to indicate that units in which the chemical oxygen storage or chemical carbon dioxide scrubber can be altered by impact or any other effect must include the chemical bed integrity indicator.

HHS has not added any specific requirements for the design of such an indicator. An indicator, when required, must accurately and reliably indicate when the capacity or performance attributes of the CCER have been degraded such that the unit does not meet the capacity and performance testing requirements of this final rule. NIOSH will examine and/or test the accuracy and reliability of the indicator appropriate to the indicator's design attributes and their potential susceptibilities to failure. The manufacturer is not limited with respect to the possible indicator designs permissible to achieve this performance standard.

2. Instructions and Service Life Plan

Comment: The proposed rule would have required manufacturers to include instructions and a service life plan with each new CCER unit. One commenter found the requirement unwarranted while another asserted in support of the proposal that the service life plan is an essential requirement.

Response: Manufacturers include instructions with currently approved units in a variety of manners and this information is often lost or damaged because of the way in which units are handled in the field. Users are required to be trained in the donning and use of CCERs such that users should be thoroughly familiar with the devices in the event of an emergency. Accordingly, HHS agrees with the commenter noted above that manufacturers should not be required to provide instructions or a service life plan with each individual unit. The final rule has been modified accordingly.

3. Labeling

Comment: HHS received one comment recommending that the capacity rating be identified on the device.

Response: The Department does intend to require manufacturers to indicate the capacity rating (e.g. Cap 3) as well as the number of liters of oxygen as determined by the capacity test on the label of each CCER unit. This intent was implicit in the proposed rule's provisions for capacity ratings and NIOSH reporting of achieved capacity values under § 84.304. This comment is adopted in the final rule and the language in the rule text has been clarified.

K. Section 84.303 General Testing Conditions and Requirements

1. Breathing & Metabolic Simulator

Comment: HHS received several comments on the conduct of capacity and performance testing using the breathing and metabolic simulator for quantitative evaluation, and the use of human subjects for qualitative evaluation of units.

One commenter supported the retention of some human subject testing to assess the human factors associated with CCERs; several commenters supported the use of simulators to conduct quantitative analysis on CCER units, however one of those commenters would have preferred that the use of human subjects represent the broader mining community and not be limited

to a single subject. Finally, one commenter requested that capacity and/or performance testing include a simulation of multiple realistic demand models, which should not terminate until the breach of specific performance thresholds.

Response: HHS continues to find it appropriate to shift from human-based testing to the breathing and metabolic simulator model to assess the quantitative aspects of CCER capacity and performance and has retained the breathing and metabolic simulator testing in the final rule. Breathing and metabolic simulator testing will provide a uniform, consistent basis for evaluating the functional characteristics of CCERs and allows NIOSH to evaluate CCER performance to the point at which the CCER gas supply is completely depleted, ensuring that the CCER's capacity and performance is fully evaluated. HHS has also retained limited human subject testing in the final rule, as specified in the proposed rule, to make ergonomic assessments and to ensure consistency with statutory requirements applicable to mining.[7]

In the Agency's judgment, it is not feasible for NIOSH to conduct scenario testing. The capacity testing protocol cannot fully predict a range of escape scenarios to address all situations in which CCERs might be deployed. Man test 4, required for capacity testing units intended for use in coal mines, is not designed to represent a mine escape; it is included as an ergonomic assessment of the physical orientations that may be required during a mine escape. This ergonomic assessment is sufficiently realistic; in NIOSH's judgment, a more realistic demand model is unwarranted.

Comment: Two commenters said the proposed rule lacks test protocols to determine which respirators will pass or fail.

Response: HHS has clearly specified in the proposed rule and in this final rule the performance standards by which respirators will be evaluated using the breathing and metabolic simulator and through human testing, addressing respirator capacity and performance. Upon request, NIOSH will make available to manufacturers its specific protocols and breathing and metabolic simulator performance specifications so that manufacturers can duplicate NIOSH testing methods. Standard test procedures will be posted on the NIOSH Web site at *http://www.cdc.gov/niosh/npptl.*

Comment: One commenter has requested that HHS provide verification of the performance and accuracy of each breathing and metabolic simulator used by NIOSH for capacity and performance testing.

Response: NIOSH is willing to share fully its experience over many years with its breathing and metabolic simulator, as well as its design specifications, as noted above. The technology used in the breathing and metabolic simulator used by NIOSH is readily calibrated and when calibrated, is not subject to significant variability in relation to the simulation and measurement performance required for testing specified under this final rule.

To ensure the accuracy of the breathing and metabolic simulator, the analyzers are calibrated before each test along with transport and response time of the gas measurement system. All of these will be documented in the standard test procedures developed for the certification tests.

Comment: HHS received one comment suggesting that the manufacturer's respirator donning and use instructions be applied during capacity and performance testing. The commenter offered text changes to provide that capacity and performance tests would be conducted in accordance with the manufacturer's instructions. While earmarked for § 84.303(a), it appears this comment is meant to refer specifically to the hypoxia testing component of § 84.305.

Response: HHS believes the hypoxia test procedure is well-conceived and essential for determining whether a unit will expose a user to low inhaled oxygen concentrations. Many CCER users are trained to exhale into a CCER upon donning it because this is the recommended practice for CCERs supplied with chemical oxygen if the oxygen starter fails. In an emergency, it is likely that some users will exhale into the CCER regardless of its design, in which case NIOSH needs to ensure that the respirator will perform adequately. The final rule's requirements assume that a reasonably likely donning procedure will be applied by the user irrespective of the specific type of CCER available to the user. Therefore, performance tests will begin with two exhalations into the unit and then the manufacturer's instructions will be followed in order to determine the design's susceptibility to hypoxia.

HHS also received many comments concerning the values included in Table 1—Monitored Stressors and Their Acceptable Ranges, including all four criteria (average inhaled carbon dioxide, average inhaled oxygen, peak breathing pressures, and wet-bulb temperature). Capacity, performance, and wearability tests will continuously monitor the stressors listed in this table. Those comments and HHS's responses follow below.

2. Carbon Dioxide

Comment: Three commenters addressed acceptable operating average and acceptable range excursion values for carbon dioxide in Table 1. One commenter objected to the 1.5 percent average carbon dioxide concentration, and requested that HHS justify the change in this value for closed-circuit devices when the value for open-circuit devices (currently 2.5 percent) remains unchanged. The other two commenters objected to the proposed 4 percent carbon dioxide ''parameter,'' given the potential for slightly impaired decision-making in some subjects when exposed to this amount of carbon dioxide.

Response: HHS has retained the average and acceptable range excursion values in the final rule. The 1.5 percent average limit for carbon dioxide is feasible using current technology (based on NIOSH testing of existing designs) and it is an important improvement for assuring the protection of users. As carbon dioxide levels rise users are increasingly likely to interpret the breathing experience as faulty and possibly indicative of a malfunctioning CCER. This could lead the user to abandon the CCER when its use is critical for survival.

An excursion limit of 4 percent is physiologically tolerable for brief periods[8] and its application to all CCER

[7] The Federal Mine Safety and Health Act which governs the mandatory health and safety standards issued by the Secretary of Labor requires that ''no mandatory health or safety standard * * * shall reduce the protection afforded miners by an existing mandatory health or safety standard.'' 30 U.S.C. 811(a)(9). The continued use of man test 4, as a supplement to the new testing requirements and capacity rating system, will be the most practical method of ensuring that the use of these respirators, as approved under this final rule, is consistent with the standard set by the Act.

[8] Glatte HA, Motsay GJ, Welch BE. Carbon dioxide tolerance studies. Brooks AFB, TX. U.S. Air Force, Aerospace Medicine Division, USAF School of Aerospace Medicine. Report #SAM–TR–67–77; 1967:1–22.

Henning RA, Sauter SL, Reddan W, Lanphier EH. Behavioral impairment with altered ventilatory response to CO_2. Federation of American Societies for Experimental Biology, Abstracts of 67th Annual Meeting, Chicago, IL, 10–15 April 1983. *Federation Proceedings:* 1983;42(4):1013.

Kamon E, Deno S, Vercruyyen M. Physiological responses of miners to emergency. *Vol. 1—Self-contained breathing apparatus stressors.* University Park, PA: The Pennsylvania State University. U.S. Bureau of Mines contract No. J0100092; 1984:13.

Sheehy JB, Kamon E, Kiser D. Effects of carbon dioxide inhalation on psychomotor and mental performance during exercise and recovery. *Human Factors.* 1982;24(5), 581–588.

Storm WF, and Giannetta CL. Effects of hypercapnia and bed rest on psychomotor performance. *Aviation, Space, and Environmental Medicine.* 1974;45:431–33.

designs would improve the quality of breathing gas in these respirators, as discussed above with respect to the average limit. With respect to the concern that the 4-percent level might be too high, HHS notes that 4 percent is allowed only as an excursion level. Excursions are recorded during testing in 1-minute increments, with the average level determined over the entire expended breathing gas supply of the unit. CCER designs that allow carbon dioxide levels to approach the excursion limit repeatedly or for significant time would not achieve the specified limit on the average carbon dioxide level. Accordingly, NIOSH will not approve units that would allow a carbon dioxide excursion for a duration that would impair the user during an escape.

Finally, capacity and performance standards for open-circuit designs will be addressed in a future rulemaking.

3. Oxygen

Comment: Two commenters discussed the proposed acceptable range excursion value for oxygen: One commenter found the excursion range unwarranted, and expressed concern that manufacturers would attempt only to meet this ''minimum threshold.'' The other commenter opposed the excursion limit and recommended further study.

Response: HHS disagrees with the commenters and has retained the proposed acceptable excursion value for oxygen in Table 1. The 15 percent range excursion limit for oxygen is not an operating parameter. As discussed above with respect to the carbon dioxide excursion limit, it allows only for brief variation to a low oxygen level, within physiologically established tolerance.[9] To raise this excursion limit would require CCERs that would be ''overbuilt,'' resulting in unnecessarily large and/or heavy designs. The average limit of 19.5 percent, which is the level of oxygen available at approximately 2,000 feet above sea level, will ensure that users receive a fully adequate oxygen supply to execute their escapes. The brief excursions that would be allowed by this average level limit do not pose any impairment risk to the user.

During testing, readings are taken in 1-minute intervals, with the average level determined over the entire expended breathing gas supply of the unit; oxygen concentrations from 20 to 100 percent are recorded as 20 percent. Concentrations between 19.5 percent and the lowest allowable level, 15 percent, are recorded as the actual value. The average of these values must remain at or above 20 percent over the entire test. In a worst case scenario, this method of averaging allows for approximately 10 percent of the sample intervals to be at the excursion limit of 15 percent. For example, during a test composed of 60, 1-minute sample intervals, five samples could indicate an oxygen level of 15 percent. If an additional 1-minute interval were to exhibit an oxygen level of less than 19.5 percent, the unit would not pass the test.

Comment: One commenter requested that HHS consider CCER designs equipped with hoods, which effectively store unused oxygen for use after the oxygen source has been expended. This commenter believes that § 84.303(c) restricts manufacturers' design options.

Response: Section 84.303(c) would not restrict CCER designs. Section 84.303(c) specifies that tests will conclude when the oxygen supply has been fully expended. This would include oxygen that remains stored in a hood if a hood is part of the CCER design.

4. Peak Breathing Pressures

Comment: HHS received two comments pertaining to peak breathing pressures. One commenter suggested that that the proposed values should be more conservative. Specifically, the commenter has proposed the value ±100 millimeters of water (mm H_2O) for the acceptable range operating average, and ±200 mm H_2O for the acceptable range excursion, on the grounds that the operating and excursion ranges offered in the proposed rule are unacceptable and may result in the user discarding the unit prematurely. Similarly, another commenter objected to the assertion that ''Users who cannot generate these [peak breathing] pressures may be forced at some point to slow the pace of their escape.''[10]

Response: The values proposed by HHS are based on human physiological capability[11] and are retained in the final rule. The lower pressure range suggested by the commenter would result in a bulkier, heavier device than is practical. The assertion that some users may be forced to slow their escape is based on the mechanical and chemical limitations of this type of respirator; certain users, especially very large individuals, would be able to exceed the supply capability required for an unlimited level of exertion. This inherent limitation of the technology is appropriately addressed through the training provided to users.

5. Wet-Bulb Temperature

Comment: HHS received four comments regarding wet-bulb temperature, included in the table of monitored stressors to represent the temperature of the inhaled breathing gas in the CCER user's trachea. One commenter warned against adopting the highest threshold number for evaluating wet-bulb temperatures. Another suggested that the proposed standard should rely on dry-bulb instead of wet-bulb temperature because dry-bulb temperature is technically easier to measure in the laboratory. This commenter further suggested that the comparison of wet-bulb temperature to a user's trachea is not accurate, as the trachea is not always a wet surface. Another commenter expressed concern that standardizing humidity responses between different simulators will be difficult, as the temperature reading is not a fundamental property and is specific to each breathing and metabolic simulator. For example, the commenter asserted that wet-bulb response will ''vary with different flow rates, different amounts of water on the thermocouple, or different size thermocouples,'' and suggested that HHS consider using a fast-response sensor. Finally, one commenter asserted that the inhaled gas temperature (<43 °C acceptable range operating average) is arbitrary, and suggested adopting International Organization for Standardization (ISO) 23269–1:2008, *Ships and marine*

Vercruyssen M, Kamon E. Behavioral effects of breathing 3% and 4% carbon dioxide during and following physical work. Toronto, Ontario, Canada, 7–9 May, 1984. *Proceedings of the 1984 International Conference on Occupational Ergonomics.*

[9] Ainslie PN, Barach A, Cummings KJ, Murrell C, Hamlin M and Hellemans J. Cardiorespiratory and cerebrovascular responses to acute poikilocapnic hypoxia following intermittent and continuous exposure to hypoxia in humans. *Journal of Applied Physiology.* 2007;102:1953–1961.

Fowler B, Paul M, Porlier G, Elcombe DD, Taylor M. A re-evaluation of the minimum altitude at which hypoxic performance decrements can be detected. *Ergonomics.* 1985;28(5): 781–791.

Malkin VB. Barometric pressure and gas composition. In *Foundations of Space Biology and Medicine.* Vol II, Book 1 (Ecological and physiological bases of space biology and medicine). 1975;25–31.

Paul MA, Fraser WD. Performance during mild acute hypoxia. *Aviation, Space, and Environmental Medicine.* 1994;65(10):891–899.

West JB, *et al.* Maximal exercise at extreme altitudes on Mt. Everest. *Journal of Applied Physiology.* 1983;55:688–698.

Zoll J, *et al.* Exercise training in normobaric hypoxia in endurance runners. *Journal of Applied Physiology.* 2006;100:1238–1248.

[10] 73 FR 75,027 at 75,032 (December 10, 2008).

[11] Hodgson JL. *Physiological costs and consequences of mine escape and rescue.* University Park, PA: The Pennsylvania State University. U.S. Bureau of Mines contract No. J0345327; 1993:19.

technology—Breathing apparatus for ships—Part 1: Emergency escape breathing devices (EEBD) for shipboard use, which sets the maximum inhaled gas temperature at 50 °C.

Response: HHS has retained in the final rule the use of wet-bulb temperature and the average and excursion ranges specified (<43 and ≤50 °C, respectively) because the trachea is always wet and because monitoring wet-bulb temperature provides a more accurate measure of the heat content of the inhaled gas and human thermal sensitivity is related to the wet-bulb temperature.[12] As with other testing protocols, manufacturers may copy the technology and technique to be applied by NIOSH for certification testing.

The ISO 23269–1:2008 performance requirements establish that ''the temperature of inhalation gas shall not exceed 50 °C'' for respirators deployed for shipboard use. In accordance with the ISO standard, this final rule also establishes that the acceptable range excursion for CCERs is 50 °C, while the average operating temperature must be less than 43 °C.

From running many treadmill tests on both compressed- and chemical-oxygen breathing apparatus, NIOSH knows that the exhalation temperature of human subjects rises as inhalation temperature rises. The exhalation temperature of human subjects breathing room air varies from 30 to 33 °C. As inhalation temperature rises, NIOSH has observed the exhalation temperature rise to as high as 45 °C. The ventilatory components of our breathing and metabolic simulator were designed to simulate human subjects based on shape, size, and orientation. There is a water reservoir which heats the water and pumps it into a plenum above the lung where it spreads out and rains down onto the piston. The water in the lung is a moderate quantity, unlike most other simulators which have a larger quantity. This enables our simulator to be overwhelmed by higher inhalation temperatures, emulating human beings. The air pathway between the lung/piston and the mouth port is divided into three pipes covered both with heat tape and metal fins. This simulates the volume and surface area of the trachea, enabling heat transfer to and from the air stream, respectively, again emulating human response to the temperature of inhalation gases. NIOSH can set and specify the exhalation temperature of the airway gas while breathing room air, but cannot specify the breathing and metabolic simulator exhalation temperature for every combination of inhalation wet- and dry-bulb temperature. Because it is designed to physically simulate the human lung and airway, the simulator responds in a human-like manner to rising inhalation temperatures.

The wet-bulb thermocouple, designed and built in-house at NIOSH, is the only such instrument known which has a response time of <1 second. Since the human respiratory tract is essentially a wet-bulb thermometer, human beings are sensitive to wet-bulb temperature, not dry-bulb temperature. For this reason, the inhalation temperature limits are specified in terms of wet-bulb temperature. Large wet-bulb thermometers have long response times due to their large size and, thus, large thermal inertias. They need high flows and long times to achieve the full wet-bulb depression. The NIOSH wet-bulb thermocouple, due to its small size, requires neither high flow rates nor long response times to achieve the full wet-bulb depression. Also, the miniscule quantity of water on the wet-bulb thermocouple will have a commensurately miniscule effect on the apparatus bed reaction.

L. Section 84.304 Capacity Test Requirements

Section 84.304(a)(5) is changed from the proposed rule to require that CCER designs of any capacity submitted to NIOSH for deployment in U.S. coal mines pass man test 4 which is set forth in the present regulation at § 84.99 and § 84.100. The test provides assurance that the CCER certification testing for devices used in mine escape remains at least as rigorous as testing under the current standards. Section 84.304(d) establishes a new rating system for CCERs, shifting the classification scheme from duration to oxygen capacity.

1. Man Test 4

Comment: HHS received several comments regarding the proposed use of man test 4: One commenter objected to the use of the 50th percentile weight test subject, and suggested that the rule should be expanded to include a wider range of workers. Another commenter requested clarification regarding use of the 50th percentile worker and whether that standard is consistent with established certification test practices (which, according to the commenter, represents the 95th and at times the 99th percentile miner). Another questioned whether it is possible that the device could pass the duration test on the breathing and metabolic simulator but fail man test 4, and recommended that the breathing and metabolic simulator be used to determine duration and the man test for wearability. Finally, one commenter suggested that the inclusion of man test 4 does not address the legal duty under the Federal Mine Safety and Health Act requiring that ''no mandatory health or safety standard promulgated under this title shall reduce the protection afforded miners by an existing mandatory health or safety standard.''[13]

Response: HHS has retained the provision in the final rule that requires those units used in coal mines pass man test 4. HHS, however, has amended the provision slightly to indicate that any size unit submitted to NIOSH for approval for use in coal mining will be subject to man test 4. Man test 4 is an exceptionally challenging test with the average miner in mind, and translates to demanding performance requirements. Neither the present regulation nor this final regulation specifies the weight range of the test subject for man test 4.

With regard to the established approval testing, this improved standard is changing the metrics used to approve CCERs. The work rate for the 50th percentile miner is already used to assess deployed units during the long-term field evaluations conducted by NIOSH. Using that standard here is consistent with current NIOSH practices.

Finally, as of the effective date of this rule, NIOSH will no longer approve CCERs according to the duration of breathing gas supply. The breathing and metabolic simulator will be used to evaluate the oxygen capacity of a given CCER design; man test 4 is included here to establish that approval of devices intended for use in a specific application—underground coal mines—is at least as effective as the current standard, and that the devices will perform as required by the Federal Mine Safety and Health Act. However, with regard to the comment that a unit might fail the simulator testing but pass man test 4, a unit that fails on the simulator at the capacity rating indicated by the manufacturer will not proceed to man test 4.

With respect to Federal Mine Safety and Health Act sec. 811(a)(9), HHS is promulgating these CCER approval standards because they are an improvement over the current standards. The main developments are that the new standards shift to a more instructional and informative rating

[12] Kamon E, Deno S, Vercruyyen M. Physiological responses of miners to emergency. *Vol. 1—Self-contained breathing apparatus stressors.* University Park, PA: The Pennsylvania State University. U.S. Bureau of Mines contract No. J0100092; 1984:117, 119.

[13] 30 U.S.C. 811(a)(9).

system that addresses the documented shortcomings with the traditional, duration-based system; the new standards avoid human test subject variability in defining capacity by relying on the breathing and metabolic simulator; the quality of breathing gas is more closely monitored; and requirements for durability and functionality checks are codified.

2. Duration Versus Capacity

Comment: HHS received ten comments on the proposal to rate these respirators by capacity rather than by duration, as has been done historically. Several of these commenters acknowledged that rating CCERs according to their duration of breathing air poses problems for users in the field, because, for example, 1-hour rated units often do not provide 1 hour of air. One commenter in particular noted a concern that ''miners have historically complained about units that stop working prematurely,'' and that ''the criterion, 'good for one hour,' is misleading, at best.'' Two commenters said the change from duration to capacity ratings will aid in the selection of CCERs for specific industrial applications and will benefit physiologists and other knowledgeable professionals. However, many commenters claimed the change would be confusing to users and one commenter noted this would be especially true where other self-contained breathing apparatus used in the same workplace were still rated by duration. Some asserted that no evidence exists to justify the need for such a change. Two of these commenters opposing the change were among those who also acknowledged that certifying CCERs according to duration is problematic and potentially dangerous, as discussed above. One commenter asserted that the proposed change is inconsistent with the rating system for every open- and closed-circuit escape respirator in the world. Several commenters requested that the final rule prescribe ''common sense'' instructions intended for use by the end-user, to provide a ''rule of thumb'' example of the relationship between capacity and duration. One commenter was particularly concerned that the change to a capacity rating system will undermine the current 1-hour duration standard for respirators used in underground coal mines, and sees no benefit to miners of having information about capacity rather than duration. This commenter suggested that the formula for assessing duration is not rigid enough to ensure a full 1-hour duration and referred to complaints by miners that, at times, units have appeared to stop working prematurely or failed to function during escapes. The commenter requested that HHS establish in the rule that units of less than 1-hour duration cannot be used as a substitute for 1-hour units. Finally, one respondent further commented that capacity-based certification could result in conflicts under the Rail Safety Improvement Act (RSIA) of 2008; another expressed concern that capacity-based certification could result in conflicts with ISO 23269–1:2008 *Ships and marine technology—Breathing apparatus for ships—Part 1: Emergency escape breathing devices (EEBD) for shipboard use.*

Response: HHS has considered these comments carefully, and has decided to retain the provision that approved devices will be classified according to capacity in the final rule. Because the duration of adequate breathing gas supply actually provided to a user by a CCER will depend on the degree of exertion involved in the particular escape and the size of the respirator user, HHS believes the change from an approval based on duration to one based on capacity is important. The present duration rating is misleading and potentially dangerous to users. The capacity rating system in the final rule provides important information to those selecting CCERs that will permit them to decide which respirator meets their needs.

The final rule establishes a 3-capacity ratings system: ''Cap 1,'' ''Cap 2,'' and ''Cap 3.'' Cap 1 provides 20 to 59 liters of oxygen for short escapes that could be accomplished quickly; Cap 2 provides 60 to 79 liters for escapes of moderate distance; and Cap 3 provides 80 or more liters for the lengthiest escapes. The three capacity ratings correspond to the liter quantities of breathing gas supplies that are expended during the NIOSH capacity testing within approximately 10, 30, and 60 minutes, respectively.

As several commenters recognized, there is evidence that the present duration system causes the user to believe that the apparatus will last for a specific time, regardless of the user's weight, physical condition, or activity.[14] This is not an accurate interpretation. Relying on a 1-hour unit to supply 1 hour of oxygen to all users under all circumstances can lead to inappropriate deployment and misuse in emergencies.

It is important to remember that a CCER contains a fixed quantity of oxygen; the duration of the oxygen it ultimately supplies will be inversely proportional to its rate of use. A CCER will operate for a shorter duration when the oxygen consumption rate is high. Hypothetically, a 190-pound man, at rest, is estimated to consume a volume of oxygen of .5 liters per minute. If he were walking in an upright position at 3 miles per hour, it is estimated that he could consume 1.18 liters per minute. The same man running in an upright position at 5 miles per hour is estimated to consume 2.72 liters per minute.[15]

Under the final rule, NIOSH will measure the capacity of a CCER in terms of the volume of oxygen, in liters, that the CCER effectively delivers for consumption by the user. The final rule will require the manufacturer to list on its label the liters of oxygen actually delivered to the user as measured during the NIOSH capacity testing (see § 84.304(e)).

This information will enable employers to readily compare differences in respirator capacity within a given rating, more closely match a respirator model to their particular needs, and choose the respirator model that best serves their employees. An employer might determine through simulation or analysis of possible escape scenarios that its employees will need a Cap 3 CCER model that provides 95 liters to allow for the worst contingencies. Alternatively, an employer might determine that a Cap 3 model that provides 80 liters is sufficient and better designed, in terms of physical dimensions or operational characteristics of its workplace, to accommodate the routine work tasks and escape contingencies of the employees. HHS believes that providing the employers and the other professionals doing this analysis with information as to the general capacity of the unit (low (Cap 1), moderate (Cap 2) and high (Cap 3)) and the actual least achieved quantity of oxygen the specified CCER will supply will greatly aid in their ability to select the proper respirator.

This change to capacity rating will not result in a rating system that is inconsistent with how other countries classify or are considering classifying similar types of self contained breathing apparatus. The European Norms (EN standards) currently categorize open- and closed-circuit self-contained breathing apparatus (a type of respirator similar to the CCER but used for entry

[14] See, e.g., U.S. Mine Safety and Health Administration. *Report of Investigation: Fatal underground coal mine explosion; January 2, 2006; Sago Mine, Wolf Run Mining Co.; Tallmansville, Upshur County, WV.* ID No. 46–08791.

[15] Kamon E, Bernard T, Stein R. Steady state respiratory responses to tasks used in Federal testing of self-contained breathing apparatus. *AIHAJ.* 1975;36:886–896.

as well as escape) by volume and pressure of breathing gas;[16] users decide what size unit best meets their application. Moreover, while CCERs are currently certified in Europe according to the duration of oxygen provided by a unit, the International Standards Organization, whose standards are intended to replace this current system, is also considering a change to capacity ratings. HHS plans, in future rulemakings, to move toward this capacity rating system for other self-contained breathing apparatus that it regulates.

HHS will not require manufacturers to provide users with capacity versus work activity information, although manufacturers are not prohibited from providing such information. However, HHS does not encourage or support the provision of such information, as it may misinform CCER users about the actual amount of oxygen available to them in any given escape, as discussed in the notice of proposed rulemaking.[17] Employers and their employees should test CCERs in realistic scenarios and engage in appropriate training to identify CCER models that meet their needs and to establish a clear understanding of related performance factors. In particular, training is essential for the employees to understand that the duration of time that they receive protection from the device varies according to the actual amount of oxygen in the unit and the rate of oxygen use which depends on the escape conditions and the employee's body size and the employee's physical condition.

With regard to the use of CCERs in coal mines, the record of perceived and actual failures in coal mining played a substantial role in instigating these improvements in respirator certification standards. CCERs intended for use in mines will be so identified in the NIOSH application for approval and subject to man test 4 as a condition of MSHA co-approval. In addition to Cap 3 devices, Cap 1 and Cap 2 devices may be very appropriate for certain deployment conditions. This deployment issue is not subject to HHS regulation or oversight.

With regard to the RSIA, the regulations required under that statute concerning the use of emergency escape breathing apparatus (nomenclature used by the railroad industry) have not yet been promulgated. There is no reason to believe, however, that the capacity rating to be implemented under this final rule would be problematic with respect to such regulations. Similarly, with regard to the maritime consensus standard, ISO 23269–1:2008, HHS does not find any element of this final rule to conflict with the standard, which is more restrictive than this rule. The maritime industry would not be prevented from identifying CCERs as having a service duration of at least 10 minutes, as specified under its consensus standard.

3. Capacity Ratings

Comment: HHS received several comments concerned with the capacity ratings themselves, and the values proposed to achieve them. Two comments questioned the proposed work rates for Cap 1 and 2 capacity testing; in particular, the comments claimed that no evidence supports the Cap 1 and 2 work rates. One comment disputed the use of the 1975 Kamon study[18] to justify the proposed work rates, and also argued that a 2005 University of Maryland study,[19] which found that exceptionally high work rates can exhaust current 60-minute CCERs in far less than 60 minutes, provides evidence that the proposed capacity work rates for Cap 1 and Cap 2 CCERs would require that these CCERs increase in size and weight. Another comment proposed adding two capacity ratings, and modifying Cap 3 oxygen capacity to range from $80 \leq L \leq 89$. Finally, one comment suggested that the ventilation rate for Cap 1 devices is contrary to experience with open-circuit escape respirators that function with lower ventilation rates.

Response: With regard to the Cap 1 and 2 work rates, higher sustained work rates over shorter durations are fully supported by human physiology research as cited in the proposed rule[20] and by the Kamon study. While the commenter notes the discrepancy between the values determined by Kamon and the values applied in this rule, Kamon cautioned that his data presented ''do not include the effects of a breathing apparatus,'' and thus ''represents a *minimum* of the oxygen requirements.''[21] HHS has taken into account the increased work rate demands associated with the use of a breathing apparatus and with the physiological limits defined by research. The work rates in this final rule, including the higher rates specified for lower capacity devices, were supported by the Navy in their comments during the concept development stage of this rulemaking.[22] The Navy makes extensive use of these lower capacity CCERs and expects them to be designed to support the high exertion levels expected for sailors escaping during below-deck emergencies.

With regard to the University of Maryland study, NIOSH notes that CCER capacity testing will be determined ''depending on the capacity specified by the manufacturer.''[23] Thus, for example, a device identified as an 80 liter unit by the manufacturer will be tested at the Cap 3 work rate (1.35 VO_2 liters/minute), not at the high work rate tested in the University of Maryland study. The study does not provide any indication of size or weight changes to CCERs that might be produced in response to this final rule. It does validate the basis indicated by HHS for changing from a duration-based rating system to one that is capacity-based by demonstrating that test subjects of differing sizes and walking at variable speeds will not receive the same duration of breathable oxygen. The study reinforces the point that the only reliable metric for rating a respirator's capacity is the quantity of oxygen supplied by the respirator.

HHS has retained in this final rule the 3-tier rating system proposed. Since the actual liters of oxygen capacity achieved during testing by NIOSH will be specified on the label of the respirator, more capacity rating categories would be unnecessary. Nor would finer categorical distinctions be meaningful with respect to the differing escape contingencies or the need for further testing differences contingent on such distinctions. The three broad categories sufficiently delineate low, medium, and high capacity devices as general reference points for purchasers to identify devices potentially suited to the emergency needs of their employees. Similarly, they sufficiently delineate capacity for the assignment of appropriate testing regimens.

The current ventilation rate for testing open-circuit escape respirators is not a

[16] See European Standard BS EN 137:2006. *Respiratory protective devices—Self-contained open-circuit compressed air breathing apparatus with full face mask—Requirements, testing, marketing.* British Standards Institute.

[17] 73 FR 75,027 at 75,032 (December 10, 2008).

[18] Kamon E, Bernard T, Stein R. Steady state respiratory responses to tasks used in Federal testing of self-contained breathing apparatus. *AIHAJ.* 1975;36:886–896.

[19] Johnson, AT. A review of self-contained self-rescuer research. University of Maryland, Biological Resources Engineering, Human Performance Laboratory; 2005.

[20] Louhevaara V, *et al.* Cardiorespiratory strain in jobs that require respiratory protection. *Int. Arch. Occup. Environ. Health.* 1985;55:195–206. Lemon PW and Hermiston TT. The human energy cost of fire fighting. *J. Occup. Med.* 1977;19:558–562.

[21] Kamon E, Bernard T, Stein R. Steady state respiratory responses to tasks used in Federal testing of self-contained breathing apparatus. *AIHAJ.* 1975;36:886–896 [emphasis in original].

[22] 73 FR 75,027 at 75,033 (December 10, 2008).

[23] 73 FR 75,027 at 75,042 (December 10, 2008).

consideration for determining the rate to be applied to testing Cap 1 devices under this final rule for CCERs. As discussed above, the rates for CCERs are based on physiological capacity. The current rate for open-circuit escape respirators is a matter that will be considered in future rulemaking addressing that different technology.

4. Achieved Capacity

Comment: HHS received one comment regarding how the capacity rating is assigned. The commenter suggested that the rating be based on the average of the seven units tested, rather than on the least value achieved by the seven units tested using the breathing and metabolic simulator as proposed, and that all of the values should be within the capacity rating requested by the applicant. The commenter recommended corresponding text edits to § 84.304(e).

Response: HHS has retained in the final rule the approach presented in the proposed rule to use the least value achieved by the seven units tested. The use of the breathing and metabolic simulator to conduct these tests will indicate variability attributable to the CCER. HHS is using the lowest capacity demonstrated by testing to err on the side of safety. This conservatism is particularly important considering the small number of units being tested.

M. Section 84.305 Performance Test Requirements

1. Performance Testing

Comment: HHS received one comment requesting the rate of speed and incline of the treadmill test (§ 84.305(a)(3)). Another commenter offered that the rule should require evaluation of the quality of the breathing gas at the first inhalation by the user.

Response: Manufacturers must calibrate the treadmill to the specific physiology of each test subject. This standard is work rate, not exercise driven. So, for example, a smaller subject will require a steeper grade and faster speed than a larger subject to achieve the same work rate.

HHS agrees that a performance standard might be appropriate for governing the quality of the breathing gas supplied by a CCER at the first inhalation. Such performance parameters and related testing have yet to be developed but the possibility will be evaluated for future rulemaking.

2. Work Rates

Comment: HHS received a number of comments addressing the proposed performance test work rates; two suggested that the work rates are not supported by data. One of these commenters questioned why NIOSH has not conducted empirical testing of realistic mine escapes. Another commenter suggested modifying the proposed work rate test sequence to repeat only the high and low work rates, rather than cycling through the peak (highest) work rate as well. This commenter also recommended that units that are exhausted before the completion of the full test sequence only be permitted to continue with testing if the entire initial peak flow test was successfully completed. One commenter expressed concern that the 30-minute performance test will not provide accurate performance data for ''shorter duration'' units, and offered the example that some carbon dioxide scrubbers absorb less in the first minute of operation; if multiple units were required for completion of the test sequence, higher concentrations of carbon dioxide would result each time a new unit replaced a spent unit, thus skewing the test results. This commenter suggested that HHS design a test for the capacity of the unit being tested, rather than requiring the testing of multiple units. Finally, one commenter asserted that the work rates for Cap 1 and 2 devices can only be met by large increases in the sizes of units.

Response: The performance tests are applicable to all uses of CCERs, representing realistically achievable and varying work rates for each category of devices (Cap 1 through Cap 3). Lower work rates would result in smaller, lighter devices more suitable for carrying, but if using such a device stresses the wearer beyond the human tolerance level, it may very well fail to meet their need for a successful escape.

The performance test is a composite test including both high and low work rates intended to draw into use all the components of the apparatus, including the demand and relief valves. According to physiological research [24] as well as common experience, the higher the work rate, the less time one can sustain that work rate. Accordingly, NIOSH is applying a high work rate for 5 minutes and then a lower work rate for 15 minutes. This protocol tests the ability of the carbon dioxide absorbent canister to absorb high rates of exhaled carbon dioxide and the accompanying breathing pressures at a high ventilation rate, due to both the canister and the demand valve. Reducing the work rate after 5 minutes reflects human physiological limits while examining the performance of the carbon dioxide absorbent in a low demand mode.

The work rates in the standard were not intended to simulate an escape. There are an infinite number of escape scenarios, ranging from walking at a very slow pace, feeling one's way out of the mine while impeded by heavy smoke and debris to running at speed or carrying an impaired victim. Given the impossibility of conducting representative simulations, NIOSH selected reasonable, scientifically-evaluated limits of likely human performance [25] which are consistent with NIOSH's own laboratory experience.[26] A well-established model developed by physiologists (the Bink-Bonjer curve) predicts that 95th percentile miners can maintain 3.0 liters/minute VO_2 for 30 minutes and 2.0 liters/minute VO_2 for 160 minutes. Accordingly, the peak work rate value is set at 3.00 VO_2, which reflects a very high work rate attainable by an average adult. The high work rate is set at 2.00 VO_2, which represents a reasonably hard work rate. Longstanding laboratory testing of respirator users by NIOSH supports this work rate, which is expected to exceed the work rate experienced by users during escape under oxygen.[27] The low work rate is set at 0.50 VO_2, which represents a sedentary rate. NIOSH laboratory testing experience also supports this work rate, which is expected during escape under oxygen when the wearer is sedentary, as if awaiting rescue. With regard to the conduct of empirical studies, NIOSH has not conducted further research as suggested.

The performance test requirements are suitable for Cap 1 units and do not require a specialized test sequence. As discussed above, the purpose of the performance test is to ensure that an apparatus is able to provide life support to a user at high work rates for

[24] Bink B. The physical working capacity in relation to working time and age. *Ergonomics.* January 1962;5:25–28.

[25] See U.S. Air Force School of Aerospace Medicine. *Physical fitness status of USAF firefighters.* Final Report ESL–TR–86–05; 1986. U.S. Bureau of Mines. *Biomechanical and work physiology study in underground mining excluding low coal.* Final Contract Report #J0308058; July 1984.

[26] Kyriazi N. Proposal for certification tests and standards for closed-circuit breathing apparatus. Pittsburgh, PA: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; 1999. DHHS (NIOSH) Publication No. 99–144, IC 9449.

[27] Kyriazi N. Proposal for certification tests and standards for closed-circuit breathing apparatus. Pittsburgh, PA: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; 1999. DHHS (NIOSH) Publication No. 99–144, IC 9449.

reasonable lengths of time, and to draw into use all the components of the apparatus that could be activated by a user, in order to ensure that stressor levels do not exceed human tolerances. If an apparatus contains <45 L of oxygen, more than one unit must be tested in order to be able to evaluate the relief valve which may not yet have been used. For example, testing a CCER which has approximately 24 L of oxygen would theoretically result in that unit running out of oxygen 4.5 minutes into period 2. This will sufficiently test the demand valve and carbon dioxide absorbent canister; however, the pressure required to operate the relief valve will still be unknown. Therefore, a second unit would have to be tested at the sedentary work rate (0.5 liters/minute VO_2) in order to evaluate the characteristics of the relief valve.

The 1-minute average carbon dioxide measurement will not be tested cumulatively over the duration of multiple units; carbon dioxide cannot accumulate during testing and skew the test results, as suggested by one commenter. If the first unit tested fails to scrub carbon dioxide within the first minute at a 3-liter per minute demand, it will not pass the test; testing will conclude at that point, eliminating the need for multiple units.

With respect to the comment that Cap 1 and Cap 2 devices would have to be larger than currently available devices to perform adequately under the proposed work rates for capacity testing, HHS does not believe this is accurate. At least one currently approved device meets the capacity requirements specified for a Cap 1 rating. This also suggests that higher capacity devices intended for the Cap 2 and Cap 3 ratings would also not need to be larger than currently approved devices and certainly manufacturers have market incentive to minimize size and weight at any given capacity.

3. Hypoxia

Comment: One commenter supported the proposed hypoxia testing, but requested that HHS address the problem posed by the utilization of units of different designs on user proficiency. Another stated that the hypoxia test could not be conducted on designs that include an initial oxygen starter, and suggested that the rule follow the hypoxia test with activation of the starter. Finally, a commenter opposed the hypoxia test on the grounds that the expectation by NIOSH that some users would exhale into a unit in opposition to manufacturer instructions, is an ''arbitrary assumption.'' This commenter also stated the performance test should be conducted in accordance with approved donning procedures for chemical oxygen units, including cold start procedures without the use of oxygen starters.

Response: HHS does not have authority to govern whether CCERs from multiple manufacturers or otherwise of different designs can be used in a single locale or workplace, although the Department does recognize that problems can arise from this situation. The assumption that some users will inappropriately exhale into a CCER upon donning it or in an attempt to improve its performance is not arbitrary, and is supported by evidence from actual practice during emergencies. For example, in the MSHA investigation report on the Greenwich Collieries Number 1 mine explosion of 16 February 1984, the miners were asked the general question, ''Did you have any problems breathing after you put on the self-rescuer?'' Their testimony provides evidence that (1) some users do fill up the breathing bag apparatus with exhaled air, and (2) some users attempt to escape at an oxygen consumption rate higher than the apparatus' constant flow rate, which together cause the hypoxia scenario evaluated in the performance test. In the Department's judgment, it is important to evaluate the potential for the user to experience hypoxia. HHS is retaining the requirement that the performance test will begin with two exhalations and then follow the manufacturer's instructions, and has clarified in the rule text that the hypoxia test will be conducted upon initial donning.

NIOSH does agree with the commenter that the performance test should evaluate the ability of chemical oxygen units to function using a cold (manual) start procedure. Accordingly, NIOSH will begin the hypoxia test with sufficient breaths to start chemical units without the benefit of their oxygen starters. Since not all CCER designs employ oxygen starters and this is a very specific testing protocol detail, it is not specified in the rule text.

N. Section 84.306 Wearability Test Requirements

Comment: HHS received three comments addressing wearability testing: One suggested that test subjects should receive instruction in the use of the CCER prior to testing their ability to don it within the 30-second limit. The other two comments requested that HHS address the potential need to ''cold-start'' a second unit when transitioning between units while in a toxic environment. Cold starting means exhaling sufficiently into a unit to stimulate the oxygen supply when the oxygen starter has malfunctioned.

Response: The intent of the provision of concern is to ensure that the CCER can be donned and fully functional (under oxygen) within 30 seconds. Test subjects will be provided with the manufacturer's instructions for donning and will be trained in their use, but an integral part of this test will be to observe the effectiveness of the supplied instructions; therefore, NIOSH will not supplement the manufacturer's instructions with any further information.

A cold start is an aberrant situation but may not be a critical failure; depending on the system design, the CCER may still provide protection even if the user has to take additional steps to stimulate an increase in the level of oxygen supply. Nevertheless, this wearability test will require that CCERs that make use of oxygen starters can be donned and operational within the 30-second limit, irrespective of whether the oxygen starter functions.

O. Section 84.307 Environmental Treatments

Comment: HHS received one general comment suggesting that evidence to support the proposed environmental treatments is lacking. The same commenter noted that the proposed rule does not address the environmental conditions in other industrial applications aside from mining.

Response: The environmental treatments are not intended to be accelerated aging tests or to replicate the most severe field conditions in which units might be deployed. The purpose of these treatments is to expose CCERs to realistically harsh conditions representative of many industrial applications in order to assess that they are reasonably robust for their intended uses. HHS believes that these treatments are adequate for this purpose.

1. Humidity

Comment: Two comments recommended adding a test of humidity resistance.

Response: NIOSH will conduct a review to examine potential impact of humidity on CCER capacity or performance. If the review indicates that humidity degrades certain CCER designs within their expected service life, then HHS would consider further rulemaking to add such a requirement. Until such time, purchasers could use their acquisition processes to require humidity testing by manufacturers of designs they purchase, or conduct such testing through an independent testing laboratory, should they be concerned

about the potential impact of humidity in the environments where their CCERs are stored and worn.

2. Temperature

Comment: HHS received one comment asking for clarification on whether the extreme temperature storage test is designed to evaluate the effect of temperature shock by changing the test temperature applied to the CCER from one extreme temperature immediately to the other (hot to cold or cold to hot). This commenter suggested allowing the units to return to room temperature between testing steps.

Response: HHS agrees with the suggestion and has adopted it in the final rule. NIOSH did not intend to simulate temperature shock, which is not an expected environmental condition.

3. Shock

Comment: HHS received two comments regarding shock testing of CCER units. One commenter sought clarification regarding which six orientations are to be tested, and recommended that a diagram be included in the final rule. The second commenter requested clarification regarding whether the shock testing should be conducted with units packed in their stowage containers, or whether the testing is meant to simulate the unit being dropped while being removed from its packaging.

Response: The intent of the requirement is to test the CCER along its three principal axes: Top to bottom, left to right, and front to back. HHS has revised the text in the final rule to clarify the definition of these axes.

NIOSH intends for testing to be conducted in the packaging condition designed by the applicant for individual use while deployed. If the CCER is provided within a container intended for storage, versus the state in which it is worn on a belt, carried, or transported by the user, the unit would be removed from the storage container. The text of the final rule reflects this intent.

4. Vibration

Comment: HHS received one comment suggesting that vibration testing to high frequencies is not relevant if CCERs are properly stored or worn.

Response: HHS has retained the vibration testing in the final rule because CCERs deployed in the mining environment experience such vibration when set on or near certain mining equipment (e.g. continuous miners, mantrips). Exposure to vibration would also be expected in association with engines and other machinery on ships and in tunneling and other underground construction and maintenance operations as well as during the transportation of CCERs.

P. Section 84.308 Additional Testing

Comment: Three comments were received regarding issues not addressed in the proposed rule: Fire hazard attributable to the use of potassium superoxide and chlorate candles in chemical oxygen units.

Response: With regard to the potassium superoxide and chlorate candles used in some chemical oxygen units, while NIOSH is aware of the potential for this chemical to create a hazard, experience with CCERs has shown that such hazards are generally created by misuse or mishandling of a device. Potassium superoxide is not known to pose a hazard to the individual when the unit is properly worn on a belt, but has been known, for example, to ignite upon being crushed by mining machinery. Use of CCER designs that employ potassium superoxide and chlorate candles is not within the purview of HHS; HHS is not authorized to address safety issues related to the proper transport and storage of these respirators.

Comment: HHS received five comments regarding the provisions for eye protection. Two supported the proposed standards; two suggested that impact-resistant eye protection is not supported by end users and would increase the size of CCER units. A final commenter requested that goggles meet the high impact and flammability requirements of ANSI Z87.1–2003 *Occupational and Educational Personal Eye and Face Protection Devices* for maritime applications.

Response: All manufacturers provide eye protection with currently certified 1-hour CCERs. The requirement for reasonable durability according to the cited consensus standard (Sub-clause 3.1 of ISO 4855:1981, *Personal Eye Protectors—Non-Optical Test Methods*) is appropriate for the potentially physically challenging conditions while CCERs are belt-worn and during their use for an escape. NIOSH does not expect that compliance with this consensus standard would result in an increase in the size of the eye protection or, consequently, the CCER units in which they are stored.

HHS does not find that the high impact and flammability requirements of ANSI Z87.1–2003 are relevant to most escape scenarios. Under particular use conditions, more stringent performance requirements could be specified in the acquisition process if deemed necessary by the purchaser.

HHS has made clarifications to the text of § 84.308(c)(3) and (4) which indicate the intent of the durability and fogging tests. It is imperative for the users' vision to be unimpeded by the eye protection when attempting to use the respirator for an escape.

Q. Section 84.309 Additional Testing and Requirements for Dockable CCERs

Comment: One comment submitted to HHS supported the intent behind the dockable CCER provisions but was concerned that the provisions were not extensive enough. In particular, the commenter recommended HHS ''force'' the introduction of this new technology for use in the mining industry.

Response: The proposed provisions for dockable CCERs have been retained in the final rule. These provisions cover the apparent potential technical concerns associated with such technology that HHS has been able to identify. The use of this technology in mining is not regulated by HHS. Accordingly, this final rule includes provisions that will allow the approval of such devices, but does not include provisions to force the development of this technology and its introduction into the mining industry.

R. Section 84.310 Post-Approval Testing

Comment: HHS received various comments on post-certification testing of deployed CCERs. One commenter encouraged HHS to expand the program. Another supported the program but suggested that the government should not be obligated to replace units that it tests. In relation to the replacement of CCERs obtained by NIOSH for post-approval testing, another commenter questioned the ramifications of a manufacturer's decision to discontinue production of a certain unit, and whether manufacturers would be required to produce more of the discontinued units to replace those tested. Another commenter suggested that field evaluations do not accurately demonstrate the extent of problems associated with respirators in field, and suggested that at least 3 percent of all deployed units be tested at random. A final commenter suggested that the text of the rule specify that only units passing user inspection criteria should be examined in the post-certification testing.

Response: HHS has specified in the final rule under § 84.310(f) that manufacturers who discontinue a particular line of respirators selected for field evaluation can replace those units

with similar, NIOSH-approved CCERs. HHS does not intend for the replacement requirement to create any barriers to the market exit of a discontinued product. Furthermore, NIOSH would continue to purchase replacement units, as currently practiced and proposed. The cost of these field evaluations, which are carried out as part of the research and assurance function of the NIOSH respirator certification program, would not be appropriate to impose on CCER owners. NIOSH believes this life-cycle evaluation (inspection and testing) program, as enhanced by the provisions of this final rule, will continue to be an effective method for the early identification of possible problems in these respirators after deployment.

NIOSH randomly selects deployed CCER units for testing. The availability of resources has determined and will continue to determine the sample size. The evaluations select units from the field that are identified by the employer as having passed user inspection criteria; furthermore, the NIOSH evaluation itself begins with application of these same inspection criteria.

III. Summary of the Rule

This rule establishes new requirements for testing and approval of CCERs under a new Subpart O of 42 CFR Part 84—Approval of Respiratory Protective Devices. The new subpart replaces all current requirements for testing and approval of CCERs found under Subpart H. The following is a section-by-section summary which describes and explains the provisions of the rule. The complete, final regulatory text is provided in the last section of this notice.

In the summary below, HHS indicates the changes made in provisions of this rule since the notice of proposed rulemaking. These occur under §§ 84.300, 84.301, 84.302, 84.304, 84.307, 84.308, and 84.310.

A. Subpart O—Closed-Circuit Escape Respirators

1. Section 84.300 Closed-Circuit Escape Respirator, Description

This section provides a general description of the CCER as a class of respirator. It is intended to inform the public and to serve as a legal and practical definition for the purposes of the NIOSH and MSHA respirator approval program. In response to public comments, the definition of CCER now includes a brief description of respirator uses in the maritime and railroad industries, in addition to underground coal mining.

2. Section 84.301 Applicability to New and Previously Approved CCERs

This section establishes a 3-year period for continued manufacture and labeling of CCERs approved under the current regulations and sold by manufacturers in order to phase-in the implementation of the testing and approval requirements of this final rule. This provision, which is changed slightly from the proposed rule, allows respirator manufacturers a reasonable period of time to modify existing CCER designs, if necessary, or to develop entirely new designs that respond to the new testing and certification requirements. It also ensures that during the interim, a constant supply of approved CCERs will remain available for purchase. The new requirements will be applied to all new CCER designs that are submitted for approval after the effective date of this rule. Manufacturers may continue to manufacture and label as NIOSH-approved and sell CCERs with current approvals for up to 3 years after the effective date.

As discussed in the public comment section of the preamble above, HHS has eliminated from the final rule the proposal that currently approved CCERs be re-approved under the new requirements of this final rule to retain their approval beyond a 6-year grandfather period. CCERs with current approvals that are already deployed or are manufactured and labeled NIOSH-approved within the 3-year phase-in period will remain as NIOSH-approved devices until the conclusion of their service life.

3. Section 84.302 Required Components, Attributes, and Instructions

This section specifies the components, attributes, and instructions required for each CCER. Some of these requirements simply continue the current Subpart H requirements, including the requirements for eye protection (paragraph (a)(1)); oxygen storage vessel (paragraph (a)(4)); and general construction (paragraph (c)).

Paragraph (a)(2) requires that manufacturers include thermal exposure indicators to allow a person to determine whether the unit has been exposed to temperatures that exceed any temperature storage limits specified by the manufacturer. Currently, one manufacturer includes such indicators in response to NIOSH evaluations finding that exceptionally low and high storage temperatures degrade the functionality and performance of certain CCER designs. Adverse effects of low temperature storage on current products are reversible, but high storage temperatures can damage critical internal CCER components, as documented in the manufacturers' service life plans. There must be a means to detect and replace units exposed to such storage conditions.

Paragraph (a)(3) requires that manufacturers include a means by which a person can detect any damage or alteration of the chemical oxygen storage or chemical carbon dioxide scrubber that could diminish the NIOSH-certified performance of the unit or pose a hazard to the user. These chemical components of CCERs, as presently designed, are susceptible to such degradation.[28] Two manufacturers currently design their CCERs with a means of detecting such damage.

Paragraph (a)(4) maintains an existing requirement under Subpart H that if a CCER includes an oxygen storage vessel, the vessel must be approved by the U.S. Department of Transportation (DOT) under 49 CFR Part 107: ''Hazardous Materials Program Procedures,'' unless exempted under Subpart B of the DOT regulation.

Paragraph (a)(5) requires that manufacturers design and construct the protective casing of the CCER to prevent the user from accidentally opening it and to prevent or clearly indicate its prior opening, unless the CCER casing were designed for such openings, for inspection or purposes other than use in an actual escape. These protections are needed because the opening and re-closing of a unit not designed for such operations, and the replacement of parts not intended for replacement, can damage the unit and degrade its performance. NIOSH has investigated circumstances in which units were opened and modified by unauthorized persons, effectually altering the design from the version that received NIOSH testing and certification.[29]

Paragraph (a)(6) requires that manufacturers include a means to detect the ingress of any water or water vapor that could degrade the performance of the unit, unless the CCER was designed for its casing to be opened for frequent inspection. Because the chemical

[28] Kyriazi N, Shubilla JP. *Self-contained self-rescuer field evaluation: seventh-phase results.* Pittsburgh, PA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; March 2002. DHHS (NIOSH) Publication No. 2002–127, RI 9656.

[29] Kyriazi N, Shubilla JP (2000). *Self-contained self-rescuer field evaluation: sixth-phase results.* Pittsburgh, PA: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; July 2000. DHHS (NIOSH) Publication No. 2000–128, RI 9451.

components of CCERs are especially susceptible to damage or degradation from moisture, the user must be able to readily and reliably check a unit for potential water damage before each work shift.

Paragraph (a)(7) is new (as discussed above), and requires that manufacturers provide a means to detect damage or deficiencies to units with oxygen starters if they are a component critical to the satisfactory performance of the CCER.

Paragraph (b) requires that an indicator must clearly and unambiguously indicate the occurrence of the monitored condition.

Paragraph (c) requires that manufacturers provide NIOSH with information about indicators, where they are required, to enable thorough evaluation by NIOSH. Such information should include an explanation of the operation and function of the indicator, data generated by the manufacturer, and any equipment or special devices used by the manufacturer to develop or test the indicators.

Paragraph (d) mandates that CCER components must meet the general construction requirements in § 84.61.

Paragraph (e) requires that manufacturers construct the CCER to protect the user from inhaling most toxic gases that might occur in a work environment during an escape. To ensure such gases cannot readily penetrate the breathing circuit of the CCER during its use, NIOSH will test the integrity of the CCER breathing circuit by following the gasoline vapor test procedure for breathing bags available from the NIOSH Web site *http://www.cdc.gov/niosh/npptl.* The test will be conducted on a single CCER unit.

The specified gasoline vapor test provides reasonable assurance that the breathing gas supply of the user will be protected from atmospheres that include hazardous vapors possibly associated with escapes from mines and most other enclosed or confined spaces. The proposed requirement for this testing is not new. It is included under Subpart H of this part (§ 84.85) for all self-contained breathing apparatus (the class of respirators to which CCERs belong) currently approved by NIOSH.

Paragraphs (f) and (g) require that the design, construction, and materials of CCERs not introduce combustion or other unspecified safety or health hazards.

In response to public comments, paragraph (h) requires that manufacturers provide purchasers with instructions, rather than requiring instructions to accompany each individual unit, as was proposed in the notice of proposed rulemaking. A service life plan must accompany each application to NIOSH for CCER approval. These requirements generally reflect current practice.

In response to the public comment regarding labeling, paragraph (i) requires manufacturers to identify on each CCER approval label the capacity rating and number of liters of oxygen as determined by NIOSH through capacity testing.

4. Section 84.303 General Testing Conditions and Requirements

This section establishes the general testing conditions and requirements for the approval of CCERs.

Paragraph (a) specifies that NIOSH will use the breathing and metabolic simulator tests specified in this subpart for all quantitative evaluations of the performance of a CCER. NIOSH will use human subject tests for qualitative evaluations, which include evaluations of the ''wearability'' of the CCER design (e.g., ergonomic considerations concerning its practical impact on the user's escape).

Breathing and metabolic simulators are mechanical devices that simulate human respiratory functions.[30] They allow for precisely controlled and monitored tests, whereas comparable testing conducted using human subjects on a treadmill involves substantial variability with respect to one or more metabolic parameters. The use of these simulators to evaluate respirator performance has been validated by NIOSH through a series of MSHA peer-reviewed studies over the past 20 years.[31] These studies, which include side-by-side comparisons using three-person panels of human subjects on treadmills against testing using an ABMS, demonstrate that the simulator replicates the performance of human subjects with respect to all important metabolic variables, including oxygen consumption rate, average rates of carbon dioxide production, ventilation rates, respiratory frequencies, respiratory temperatures (dry- and wet-bulb), and breathing pressures. An advantage of the simulators is that their performance for all metabolic parameters can be calibrated and replicated, whereas each human test subject performs uniquely, making the testing more difficult to replicate.

Manufacturers and others who would wish to duplicate NIOSH breathing and metabolic simulators in their own testing facilities can obtain technical specifications from NIOSH. General, non-proprietary information on the design and operation of the simulators is also available from the NIOSH Web site: *http://www.cdc.gov/niosh/npptl.*

Paragraph (b) specifies that 4 stressors will be monitored constantly throughout testing: The average concentrations of inhaled carbon dioxide and oxygen, peak breathing pressures at inhalation and exhalation, and the wet-bulb temperature (the temperature of inhaled breathing gas as would be? sensed by the CCER user's trachea). Paragraph (d) establishes that CCERs must perform within the acceptable ranges of measurement specified in Table 1 below.

[30] Kyriazi N. *Development of an automated breathing and metabolic simulator.* Pittsburgh, PA: U.S. Department of the Interior, Bureau of Mines; 1986. IC 9110.

[31] Kyriazi N, Kovac JG, Shubilla JP, Duerr WH, Kravitz J. *Self-contained self-rescuer field evaluation: first-year results of 5-year study.* Pittsburgh, PA: U.S. Department of the Interior, Bureau of Mines; January 1986. RI 9051.

Kyriazi N, Shubilla JP. *Self-contained self-rescuer field evaluation: results from 1982–1990.* Pittsburgh, PA: U.S. Department of the Interior, Bureau of Mines; January 1992. RI 9401.

Kyriazi N, Shubilla JP. *Self-contained self-rescuer field evaluation: fourth-phase results.* Pittsburgh, PA: U.S. Department of the Interior, Bureau of Mines; January 1994. RI 9499.

Kyriazi N, Shubilla JP. *Self-contained self-rescuer field evaluation: fifth-phase results.* Pittsburgh, PA: U.S. Department of Energy; December 1996. RI 9635.

Kyriazi N, Shubilla JP. *Self-contained self-rescuer field evaluation: sixth-phase results.* Pittsburgh, PA: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; July 2000. DHHS (NIOSH) Publication No. 2000–128, IC 9451.

Kyriazi N, Shubilla JP. *Self-contained self-rescuer field evaluation: seventh-phase results.* Pittsburgh, PA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; March 2002. DHHS (NIOSH) Publication No. 2002–127, RI 9656.

[32] Wet-bulb temperature is a measurement of the temperature of a wet surface. It represents the temperature of the inhaled breathing gas in the CCER user's trachea.

TABLE 1—MONITORED STRESSORS AND THEIR ACCEPTABLE RANGES

Stressor	Acceptable range operating average	Acceptable range excursion
Average inhaled CO_2	<1.5%	≤4%.
Average inhaled O_2	>19.5%	≥15%.
Peak Breathing Pressures	$\Delta P \leq 200$ mm H_2O	$-300 \leq \Delta P \leq 200$ mm H_2O.
Wet-bulb temperature.[32]	<43 °C	≤50 °C.

The acceptable ranges for inhaled carbon dioxide were determined by physiological testing performed at the Noll Lab for Human Performance Research at Pennsylvania State University. This research showed no disabling physical effects in active men breathing 5 percent carbon dioxide for long periods of time.[33] Decision-making was slightly impaired in some subjects after breathing 4 percent carbon dioxide for 1 hour. NIOSH has found in the testing of escape respirators that carbon dioxide levels of 1.5 percent can be tolerated for the limited periods for which these devices are designed without any deleterious effect on the test subjects. Therefore, NIOSH requires the CCER to maintain the inhaled levels of carbon dioxide below 4 percent (as a 1-minute average) during all testing and below an average of 1.5 percent over the full duration of the test.

The normal, sea-level oxygen content of air is approximately 21 percent. The minimum acceptable operating average of 19.5 percent for inhaled oxygen that NIOSH requires the CCER to provide over the full duration of the certification tests was determined based on OSHA's respiratory protection standard 29 CFR 1910.134, which establishes a minimum level of oxygen for protecting the health and safety of workers. However, permitting oxygen levels to go as low as 15 percent enables size and weight reductions of CCERs with little user impact.[34] The acceptable range for these excursions was determined based on testing of pilots at various altitudes. This research indicates that judgment, reaction time, spatial orientation, and other cognitive processes begin to become impaired from chronic exposure at oxygen levels below 15 percent.[35] Therefore, NIOSH requires the CCER to provide levels of oxygen above 15 percent (as a 1-minute average) during all testing and above an average of 19.5 percent over the full duration of the test. These limits would provide assurance that the CCER user would never be prevented from escaping due to an insufficient concentration of oxygen in the breathing gas supplied by the CCER.

The acceptable ranges for wet-bulb[36] temperature are based on physiological research conducted at Pennsylvania State University. Researchers found the highest tolerable wet-bulb temperature of inhaled air was approximately 50 °C.[37] Based on such research and NIOSH findings from testing escape respirators, NIOSH establishes 50 °C as an excursion limit and 43 °C as an average operating requirement. Test subjects have found this temperature to be tolerable during the 1-hour certification tests.

The ranges for peak breathing pressures were determined based on physiological research indicating that most individuals can generate peak breathing pressures equaling or exceeding −300 to 200 mm of H_2O for only a short period of time.[38] Based on NIOSH findings from testing escape respirators, the 200 mm average operating requirement provides a tolerable limit for the duration of an escape. Use of these values as limits will allow most CCER users to escape without any constraint on their level of exertion. Users who cannot generate these pressures may be forced at some point to slow the pace of their escape.

In addition to establishing these stressor limits for testing, this section provides under paragraph (c) that capacity and performance tests conclude when the stored breathing gas supply has been fully expended. This is important because the adequacy of the performance of a CCER depends upon the user clearly recognizing when the breathing gas supply is expended. High carbon dioxide levels can deceive the user into believing the respirator is not working and hence to prematurely abandon use of the CCER during an escape. Designing CCERs so that carbon dioxide levels are controlled until the oxygen supply is fully expended will help ensure that a user can make use of all of the available oxygen.

This section also provides under paragraph (d)(2) that a CCER will fail a wearability test if a human subject cannot complete the test for any reason related to the CCER. Any design, construction, or performance attribute of a CCER that prevents a user from completing the wearability test will threaten the successful use of the CCER for an escape.

5. Section 84.304 Capacity Test Requirements

This section specifies the testing regime that will be used to rate and quantify the capacity of the CCER, in terms of the volume of oxygen that the respirator provides to the user. It ensures the CCER will provide the quantity as measured in the NIOSH testing as a constantly adequate supply of breathing gas, in terms of the stressors addressed in § 84.303 of this part. The capacity will be evaluated in terms of

[33] Kamon E, Deno S, Vercruyyen M. Physiological responses of miners to emergency. *Vol. 1—Self-contained breathing apparatus stressors.* University Park, PA: The Pennsylvania State University. U.S. Bureau of Mines contract No. J0100092; 1984:13.

[34] Paul MA, Fraser WD. Performance during mild acute hypoxia. *Aviation, Space, and Environmental Medicine.* 1994;65(10):891–899; Malkin VB. Barometric pressure and gas composition. *Foundations of Space Biology and Medicine,* Vol. II, Book 1: Ecological and Physiological Bases of Space Biology and Medicine. 1975 at 25–31; and Fowler B, Paul M, Porlier G, Elcombe DD, and Taylor M. A re-evaluation of the minimum altitude at which hypoxic performance decrements can be detected. *Ergonomics.* 1985;28(5):781–791.

[35] Fowler B, Paul M, Porlier G, Elcombe DD, Taylor M. A reevaluation of the minimum altitude at which hypoxic performance decrements can be detected. *Ergonomics.* 1985;28(5):781–791.

[36] For the same inhaled air temperature, the thermal load of humid air is higher than that of dry air. The maximum thermal load tolerated by a human being can be specified by many combinations of dry-bulb temperature and relative humidity, or by one wet-bulb temperature, for which the temperature is measured using a wet thermometer surface. Researchers have demonstrated that the wet-bulb temperature of the inspired air most accurately measures heat stress to the tissues of the mouth, as compared to temperature readings from an ordinary, dry thermometer, even when combined with the control of relative humidity. Kamon E, Bernard T, Stein R. Steady state respiratory responses to tasks used in Federal testing of self-contained breathing apparatus. *AIHAJ.* 1975;36:886–896.

[37] Kamon E, Bernard T, Stein R. Steady state respiratory responses to tasks used in Federal testing of self-contained breathing apparatus. *AIHAJ.* 1975;36:886–896.

[38] Hodgson JL. *Physiological costs and consequences of mine escape and rescue.* University Park, PA: The Pennsylvania State University. U.S. Bureau of Mines contract No. J0345327; 1993:19.

the volume of oxygen, in liters, that the CCER effectively delivers for consumption by the user. All volumes are given at standard temperature (0 °C) and pressure (760 mm Hg), dry, unless otherwise noted. This capacity can differ from the volume of oxygen stored by the CCER, some of which may be wasted rather than inhaled by the user, depending on the particular design of the CCER and the work rate of the user. A CCER will operate for a shorter duration when the oxygen consumption rate is high. Hypothetically, a 190-pound man, at rest, is estimated to consume a volume of oxygen of .5 liters per minute. If he were walking in an upright position at 3 miles per hour, it is estimated that he could consume 1.18 liters per minute. The same man running in an upright position at 5 miles per hour is estimated to consume 2.72 liters per minute.[39]

A 3-capacity ratings system is established in this section: ''Cap 1—Cap 3.'' Cap 1 provides 20 to 59 liters of oxygen for short escapes that could be accomplished quickly; Cap 2 provides 60 to 79 liters for escapes of moderate distance; and Cap 3 provides 80 or more liters for the lengthiest escapes. The 3 capacity ratings correspond to the liter quantities of breathing gas supplies that are expended during the NIOSH capacity testing within approximately 10, 30, and 60 minutes, respectively.

The Cap 3 rating is comparable to the current NIOSH-certified 60-minute rating for CCERs; 10-minute units provide approximately 25 liters of oxygen, comparable to a Cap 1. The oxygen consumption rate associated with this rating is the average rate demonstrated through NIOSH testing of the 50th percentile miner by weight (191 pounds) performing the 1-hour ''man test 4.''[40] The test is a series of laboratory-based physical activities similar to those involved in coal mine rescues and escapes, including vertical treadmill climbs, walks, runs, and carries and pulls of substantial weights. As discussed under II(C), however, the duration of adequate breathing gas supply actually provided to a user by a respirator of a given capacity rating will depend on the degree of exertion involved in the particular escape and the size of the respirator user. For this reason, as discussed under II(C), NIOSH believes the change from a certification based on duration to one based on capacity is important. Using the hypothetical example of the 190-pound man above, the following table provides a set of possible use durations for illustrative purposes. These are calculated based on a consideration of limited factors and ideal use conditions and would be unlikely to match actual durations achieved by users in actual or simulated escapes.

CAPACITY VERSUS WORK ACTIVITY

	Capacity 1 (20 liters)	Capacity 2 (60 liters)	Capacity 3 (80 liters)
At Rest (.5 L/minute)	40 minutes	120 minutes	160 minutes.
Run at 3 mph (1.18 L/minute)	17 minutes	51 minutes	68 minutes.
Run at 5 mph (2.72 L/minute)	7 minutes	21 minutes	28 minutes.

In addition to having a capacity rating system to categorize products, manufacturers will use the actual tested capacity of approved respirator models, which NIOSH will report to the manufacturer in increments of 5 liters, to specify more precisely the capacity of each product. This will enable employers to readily compare differences in respirator capacity within a given rating, more closely match a respirator model to their particular needs, and choose the respirator model that best serves their employees. For example, an employer might determine through simulation of escapes that employees will need a Cap 3 CCER model that provides 95 liters to allow for the worst contingencies. Alternatively, an employer might determine that a Cap 3 model that provides 80 liters is sufficient and better designed, in terms of physical dimensions or operational characteristics, to accommodate the routine work tasks and escape contingencies of the employees.

The capacity testing will evaluate seven CCER units using the breathing and metabolic simulator. Three will be tested in the condition received from the applicant (i.e., ''new'' condition), two will receive environmental treatments prior to capacity testing, and the remaining two units will be tested at the cold-temperature limit specified by the manufacturer, after being stored at the specified temperature.

Each unit will be tested at the work rate identified in Table 2 below, according to the capacity level designated by the applicant. In terms of the rate of oxygen usage, carbon dioxide production, ventilation rate, and respiratory frequency, the work rates are representative of the average work rate that the typical CCER user might sustain during an escape, based on laboratory physiological testing involving miners.[41] As Table 2 shows, the greater the capacity of the CCER, the lower the work rate that would be used to test the CCER, reflecting the lower average rate of exertion that the typical user would be capable of sustaining for escapes of longer duration. Low capacity devices are likely to be used for short, very challenging escapes that would induce exceptionally high work rates. NIOSH finds it is appropriate to apply a work rate that represents the level of exertion sustainable by a typical user while using a device of a particular capacity. Hence, NIOSH specifies such an approach in this rule.

One of the units submitted will be tested by a human subject on a treadmill. 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.

[39] Kamon E, Bernard T, Stein R. Steady state respiratory responses to tasks used in Federal testing of self-contained breathing apparatus. *AIHAJ.* 1975;36:886–896.

[40] See 42 CFR 84.100, Table 4 for the specific requirements of man test 4.

[41] Kamon E, Bernard T, Stein R. Steady state respiratory responses to tasks used in Federal testing of self-contained breathing apparatus. *AIHAJ.* 1975;36:886–896.

TABLE 2—CAPACITY TEST REQUIREMENTS

Capacity rating	Capacity (L of O_2)	VO_2 (L/min)	VCO_2 (L/min)	Ve (L/min)	RF (Breaths/min)
Cap 1	20 ≤ L ≤ 59	2.50	2.50	55	22
Cap 2	60 ≤ L ≤ 79	2.00	1.80	44	20
Cap 3	L ≥ 80	1.35	1.15	30	18

VO_2 = volume of oxygen consumed per minute; VCO_2 = volume of carbon dioxide produced per minute.
Ve = ventilation rate in liters of air per minute; RF = respiratory frequency.

In addition to this standard testing regime to be used for all CCERs, when testing CCER models to be co-approved with MSHA for use in coal mines, NIOSH will also continue to conduct the appropriate man test 4 protocol discussed above for determination of the suitability of these CCERs to be used in U.S. underground coal mines. This testing is the same as is required under the current 42 CFR Part 84 regulations. The Federal Mine Safety and Health Act requires that ''no mandatory health or safety standard * * * shall reduce the protection afforded miners by an existing mandatory health or safety standard.'' [42] The use of the capacity rating system and associated tests to approve equipment for use in underground coal mines will not constitute a reduction in protection or a reduction in the duration of breathing supply regulated under the current MSHA duration requirements for self-contained self-rescuers. Nevertheless, NIOSH and MSHA agree that the continued use of man test 4, as a supplement to the final new testing requirements and capacity rating system, will be the most practical method demonstrating such compliance with the cited provision of the Federal Mine Safety and Health Act. The Cap 3 unit approved for use in mining also meets the 1-hour requirement and the Cap 1 and Cap 2 units approved for use in mining also meet no less than the 10-minute requirement under MSHA's existing standards.

6. Section 84.305 Performance Test Requirements

This section specifies the performance testing regimen that will be used to certify the ability of the CCER to provide a constantly adequate breathing supply for the user immediately upon donning and under varied work rates, including a level representative of peak demand and minimal demand. The high work rates used during the test will activate the demand valve, if present in the CCER model, and stress the carbon dioxide absorbent. The low work rate would activate the relief valve, if present. The test includes a procedure (immediate exhalation into the unit upon donning) to evaluate the potential for the user to experience hypoxia (a deficient oxygen concentration) upon donning the CCER. Hypoxia could occur with a CCER using compressed oxygen and a demand valve if the user forces enough nitrogen into the breathing circuit to prevent the activation of the demand valve and the user had consumed more oxygen than the constant quantity supplied by the CCER. Such a situation is more likely to arise if a CCER user is not adequately trained in its use.

Many CCER users are trained to exhale into a CCER upon donning it because this is the recommended practice for CCERs supplied with chemical oxygen if the oxygen starter fails. In an emergency, it is likely that some users will exhale into the CCER regardless of its design, in which case NIOSH needs to ensure that the respirator will perform adequately. For this reason, NIOSH is establishing a generic performance testing protocol, irrespective of CCER design, that includes the hypoxia testing procedure in which the test will begin with two exhalations into the unit at the specified ventilation rate and then follow the manufacturer's instructions to determine the design's susceptibility to hypoxia upon initial donning.

The performance testing will evaluate CCER units using the breathing and metabolic simulator. Of these, three units will be tested in new condition, and two will receive environmental treatments prior to performance testing. The testing regimen will employ the following oxygen use-rate cycle: 3.0 liters per minute for 5 minutes, 2.0 liters per minute for 15 minutes, and 0.5 liters per minute for 10 minutes. Other parameters of the testing are specified in Table 3 below.

TABLE 3—PERFORMANCE TEST REQUIREMENTS

Work-rate test sequence	Duration per cycle (in minutes)	VO_2 (L/min)	VCO_2 (L/min)	Ve (L/min)	RF (breaths/min)
1. Peak	5	3.00	3.20	65.0	25
2. High	15	2.00	1.80	44.0	20
3. Low	10	0.50	0.40	20.0	12

VO_2 = volume of oxygen consumed per minute; VCO_2 = volume of carbon dioxide produced per minute.
Ve = ventilation rate in liters of air per minute; RF = respiratory frequency.

The 3.0 liters per minute oxygen use-rate represents peak exertion. The 2.0 liters per minute oxygen use-rate is high, representing substantial exertion. The 0.5 liters per minute oxygen use-rate is very low, representing a sedentary person, such as a worker who might be trapped and awaiting rescue.[43]

[42] 30 U.S.C. 811(a)(9).

[43] Turner N, Beeckman D, Hodous T. Evaluation of proposed methods to update human testing of self-contained breathing apparatus. *AIHAJ*. Dec. 1995;56:1195–1200.

Louhevaara V, Tuomi T, Smolander J, *et al.* Cardiorespiratory strain in jobs that require respiratory protection. *Int. Arch. Occup. Environ. Health*. 1985;55:195–206.

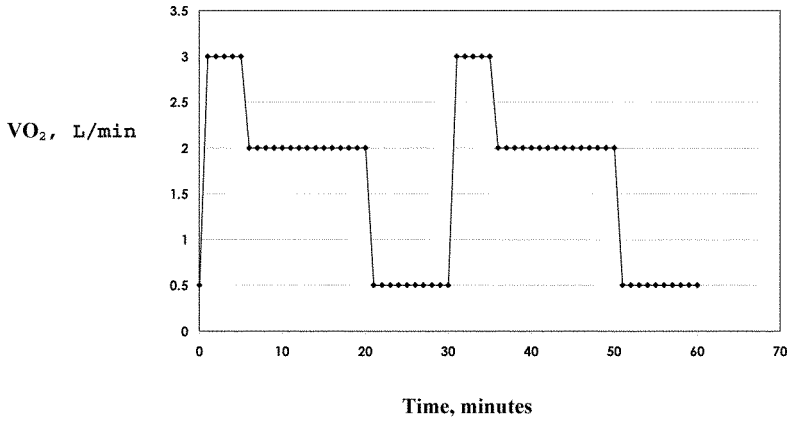
Lemon PW, Hermiston RT. The human energy cost of fire fighting. *J. Occup. Med.* Aug. 1977;19:558–562.

The test will be started by the exhalation of two large breaths into the unit before donning it. This will determine the susceptibility of the CCER to hypoxia.

Since the testing cycle requires 50 liters of oxygen, CCERs that have less than a 50 liter capacity will exhaust their capacity prior to completing a full cycle as specified. To accommodate this limitation, if a unit contains less than 50 liters of useable oxygen (as determined by the capacity test under § 84.304), NIOSH will require the submission of additional units so that the test can be completed through the testing of a sequence of two or three units, as necessary. Such a requirement ensures that the CCER is tested at each work rate in its entirety. CCERs with greater than a 50 liter capacity will repeat the cycle until the oxygen supply is exhausted, as indicated in the graph below.

One unit will be tested by a human subject on a treadmill. The purpose of the human subject test is to provide assurance that the respirator will perform effectively when responding to the more variable loading produced by a human subject.

Performance Test



7. Section 84.306 Wearability Test Requirements

This section specifies the testing regimen that will be used to ensure that the CCER can be easily and quickly donned. The testing procedures also ensure that during any reasonably anticipated activity, the CCER will not physically harm or significantly hinder the user and would provide an adequate and uninterrupted supply of breathing gas. Testing will be conducted using three human subjects of differing heights and weights,[44] as specified, to provide reasonable assurance that the results would be representative of most potential CCER users.

Subsection (b) requires that trained users be able to successfully don the CCER, initiating breathing through the device within 30 seconds. This criterion, derived from current training requirements for the use of CCERs used in mining,[45] is reasonably protective in the case of emergency scenarios involving an explosion or sudden detection of a hazardous breathing environment. This subsection allows NIOSH to determine whether any particular design, construction, or material characteristic of the CCER could hinder the user in the correct and timely donning of the CCER. These determinations may be made based on either the demonstrated ability of a human subject to don the CCER as required or the identification of plausible circumstances that would prevent the required timely donning.

Subsection (c) and the table below specify the activities that will be performed by the human subjects to test the CCER. These activities are derived from the present regulations and represent the types of activities and physical orientations that may occur during escapes. The test will continuously monitor the CCER to ensure these activities and orientations do not adversely affect the adequacy of the CCER's supply of breathing gas and to identify any potential for the CCER to harm or hinder the user during an escape.

TABLE 4—WEARABILITY TEST REQUIREMENTS

Activity	Minimum duration
Sitting	1 minute.
Stooped walking	1 minute.
Crawling	1 minute.

TABLE 4—WEARABILITY TEST REQUIREMENTS—Continued

Activity	Minimum duration
Lying on left side	1 minute.
Lying on right side	1 minute.
Lying on back	1 minute.
Bending over to touch toes.	1 minute.
Turning head from side to side.	1 minute (at least 10 times).
Nodding head up and down.	1 minute (at least 10 times).
Climbing steps or a laddermill.	1 minute (1 step/second).
Carrying 50-lb bag on treadmill at 5 kph.	1 minute.
Lifting 20-lb weight from floor to an upright position.	1 minute (at least 10 times).
Running on treadmill at 10 kph.	1 minute.

8. Section 84.307 Environmental Treatments

This section specifies the environmental treatments that will be administered to the CCER to ensure that it is reasonably durable and resistant to the potentially performance-degrading environmental factors of extreme storage temperatures, shock, and vibration.

The extreme storage temperature test specified in subsection (b) is based on worst-case scenarios. For example, the high temperature (71 °C) test is based on

[44] The size range is intended to be representative of respirator users. See: Zhuang Z and Bradtmiller B. Head-and-face anthropometric survey of U.S. respirator users. *J. Occup. Environ Hyg.* 2005;2:567–576.

[45] Vaught C, Brnich MJ, and Kellner HJ. *Instructional mode and its effect on initial self-contained self-rescuer donning attempts during training.* Pittsburgh, PA: U.S. Department of the Interior, Bureau of Mines; 1988. RI 9208.

the temperature associated with storage in the trunks of vehicles. In response to public comments, units will be allowed to return to room temperature between steps.

The shock test specified in subsection (c), which is a series of 1-meter drops onto a concrete surface, is based on the height at which the respirator would be handled and attached to the user's belt. In response to public comments, the provision specifies that the shock test will be conducted on units in the casing in which they are deployed for individual use.

The vibration test specified in subsection (d) is a composite test based on the vibration levels measured on the frames of underground longwall and continuous mining machines and on underground and surface haulage vehicles.[46]

9. Section 84.308 Additional Testing

This section specifies several other tests that NIOSH will conduct, as appropriate. Each unit tested must meet the conditions specified in the test to receive approval.

Under subsection (b), NIOSH will perform safety hazard tests on any CCER that stores more than 200 liters of oxygen or that stores compressed oxygen at pressures exceeding 3,000 psi. None of the current 1-hour CCER designs has such storage capacities. However, if such a design were submitted for approval, the applicant would have to provide an additional 15 units of the CCER for these additional tests. The specifications for the tests are provided in a series of Bureau of Mines reports referenced in the regulatory text.

Under subsection (c), NIOSH will perform a series of tests on one or more units of every CCER submitted for approval to evaluate the effectiveness of the required eye protection (goggles or an escape hood lens) against dust, gas, and fogging that could impair the user's vision, as well as for durability. The tests proposed for dust and gas and durability were established by the International Organization for Standardization (ISO), a globally recognized consensus standard setting organization.[47] The test for fogging was established by the European Committee for Standardization, a consensus standard-setting organization within the European Union.[48] These specified tests, which are widely accepted by the safety and manufacturing communities, are incorporated by reference into this rule.

10. Section 84.309 Additional Testing and Requirements for Dockable CCERs

This section will provide for NIOSH to test and approve dockable CCERs, which are CCERs that would allow the user to resupply the breathing gas source included in the CCER through the attachment (docking) of breathing gas resupply sources that would be cached at locations along escape routes. Such dockable CCERs do not presently exist in the U.S. respirator market, but substantial interest in such technology has been expressed in the mining community, most recently in response to the Sago Mine disaster in 2006.[49]

Paragraph (a) specifies that NIOSH will conduct testing to ensure that the CCER user will be able to perform the docking process safely, reliably, and quickly under escape conditions. Precise testing protocols are not specified because they will depend on the technology, which has yet to be developed; test protocols will be posted on the NIOSH Web site once they are created. However, the provisions clearly specify the qualitative performance characteristics required for approval.

Paragraph (b) provides that NIOSH will designate CCERs that meet the testing requirements of this section as ''Dockable.''

Paragraph (c) provides that NIOSH will assign the capacity rating to the dockable CCER using only the breathing gas supply included for the initial use of the wearable apparatus. In other words, the capacity of the breathing gas resupply units will not be taken into account in rating the capacity of the CCER.

Paragraph (d) provides that NIOSH test the breathing gas resupply units produced for the dockable unit and specify their capacities using capacity testing procedures consistent with those applied to testing the dockable CCER. This testing is necessary so that users have NIOSH verification of the capacity of the resupply units. The provision also provides for appropriate labeling to specify the capacity of the resupply unit and its compatibility with the CCER.

Paragraph (e) provides that NIOSH will be able to require the applicant to provide additional units of the CCER for the additional testing associated with dockable units. NIOSH cannot determine at this time whether additional units will be needed.

Paragraph (f) provides that NIOSH will not approve a CCER with docking components, even without the NIOSH ''Dockable'' designation, unless it satisfies the testing and other requirements proposed for approving dockable units. This provision is intended to avoid the plausible circumstance of users mistaking certified CCERs with docking components as having been approved by NIOSH as dockable.

11. Section 84.310 Post-Approval Testing

This section provides for NIOSH to conduct periodic testing of deployed units of approved CCERs. The purpose of such post-approval testing is to evaluate the capacity and performance of the approved CCER after it has been subject to actual field conditions including operations, storage, and handling at worksites. NIOSH will obtain such units from employers in exchange for new units, substituted at no cost to the employer. NIOSH will require, as a condition of continued approval, that the applicant make available for purchase by NIOSH a sufficient number of new units (not to exceed 100 units annually) to support the post-approval testing program. On several occasions, NIOSH has been hampered by the lack of an available supply of a CCER model, either because the manufacturer produces the products intermittently or has ceased production permanently. In response to public comments, the rule allows manufacturers that discontinue a particular line of respirators selected for field evaluation to replace those units with similar, NIOSH-approved CCERs.

If testing indicates that deployed units of a CCER are not consistently meeting the capacity and performance standards under which the CCER was approved, NIOSH will request remedial actions by the applicant. NIOSH will be authorized to revoke the approval of a CCER if the applicant does not remediate the cause(s) of the problem(s). In such a case, NIOSH will work with the relevant regulatory agencies and industry and

[46] Dayton T. Brown, Inc. *Environmental test criteria for the acceptability of mine instrumentation.* Phase 1, Final Report DTB2GR80–0643. U.S. Bureau of Mines contract No. J0100040; June 1980;72.

[47] ISO 4855:1981, *Personal eye-protectors—Non-optical test methods.* International Organization for Standardization. Clauses 13, 14; Sub-Clause 3.1. Copies are available for inspection at NIOSH (see rule text for details) and for purchase from the ISO Web site at: *http://www.iso.org/iso/catalogue_detail.htm?csnumber=10838.* Accessed October 7, 2010.

[48] European Standard BS EN 168:2002, *Personal eye-protection, Non-optical test methods.* European Committee for Standardization. January 2002. Copies are available for inspection at NIOSH (see rule text for details) and for purchase from the BSI British Standards Web site at: *http://shop.bsigroup.com/en/ProductDetail/?pid=000000000030036280.* Accessed October 7, 2010.

[49] McAteer JD, *et al. The Sago Mine disaster: a preliminary report to Governor Joe Manchin III.* Buckhannon, West Virginia; July 2006;14. *http://www.wvgov.org/SagoMineDisasterJuly2006FINAL.pdf.* Accessed October 7, 2010.

labor organizations to notify users of the revocation.

A program of post-approval testing is important for assuring users of the effectiveness of their equipment. Simulations of environmental conditions conducted in a laboratory during the approval process cannot perfectly and comprehensively replicate all conditions that might be associated with the actual storage and wearing of CCERs in mines and other work environments. The post-approval testing also serves to identify potential problems of quality control in the manufacturing process. The regulatory requirements of this section ensure the feasibility of a post-approval testing program and establish specific authorities and obligations in connection with the results of such testing.

12. Section 84.311 Registration of CCER Units Upon Purchase

This section requires that manufacturers provide each purchaser of a CCER unit with copies of procedures for registering purchased units with NIOSH. NIOSH will also work with relevant agencies and industry and labor associations to publicize the registration program. It is particularly important to reach purchasers and users of CCERs who obtain their devices from secondary markets and through equipment transfers from other work sites. This registration will enable NIOSH to notify purchasers when: (1) A problem associated with a model of CCER is identified; (2) such a problem requires a remedial action; or (3) NIOSH revokes the certification of a CCER. Presently, NIOSH has limited ability to locate users of particular CCER models. Manufacturers do not consistently retain records of purchasers and may sell product through distributors. Also, there is a secondary market for re-selling purchased CCERs as purchasers go out of business, reduce their employment, or select an alternate CCER model.

B. Subpart G—General Construction and Performance Requirements

1. Sections 84.60, 84.63–84.65

These sections of Subpart G, which provide general construction and performance requirements for respirators approved under 42 CFR Part 84, are presently limited to covering respirator types specified under Subparts H through L. Since this rule removes CCER provisions from under Subpart H and places them under a newly created Subpart O, Subpart G is revised to cover Subpart O as well as Subparts H through L. Furthermore, by technical error, existing Subparts N and KK have been inadvertently omitted from coverage under Subpart G, even though this provision was intended to apply to all respirators types. In this final rule, HHS extends the coverage of Subpart G to all respirators certified under this Part (i.e., Subparts H through KK) to clearly specify the comprehensive coverage of Subpart G to all respirator types presently approved. This change also provides coverage under Subpart G for respirator types that might be distinguished under newly created sections in the future.

C. Subpart H—Self-Contained Breathing Apparatus

1. Section 84.70 Self-Contained Breathing Apparatus; Description

This section excludes CCERs from coverage under any provisions of Subpart H, except as provided for under § 84.304(a)(5). The provisions of Subpart H concerning respirators used for escape only from hazardous environments apply solely to those with an open-circuit design.

IV. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This rule is being treated as a ''significant regulatory action'' within the meaning of E.O. 12866 because it raises novel legal or policy issues. Current MSHA regulations (30 CFR 75.1714–1) require that underground coal mine operators provide miners with CCERs (referred to in the mining community as a self-contained self-rescuer or SCSR) which have been approved by MSHA and NIOSH under 42 CFR Part 84, as follows:

(a) 1-hour SCSR;

(b) A SCSR of not less than 10 minutes and a 1-hour canister; or

(c) Any other self-contained breathing apparatus which provides protection for a period of 1 hour or longer and which is approved for use by MSHA as a self-rescue device when used and maintained as prescribed by MSHA.

By changing the nomenclature used to identify different size CCER models, the new rule will change the criteria by which NIOSH and MSHA approve CCERs intended for use in mines. MSHA, as a co-approver, will determine whether they meet the requirements of paragraphs (a) and (b) of the MSHA regulation, consistent with the NIOSH approval process. As discussed above in Section I.C. of the preamble, there is evidence that the duration rating system causes the user to believe that the apparatus will last for a specific length of time, regardless of the user's weight, physical condition, or activity. This is not an accurate interpretation. Relying on a 1-hour unit to supply 1 hour of oxygen to all users under all circumstances can lead to inappropriate deployment and misuse in emergencies. NIOSH believes that transition to the capacity rating will alleviate these misinterpretations.

The rule is not considered economically significant, as defined in sec. 3(f)(1) of E.O. 12866. HHS anticipates that respirator manufacturers will need to modify some existing CCER designs and make related changes to their manufacturing processes to meet the new capacity and performance testing requirements. However, these changes are not expected to require manufacturers to use fundamentally different or substantially more costly technology. Similarly, NIOSH does not expect the new requirements for indicators of excessive thermal exposure, moisture damage, or chemical bed integrity to have a substantial impact on the manufacturing cost of CCERs. Such indicators have already been incorporated into CCER designs by some manufacturers without substantially increasing product prices. Hence, NIOSH does not expect that manufacturers will have to engage in new manufacturing processes that would substantially increase manufacturing costs or product prices.

Moreover, even a substantial cost increase in CCERs would not be economically significant. The scope of the market for CCERs is presently very limited. According to MSHA, there are approximately 47,000 coal miners, the principal users of CCERS in the private sector, working underground in such positions as mining machine operators, excavating machine operators, roof bolters, earth drillers, electricians, helpers, and first line supervisors.[50] The

[50] U.S. Department of Labor, Mine Safety and Health Administration. Mining Industry Accident,

Continued

service lives of current CCER models range from 10 to 15 years, although some units may be damaged or used for an escape or escape simulation and consequently would be taken out of service sooner. Assuming conservatively that each CCER unit is replaced every 10 years on average and given that approximately 180,000 units [51] are currently deployed, the mining industry would purchase an average of 18,000 units annually. Given an average cost of $675 per unit,[52] these data suggest that this principal component of the current CCER market represents approximately $12.2 million in annual sales. Other major components of the CCER market include sales to the Navy and Coast Guard and possibly the maritime industry. Among these, the Navy is the largest consumer, with over 400,000 units in current use; assuming conservatively that each of the Navy's CCER units is replaced every 10 years, the Navy purchases an estimated 40,000 units annually; therefore, the annual CCER market for the Navy represents approximately $27 million.[53] In sum, the CCER market is estimated to be approximately $39.2 million per year. Although HHS does not expect the cost of individual CCER units to rise significantly in response to the new testing and approval standards, a hypothetical increase of 50 percent in the price per unit would result in an average annual market of $58.8 million. The estimated impact of the final rule on respirator sales (the difference between estimated current annual sales and estimated annual sales under the new standards calculated using a 50 percent per unit increase) is $19.6 million per year, or less than 20 percent of the $100 million threshold for a significant regulatory action having an annual effect on the economy. Further, the rule will not adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. No respirator manufacturer or underground coal mine operator offered comment on this analysis.

The new requirements will likely produce economic benefits. First, they will provide more product performance information to purchasers, which will result in a more efficient market. Respirators will be tested for their specific capacity, in addition to being rated by general categories of capacity. As discussed under Section III—84.304 of the preamble, this specificity will allow purchasers to match respirators more closely to their particular needs. As a result, manufacturers will have incentive to innovate and address the diverse needs of users. Further, having specific NIOSH-approved capacity levels will provide manufacturers with more incentive to differentiate the performance of their products from those of their competitors. This competition should result in a market of products that more closely meet the design and performance needs of different work sites, thereby improving the protection of miners and other workers who rely on CCERs in emergencies. While NIOSH is unable to quantify the benefits of a more efficient market, it is reasonable to assume that the development of products more specifically tailored to the needs of purchasers will eliminate wasteful spending by employers and improve worker protection.

Second, the new requirements for safety features (which provide for the detection of units that have undergone excessive environmental stresses or mishandling) have the potential to increase the ability of purchasers, users, inspectors, and others to contribute to assuring the reliability of deployed CCER units. This should make operator safety programs and regulatory compliance investments by the government more efficient by making it less likely that bad product will make its way to a worker's hands. While HHS cannot quantify this benefit, it is logical and reasonable to expect that a positive economic impact will derive from improved safety features.

Third, the new requirements for safety features and for capacity and performance testing are designed to better protect workers relying on CCERs for their survival. Although NIOSH lacks information on the number of workers annually who rely on a CCER for their survival and the quantifiable benefit they will derive from the improvements in this rule, the improved standards are likely to result in fewer negative outcomes and lower associated costs. In addition, substantial costs associated with rescue operations could be averted if workers escape independently.

The rule will not interfere with State, local, or tribal governments in the exercise of their governmental functions.

OMB has reviewed this proposed rule for consistency with the President's priorities and the principles set forth in E.O. 12866.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. The Department of Health and Human Services (HHS) certifies that this rule will not have a significant economic impact on a substantial number of small entities, including both small manufacturers of CCERs and the small mining operators that are required to purchase them, within the meaning of the RFA.

CCERs currently sold in the United States are manufactured by only two U.S. companies: CSE Corporation of Monroeville, Pennsylvania, and Ocenco Incorporated of Pleasant Prairie, Wisconsin. (A third company, Draeger, is based in Germany.) These manufacturing companies are small businesses as defined under the Small Business Act for this industry sector (NAICS 339113—Surgical Appliance and Supplies Manufacturing), employing fewer than 500 employees. Accordingly, HHS has given consideration to the potential impact of this rule on these two companies.

HHS did not receive any comments on the economic analysis published in the **Federal Register** (73 FR 75027, December 10, 2008).

Manufacturers will likely have to design new products and make related changes to their manufacturing processes for these products. However, in NIOSH's judgment, such new designs and production changes would not require substantial technological innovation in order to meet the improved performance standards. Similarly, NIOSH does not expect the new requirements for indicators of excessive thermal exposure, moisture damage, or chemical bed integrity to have a substantial impact on the manufacturing cost of CCERs. Such indicators have already been incorporated into CCER designs by some manufacturers without substantially increasing product prices. Most importantly, any associated costs incurred by the manufacturers for compliance with this rule could be

Injuries, Employment, and Production Data—Address & Employment Self-Extracting Files. *http://www.msha.gov/stats/part50/p50y2k/aetable.htm.* Accessed July 7, 2011.

[51] This figure was supplied by MSHA, which maintains a registry of all CCER units deployed to U.S. coal mines.

[52] NIOSH calculated this average price based on the products supplied by the three CCER manufacturers that supply U.S. coal mines, unit prices to NIOSH for its recent purchases of these products, and the approximate deployment distribution of these products among U.S. coal mines as indicated by the MSHA CCER registry for coal mines.

[53] Estimated from information provided by the Naval Surface Warfare Center, Panama City, Florida, December 20, 2004.

passed on to consumers entirely since the demand for these products is essentially inelastic.[54] HHS is unable to quantify the impact on the two small manufacturers; however, the Department believes that manufacturers did not offer comment on this analysis because the cost of compliance is not expected by any stakeholder to exceed the benefits derived from this final rule. Accordingly, HHS finds there would not be a significant economic impact on the two U.S. respirator manufacturers which produce the CCERs covered by this rule. The table below identifies the two domestic CCER manufacturers and the non-U.S. company, the products each make that are used in underground coal mining, the cost to NIOSH of purchasing an individual unit, and the market share of each type of respirator.[55]

CLOSED-CIRCUIT ESCAPE RESPIRATOR MANUFACTURERS AND COSTS

Manufacturer	Respirator	Cost	Market share (percent)
CSE	SR–100	$689	46
Ocenco	EBA 6.5	670	39
Ocenco	M–20	412	2
Draeger	OKY–X Plus	537	5
MSA *	Life-Saver 60		

* MSA supplied CCERs to 7% of the market in 2002; they have since stopped U.S. sales.

Further, because the Mine Act (30 U.S.C. 842(h)) and MSHA regulations (30 CFR 75.1714–1) require coal mine operators to supply CCERs approved by NIOSH and MSHA for the protection of coal miners working in underground coal mines, HHS has also considered the secondary or ''downstream'' economic impact of this rule on coal mine operators that would be considered small businesses, which the Small Business Administration defines as those mines employing fewer than 500 employees. CCERs are purchased by bituminous coal mining companies (NAICS 212112) and anthracite coal mining companies (NAICS 212113). According to MSHA, 488 underground coal mines can currently be considered small.[56] According to the 2007 Economic Census, the value of coal shipments made in these two industries is approximately $15.5 billion annually;[57] because nearly all bituminous and anthracite coal mining companies are considered small, it is reasonable to assume that this value approximates revenues for those small manufacturers.

NIOSH does not expect that the prices of CCERs will be substantially affected by the new approval testing requirements. Respirator manufacturers may need to modify existing CCER designs to meet the new capacity or performance testing requirements. However, these requirements should not cause the manufacturers to use fundamentally different or substantially more costly technology, as discussed above. Hence, NIOSH does not expect that manufacturers would have to engage in markedly different manufacturing processes that might substantially increase product prices. The manufacturers would incur one-time costs for redesign of products or product components and associated production operations, as well as one-time costs for obtaining certification testing and approval from NIOSH and MSHA. Attempting to calculate price increases that would cover such costs would require more data than are available to NIOSH. Instead, HHS has evaluated the relative magnitude of possible costs under the extremely conservative assumption that CCER prices would be increased permanently by 50 percent to amortize the one-time product and production redesign and NIOSH approval application costs. Currently, the weighted average price of a CCER is $675[58] and MSHA's CCER registry indicates there are approximately 180,000 CCERs deployed in underground coal mines. There were approximately 47,000 coal miners working underground in large and small U.S. coal mines in the first quarter of 2011.[59] Assuming very conservatively that each unit requires replacement every 5 years,[60] assuming that all CCERs deployed in mines would be replaced in the first year of this final rule, and assuming that the prices of all CCERs were to increase by 50 percent as a result of this rule, the annualized additional costs would amount to between approximately $282 and $315 per underground coal miner.[61] This increase in labor-associated costs would not be significant in the context of the total per capita labor costs of underground coal mine operators. The total earnings of non-union coal miners (wages and benefits), which generally represents employment for small coal mine operators, is approximately

[54] The MINER Act requires underground coal mine operators to supply each underground worker with at least 4 hours of breathable air; the International Convention for the Safety of Life at Sea similarly requires ships to carry breathable air in designated locations.

[55] Kyriazi N, Shubilla JP. *Self-contained self-rescuer field evaluation: seventh-phase results.* Pittsburgh, PA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; March 2002. DHHS (NIOSH) Publication No. 2002–127, RI 9656.

[56] U.S. Department of Labor, Mine Safety and Health Administration. Mining Industry Accident, Injuries, Employment, and Production Data—Address & Employment Self-Extracting Files. *http://www.msha.gov/stats/part50/p50y2k/aetable.htm.* Accessed July 7, 2011.

[57] U.S. Census Bureau. 2007 Economic Census. *http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-ds_name=EC0721I1&-_lang=en.* Accessed August 24, 2011.

[58] NIOSH calculated this weighted average price using the products of the three CCER manufacturers that supply U.S. coal mines, unit prices to NIOSH for its recent purchases of these products, and the approximate deployment distribution of these products among U.S. coal mines as indicated by the MSHA CCER registry for coal mines. The use of this weighted average price simplifies the analysis and is adequate considering the equivalency of these prices for the major share holders (Ocenco and CSE) as indicated in Table 1.

[59] U.S. Department of Labor, Mine Safety and Health Administration. Mining Industry Accident, Injuries, Employment, and Production Data—Address & Employment Self-Extracting Files. *http://www.msha.gov/stats/part50/p50y2k/aetable.htm.* Accessed July 7, 2011.

[60] This replacement rate is an exceptionally conservative estimate. A more realistic estimate is 10 percent annually (i.e., the replacement of a CCER unit every 10 years), based on the known service-life of CCERS of 10–15 years, the MSHA CCER registry, and NIOSH long-term field evaluation data. These latter two sources indicate the current replacement rate is well under 10 percent.

[61] The lower value was obtained using a cost of capital rate of 3 percent: $675/unit × 0.5 cost increase × 180,000 units × 0.2184 annualization factor/47,000 underground miners = annual costs per underground miner. The higher value was obtained using a cost of capital rate of 7 percent: $675/unit × 0.5 cost increase × 180,000 units × 0.2439 annualization factor/47,000 underground miners = annual costs per underground miner.

$72,000.[62] HHS finds that an average of $282 to $315 in additional annual costs per coal miner (less than 0.39 to 0.44 percent of per capita labor costs), or $13.3 to $14.8 million in estimated annual costs to the 488 small underground coal mines were this rule to increase CCER prices by 50 percent, does not represent a significant economic impact on small mine operators (.09 to .1 percent of annual revenue); nor would a 100 percent increase in CCER prices, which HHS does not find to be plausible considering the facts discussed here, impose a significant economic impact on small mine operators.[63]

HHS consulted with and received approval from the Small Business Administration on this analysis of the final rule's impact on small entities.

For the reasons provided, a regulatory flexibility analysis, as provided for under RFA, is not required.

C. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), a Federal agency shall not conduct or sponsor a collection of information from 10 or more persons other than Federal employees unless the agency has submitted a Standard Form 83, Clearance Request, and Notice of Action, to the Director of the Office of Management and Budget (OMB), and the Director has approved the proposed collection of information. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

HHS has determined that this final rule contains information collections that are subject to review by OMB. OMB has approved NIOSH's collection of information from applicants under OMB Control No. 0920–109, ''Respiratory Protective Devices,'' which covers all information collected under 42 CFR Part 84. Current OMB approval for this data collection expires August 31, 2014. The requirements of this final rule will not pose an additional burden on applicants because the application will not change from current practices.

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), HHS must report to Congress the promulgation of a final rule, once it is developed, prior to its taking effect. The report will state that HHS has concluded that the rule is not a ''major rule'' because it is not likely to result in an annual effect on the economy of $100 million or more.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and tribal governments and the private sector ''other than to the extent that such regulations incorporate requirements specifically set forth in law.'' For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million by State, local or tribal governments in the aggregate, or by the private sector.

F. Executive Order 12988 (Civil Justice)

This rule has been drafted and reviewed in accordance with Executive Order 12988, Civil Justice Reform, and will not unduly burden the Federal court system. NIOSH has provided clear testing and certification requirements it will apply uniformly to all applications from manufacturers of CCERs. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

HHS has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' The rule does not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

H. Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this rule on children. HHS has determined that the rule will have no effect on children.

I. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this rule on energy supply, distribution, or use because it applies to the underground mining sector. The rule would not result in any costs to mines. Hence this rule does not constitute a ''significant energy action.'' Accordingly, E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use, requires no further Agency action or analysis.

J. Plain Writing Act of 2010

Under Public Law 111–274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS has attempted to use plain language in promulgating the proposed rule consistent with the Federal Plain Writing Act guidelines.

V. Final Rule

List of Subjects in 42 CFR Part 84

Incorporation by reference, Mine safety and health, Occupational safety and health, Personal protective equipment, Respirators.

For the reasons discussed in the preamble, the Department of Health and Human Services amends 42 CFR Part 84 as follows:

PART 84—APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

■ 1. The authority citation for Part 84 continues to read as follows:

Authority: 29 U.S.C. 651 *et seq.,* and 657(g); 30 U.S.C. 3, 5, 7, 811, 842(h), 844.

Subpart G—General Construction and Performance Requirements

§ 84.60 [Amended]

■ 2. Amend § 84.60(a) to remove the phrase ''in subparts H through L'' and add in its place the phrase ''in subparts H through KK.''

§ 84.63 [Amended]

■ 3. Amend § 84.63(a), (b), and (c) to remove the phrase ''in subparts H through L'' and add in its place the phrase ''in subparts H through KK.''

[62] According to the National Mining Association, coal miners have average annual earnings of $72,200. See National Mining Association. *Profile of the U.S. coal miner 2008.* August 2009. *http://www.nma.org/pdf/c_profile.pdf.* Accessed October 23, 2009. This figure is consistent with the pay rate reported for non-union underground coal miners at $35.56 per hour. See InfoMine USA, Inc. *U.S. coal mines salaries, wages, and benefits, 2009.* February 2010. This non-union pay rate applied to a 2,000 hour work year represents total wages and benefits paid by small coal mine operators.

[63] HHS guidance defines ''significant economic impact'' as a 3–5 percent or more average annual impact on the total costs or revenues of small entities. See: U.S. Department of Health and Human Services. *Guidance on proper consideration of small entities in rulemakings of the U.S. Department of Health and Human Services.* May 2003.

§ 84.64 [Amended]

■ 4. Amend § 84.64(b) to remove the phrase ''of subparts H through L'' and add in its place the phrase ''of subparts H through KK.''

§ 84.65 [Amended]

■ 5. Amend § 84.65(a) to remove the phrase ''to subparts H through L'' and add in its place the phrase ''to Subparts H through KK.''

Subpart H—Self-Contained Breathing Apparatus

■ 6. Amend § 84.70 to:
■ a. Redesignate paragraphs (a) through (d) as (b) through (e), respectively; and
■ b. Add a new paragraph (a) to read as follows:

§ 84.70 Self-contained breathing apparatus; description.

(a) *Limitation on scope.* None of the provisions of Subpart H apply to closed-circuit escape respirators to be approved specifically for escape only from hazardous atmospheres, except as provided for under § 84.304(a)(5). Such respirators are covered under the provisions of subpart O of this part.

* * * * *

■ 7. Add subpart O to part 84 to read as follows:

Subpart O—Closed-Circuit Escape Respirators

Sec.
84.300 Closed-circuit escape respirator; description.
84.301 Applicability to new and previously approved CCERs.
84.302 Required components, attributes, and instructions.
84.303 General testing conditions and requirements.
84.304 Capacity test requirements.
84.305 Performance test requirements.
84.306 Wearability test requirements.
84.307 Environmental treatments.
84.308 Additional testing.
84.309 Additional testing and requirements for dockable CCERs.
84.310 Post-approval testing.
84.311 Registration of CCER units upon purchase.

Subpart O—Closed-Circuit Escape Respirators

§ 84.300 Closed-circuit escape respirator; description.

The closed-circuit escape respirator (CCER), technically a subset of self-contained breathing apparatus (SCBAs) which are otherwise covered under subpart H of this part, is used in certain industrial and other work settings in emergencies to enable users to escape from atmospheres that can be immediately dangerous to life and health. Known in the mining community as self-contained self-rescuers (SCSRs), and in other industries as emergency escape breathing devices (EEBDs) or apparatus (EEBAs), CCERs are relied upon primarily by underground coal miners, sailors in federal service, and railroad workers to escape dangerous atmospheres after a fire, explosion, or chemical release. CCERs are commonly worn on workers' belts or stored in close proximity to be accessible in an emergency. They are relatively small respirators, typically the size of a water canteen, that employ either compressed oxygen with a chemical system for removing exhaled carbon dioxide from the breathing circuit, or a chemical that both provides a source of oxygen and removes exhaled carbon dioxide. Users re-breathe their exhalations after the oxygen and carbon dioxide levels have been restored to suitable levels, which distinguishes these ''closed-circuit'' self-contained respirators from ''open-circuit'' self-contained respirators, which vent each exhalation.

§ 84.301 Applicability to new and previously approved CCERs.

This subpart applies to the following CCERs:

(a) All CCERs submitted to NIOSH for a certificate of approval after April 9, 2012; and

(b) All CCERs manufactured and labeled NIOSH-approved and sold by manufacturers after April 9, 2015.

§ 84.302 Required components, attributes, and instructions.

(a) Each CCER must include components and/or attributes appropriate to its design, as follows:

(1) Eye protection: Each CCER must include safety goggles or an escape hood lens that protects against impact, fogging, and permeation by gas, vapor, and smoke, as specified under § 84.308(c);

(2) Thermal exposure indicators: If the manufacturer specifies a maximum and/or minimum environmental temperature limit for storage of the CCER, then the CCER must include a component, an attribute, or other means by which a person can determine whether the CCER has been exposed to temperatures that exceed the limit(s);

(3) Chemical bed physical integrity indicators: If the CCER includes a chemical oxygen storage or chemical carbon dioxide scrubber that can be functionally damaged by impact, vibration, or any other environmental factor to which the CCER might be exposed, then the CCER must include a component, an attribute, or other means by which a person can detect any damage or alteration of the chemical oxygen storage or chemical carbon dioxide scrubber that could diminish the NIOSH-certified performance of the CCER, as tested under this subpart;

(4) Oxygen storage vessel: If the CCER includes an oxygen storage vessel, the vessel must be approved by the U.S. Department of Transportation (DOT) under 49 CFR part 107, ''Hazardous Materials Program Procedures,'' unless exempted under subpart B of 49 CFR part 107;

(5) Tamper-resistant/tamper-evident casing: If the CCER is not designed for its casing to be opened prior to use for an actual escape (e.g., for maintenance, escape drills, or inspection of the components), the casing must include a component, an attribute, or other means to prevent a person from accidentally opening the casing and, upon such opening, to either prevent the casing from being closed or to clearly indicate to a potential user that the casing has been previously opened; and

(6) Moisture damage indicators: If the CCER is not designed for its casing to be opened for inspection of its internal components, the casing must include a component, an attribute, or other means by which a person can detect any ingress of water or water vapor that could diminish the NIOSH-certified performance, as tested under this subpart.

(7) Oxygen starter indicators: If the oxygen starter is a critical component of the CCER design, then the CCER must include a component, an attribute, or other means by which a person can detect observable damage, premature activation, or recognized potential defect of the starter.

(b) Where an indicator is required, the indication of the occurrence of the monitored condition must be clear and unambiguous: It must not depend on a subjective interpretation of subtle, graduated, or other non-discrete changes to the indicator.

(c) Where an indicator is required, the manufacturer shall provide NIOSH with an explanation of its function and operation, and shall provide relevant data and equipment to allow NIOSH to conduct a thorough evaluation of its accuracy and reliability.

(d) The components of each CCER must meet the general construction requirements specified in § 84.61.

(e) The CCER must be resistant to the permeation of the breathing circuit by gasoline vapors. To verify such resistance, NIOSH will test one unit by applying the gasoline vapor permeation test specified on the NIOSH Web site at *http://www.cdc.gov/niosh/npptl,* using a

breathing machine applying a ventilation rate of 40 liters per minute, performing the test for the longest duration achieved by any of the units that underwent the capacity testing specified under § 84.304.

(f) Exposed parts of the CCER must not be composed of metals or other materials that could, upon impact, create frictional sparks or that could store or generate static electrical charges of sufficient energy to ignite flammable gaseous mixtures.

(g) The design, construction, or materials of the CCER must not constitute a hazard to the user as a result of the wearing, inspection, or use of the CCER.

(h) CCER instructions and a service life plan must be provided to purchasers. This document must be clearly written.

(1) Instructions must address the following topics and elements:

(i) An explanation of how the CCER works;

(ii) A schematic diagram of the CCER;

(iii) Procedures for donning and use;

(iv) Procedures for inspecting the operating condition of the CCER;

(v) Procedures and conditions for storage, including but not limited to any recommended minimum and maximum temperatures for storage;

(vi) Limitations on use, including but not limited to any recommended minimum and maximum temperatures for use;

(vii) Procedures for disposal; and

(viii) Procedures for registration of the unit with NIOSH, pursuant to § 84.311.

(2) The service life must be addressed covering at least the following topics:

(i) The maximum number of years, from the date of manufacture, that the unit may remain available for use; this limit is intended to prevent the continued use of a unit that the applicant cannot assure would continue to perform as approved by NIOSH, due to reasonably foreseeable degradation of materials used in its construction;

(ii) Any other conditions, other than that specified under paragraph (h)(2)(i) of this section, that should govern the removal from service of the CCER (including an indication given by the activation or operation of any required indicator showing the monitored condition has occurred); and

(iii) Any procedures by which a user or others should inspect the CCER, perform any maintenance possible and necessary, and determine when the CCER should be removed from service.

(i) Each individual CCER unit approval label shall identify the capacity rating and number of liters of oxygen as determined by the capacity testing, pursuant to § 84.304.

§ 84.303 General testing conditions and requirements.

(a) NIOSH will conduct capacity and performance tests on the CCER using a breathing and metabolic simulator to provide quantitative evaluations and human subjects on a treadmill to provide qualitative evaluations. Information on the design and operation of the simulator is available from the NIOSH Web site at *http://www.cdc.gov/niosh/npptl.* Technical specifications can be obtained from NIOSH by contacting the National Personal Protective Technology Laboratory (NPPTL) by mail: P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236. Telephone: 412–386–4000 (this is not a toll-free number). Email: *npptl@cdc.gov.*

(b) Capacity, performance, and wearability tests will continuously monitor the stressors listed in Table 1. The stressors and their respective acceptable ranges will be measured at the interface between the CCER and the mouth by instruments capable of breath-by-breath measurement. Stressor measurements will be evaluated as 1-minute averages. The operating averages of each stressor will be calculated upon the completion of each test as the average of the 1-minute measurements of the stressor recorded during the test. The level of any excursion for a stressor occurring during a test will be defined by the 1-minute average value(s) of the excursion(s).

TABLE 1—MONITORED STRESSORS AND THEIR ACCEPTABLE RANGES

Stressor	Acceptable range operating average	Acceptable range excursion
Average inhaled CO_2	<1.5%	≤4%.
Average inhaled O_2	>19.5%	≥15%.
Peak Breathing Pressures	$\Delta P \leq 200$ mm H_2O	$-300 \leq \Delta P \leq 200$ mm H_2O.
Wet-bulb temperature[1]	<43°C	≤50°C.

[1] Wet-bulb temperature is a measurement of the temperature of a wet surface. It represents the temperature of the inhaled breathing gas in the CCER user's trachea.

(c) Capacity and performance tests will conclude when the stored breathing gas supply has been fully expended.

(d) NIOSH will determine a CCER to have failed a capacity, performance, or wearability test if any of the following occurs:

(1) A 1-minute average measurement of any stressor listed in Table 1 occurs outside the acceptable excursion range specified in Table 1; or an average stressor measurement calculated at the completion of a performance or capacity test exceeds the acceptable operating average range specified in Table 1; or

(2) A human subject cannot complete the test for any reason related to the CCER, as determined by NIOSH.

(e) Unless otherwise stated, tests required under this subpart will be conducted at the following ambient conditions:

(1) Ambient temperatures of 23 °C ± 3 °C; and

(2) Atmospheric pressures of 735 mm Hg ± 15 mm Hg.

§ 84.304 Capacity test requirements.

(a) NIOSH will conduct the capacity test on a total of 8 to 10 of the units submitted for approval, as follows:

(1) Three units will be tested on a breathing and metabolic simulator in the condition in which they are received from the applicant;

(2) Two units will be tested on a breathing and metabolic simulator after being subjected to the environmental treatments specified in § 84.307 of this subpart;

(3) Two units will be tested on a breathing and metabolic simulator at the cold-temperature limit recommended by the manufacturer under § 84.302(h)(1), after the unit has been stored for a minimum of 24 hours at this limit; and

(4) One unit, in the condition in which it is received from the applicant, will be tested by a human subject on a treadmill.

(5) To approve a CCER for use in coal mines, two units will also be tested by a human subject under the specifications of §§ 84.99 and 84.100 that are applicable to man test 4.

(b) The capacity test will begin upon the first inhalation from or exhalation into the unit.

(c) Each unit will be tested at a constant work rate, depending on the capacity value specified by the manufacturer, according to the requirements specified in Table 2. All volumes are given at standard temperature (0 °C) and pressure (760 mm Hg), dry, unless otherwise noted.

(d) NIOSH will rate an approved CCER using the appropriate capacity rating, as specified in Table 2.

TABLE 2—CAPACITY TEST REQUIREMENTS

Capacity rating	Capacity (L of O_2)	VO_2 (L/min)	VCO_2 (L/min)	Ve (L/min)	RF (Breaths/min)
Cap 1	$20 \leq L \leq 59$	2.50	2.50	55	22
Cap 2	$60 \leq L \leq 79$	2.00	1.80	44	20
Cap 3	$L \geq 80$	1.35	1.15	30	18

VO_2 = volume of oxygen consumed per minute; VCO_2 = volume of carbon dioxide produced per minute.
Ve = ventilation rate in liters of air per minute; RF = respiratory frequency.

(e) NIOSH will document the least value achieved by the seven units tested using the breathing and metabolic simulator. NIOSH will quantify this value of achieved capacity within an increment of 5 liters, rounding intermediate values to the nearest lower 5-liter increment.

§ 84.305 Performance test requirements.

(a) NIOSH will conduct the performance test on a total of six of the units submitted for approval, as follows:

(1) Three units will be tested on a breathing and metabolic simulator in the condition in which they were received from the applicant; and

(2) Two units will be tested on a breathing and metabolic simulator after being subjected to the environmental treatments specified in § 84.307; and

(3) One unit will be tested, in the condition in which it was received from the applicant, by a human subject on a treadmill.

(b) Except as provided under paragraph (c) of this section, the performance test will apply a repeating cycle of work rates, according to the sequence and requirements specified in Table 3, until the oxygen supply of the unit is exhausted.

(c) Testing of CCERs with less than 50 liters of capacity, as determined by the capacity testing under § 84.304, will require the submission of additional test units to fully apply the work-rate test sequence and requirements specified in Table 3. The testing of each individual unit will complete the cycle specified in Table 3 until the breathing supply of the initial test unit is exhausted. This initial test unit will then be replaced by a second unit, which will continue the test cycle, beginning at the work rate in the cycle at which the initial unit was exhausted, and completing the full period specified in Table 3 for that work rate before proceeding to the subsequent work rate, if any, specified in Table 3. Each initial testing unit will be replaced as many times as necessary to complete the cycle, not to exceed two replacement units per initial test unit.

(d) The performance test will begin with two exhalations into the unit at the specified ventilation rate and then follow the manufacturer's instructions to determine the design's susceptibility to hypoxia upon initial donning.

TABLE 3—PERFORMANCE TEST REQUIREMENTS

Work-rate test sequence	Duration per cycle (in minutes)	VO_2 (L/min)	VCO_2 (L/min)	Ve (L/min)	RF (breaths/min)
1. Peak	5	3.00	3.20	65.0	25
2. High	15	2.00	1.80	44.0	20
3. Low	10	0.50	0.40	20.0	12

VO_2 = volume of oxygen consumed per minute; VCO_2 = volume of carbon dioxide produced per minute.
Ve = ventilation rate in liters of air per minute; RF = respiratory frequency.

§ 84.306 Wearability test requirements.

(a) NIOSH will conduct the wearability test on a total of three of the units submitted for approval. Three human subjects (two males and one female), one subject per unit, will conduct the test. The three subjects will range in height and weight as follows: One subject of height ≥174 cm and weight ≥90 kg; one subject of either 163 cm ≤ height <174 cm, regardless of weight, or 72 kg ≥ weight <90 kg, regardless of height; and one subject of height <163 cm and weight <72 kg. All units tested must meet all conditions specified in this section to receive approval.

(b) NIOSH will evaluate the ease and speed with which users can don the CCER, as follows:

(1) Each test subject will be provided with manufacturer instructions, and must be able to don the CCER correctly, isolating the lungs within 30 seconds; [1] and

(2) A CCER must not include any design, construction, or material characteristic that can be anticipated or demonstrated, under plausible conditions, to hinder the user in the correct and timely donning of the CCER.

(c) NIOSH will continuously monitor CCER use by each test subject during the activities specified in Table 4 to evaluate the ability of the CCER to provide an adequate and uninterrupted breathing supply, including but not limited to the requirements of § 84.303(b), without harming or hindering a user. NIOSH will not approve a CCER if the use of any unit during these activities indicates any potential for the CCER to harm or hinder the user or to fail to provide an adequate and uninterrupted breathing supply to

[1] This time limit does not apply to any additional steps that might be required after the lungs are protected to adjust the unit for wear.

the user during reasonably anticipated conditions and activities of an escape.

TABLE 4—WEARABILITY TEST REQUIREMENTS

Activity	Minimum duration
Sitting	1 minute.
Stooped walking	1 minute.
Crawling	1 minute.
Lying on left side	1 minute.
Lying on right side	1 minute.
Lying on back	1 minute.
Bending over to touch toes	1 minute.
Turning head from side to side	1 minute (at least 10 times).
Nodding head up and down	1 minute (at least 10 times).
Climbing steps or a laddermill	1 minute (1 step/second).
Carrying 50-lb bag on treadmill at 5 kph	1 minute.
Lifting 20-lb weight from floor to an upright position	1 minute (at least 10 times).
Running on treadmill at 10 kph	1 minute.

§ 84.307 Environmental treatments.

(a) Four units submitted for approval will be tested for capacity and performance, pursuant to the requirements of §§ 84.303 through 84.305, after exposure to environmental treatments simulating extreme storage temperatures, shock, and vibration.

(b) The units will be stored for 16 hours at a temperature of −45 °C and for 48 hours at a temperature of 71 °C. Units will be returned to room temperature between high and low temperature treatments. The maximum rate of change for thermal loading shall not exceed 3 °C per minute and constant temperatures shall be maintained within ±2 °C.

(c) The units, in the casing in which they are deployed for individual use, will be subjected to physical shock according to the following procedure:

(1) The unit will be dropped six times from a height of 1 meter onto a concrete surface; and

(2) Each drop will test a different orientation of the unit, with two drops along each of its three major axes (top to bottom, left to right, and front to back).

(d) The units will be subjected to vibration according to the following procedure:

(1) The unit will be firmly secured to a shaker table, which will be vibrated with motion applied along a single axis for 180 minutes;

(2) The unit will be vibrated one axis at a time along each of three axes for a total of 9 hours; and

(3) The vibration frequency regimen applied to each axis will be cyclical, repeating the sequence and specifications provided in Table 5 every 20 minutes.

TABLE 5—VIBRATION TEST SEQUENCE

Sequence	Frequency (Hertz)	Acceleration g (± peak)
1	5–92	2.5
2	92–500	3.5
3	500–2000	1.5

§ 84.308 Additional testing.

(a) NIOSH will conduct additional tests, as indicated below, on one or more of the units submitted for approval. Each unit tested must meet the conditions specified in these tests for the CCER to receive approval.

(b) NIOSH will perform safety hazard tests on any CCER that stores more than 200 liters of oxygen or that stores compressed oxygen at pressures exceeding 3,000 psi. The applicant must submit 15 units in addition to the 21–23 units required for testing under §§ 84.304 through 84.307. These units will be evaluated for fire and explosion hazards using the tests specified in RI 9333, pages 4–18; RI 8890, pages 6–62; and PRC Report No. 4294, pages 18–62.

(c) NIOSH will perform the following tests on the eye protection (gas-tight goggles or escape hood lens) of one or more units of every CCER submitted for approval:

(1) NIOSH will test the effectiveness of the eye protection against dust using the method specified in ISO 4855–1981(E) Clause 13, Test for protection against dust. The result will be satisfactory if the reflectance after the test is equal to or greater than 80 percent of its value before testing.

(2) NIOSH will test the effectiveness of the eye protection against gas using the method specified in ISO 4855–1981(E), Clause 14, Test for protection against gas. The test must not result in staining of the area enclosed by the eye protection.

(3) NIOSH will test the durability of the eye protection using the method specified in International Standard ISO 4855–1981(E), Sub-clause 3.1, Unmounted oculars. The lens shall not crack or fracture as a result of the test.

(4) NIOSH will test the eye protection's resistance to fogging in accordance with the method specified in BS EN 168:2002, Clause 16, Test for resistance to fogging of oculars. The lens shall remain free from fogging for a minimum of 8 seconds, pursuant to Clause 16.

(d) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR Part 51. All approved material is available for inspection at NIOSH, National Personal Protection Technology Laboratory (NPPTL), Bruceton Research Center, 626 Cochrans Mill Road, Pittsburgh, PA 15236. To arrange for an inspection at NIOSH, call 412–386–6111. Copies are also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) British Standards Institute, 389 Chiswick High Road, London W4 4AL, UK, *http://www.bsigroup.com/en/Standards-and-Publications:*

(i) BS EN 168:2002, Personal Eye Protectors—Non-Optical Test Methods, November 2001.

(ii) [Reserved]

(2) International Organization for Standardization, 1, ch. de la Voie-Creuse, Case postale 56, CH–1211 Geneva 20, Switzerland, *http://www.iso.org/iso/store.htm:*

(i) ISO 4855–1981(E), Personal Eye Protectors—Non-Optical Test Methods, First edition April 1, 1981.

(ii) [Reserved]

(3) U.S. Department of the Interior, Bureau of Mines, 2401 E Street, NW., MS #9800, Washington, DC 20241–0001. These reports are also available from NIOSH upon request 1–800–CDC–INFO (232–4636).

(i) Pittsburgh Research Center (PRC) Report No. 4294, Evaluation of the Safety of One-Hour Chemical Self Rescuers, July 1980;

(ii) Report of Investigations (RI) 8890, Evaluation of the Safety of One-Hour Compressed Oxygen Self-Rescuers—Results of Destructive Testing, 1984;

(iii) RI 9333 Evaluation of the Safety of the CSE SR–100 Self-Contained Self-Rescuer, 1991.

§ 84.309 Additional testing and requirements for dockable CCERs.

(a) NIOSH will conduct additional testing of the CCERs that are designed to allow the user to resupply the oxygen source and the carbon dioxide scrubber while using the respirator during an escape.

(1) NIOSH will test the docking mechanism and procedure to ensure that they maintain the integrity of the breathing circuit (against the intake of hazardous fumes or gases) and the continuity of the breathing gas supply throughout the docking process.

(2) NIOSH will test the docking mechanism and procedure to ensure that users can employ the docking process reliably, safely, and quickly under escape conditions.

(b) NIOSH will designate CCERs that pass the tests specified in this section as ''Dockable.''

(c) NIOSH will assign the capacity rating to the dockable CCER, as specified under § 84.304(d), by conducting the capacity testing using only the breathing gas supply included for the initial use of the wearable apparatus.

(d) NIOSH will test the supplemental capacities of all breathing gas resupply units produced by the manufacturer for use with the dockable CCER. Such tests will follow procedures consistent with those specified under § 84.304, including the rating requirements in § 84.304(d). The manufacturer must label the breathing gas resupply unit to indicate its capacity as tested by NIOSH and its compatibility with the CCER for which it is designed.

(e) NIOSH may require the applicant to provide additional units of the CCER and breathing gas resupply units to conduct the testing specified in this section.

(f) NIOSH will not approve a CCER with docking components, with or without the ''Dockable'' NIOSH designation, unless it satisfies the testing and other requirements of this section.

§ 84.310 Post-approval testing.

(a) NIOSH will periodically test the capacity and performance of units of approved CCERs.

(b) NIOSH may test units that are new and/or units that have been deployed in the field and have remaining service life.

(c) NIOSH will conduct such testing pursuant to the methods specified in §§ 84.303 through 84.305, except as provided under paragraph (d) of this section.

(d) The numbers of units of an approved CCER to be tested under this section may exceed the numbers of units specified for testing in §§ 84.304 and 84.305.

(e) Failure of a unit to meet the capacity and performance requirements of this section may result in revocation of the approval for the CCER or in requirements for specific remedial actions to address the cause or causes of the failure.

(f) NIOSH will replace deployed units obtained for testing with new NIOSH-approved units of the same or similar design, at no cost to the employer.

(g) To maintain the approved status of a CCER, an applicant must make available for purchase by NIOSH, within 3 months of a NIOSH purchase request, the number of units requested by the Institute. Within any 12-month period, NIOSH will not request to purchase more than 100 units for post-approval testing.

§ 84.311 Registration of CCER units upon purchase.

(a) The user instructions will include a copy of procedures for registering the units with NIOSH. The applicant can obtain a copy of these procedures from the NIOSH web page: *http://www.cdc.gov/niosh/npptl.*

(b) The applicant shall notify in writing each purchaser of the purpose of registering a unit with NIOSH, as specified under paragraph (c) of this section. If the purchaser is a distributor of the CCER, the applicant must request in writing that the distributor voluntarily notify in writing each of its purchasers of the purpose of registering a unit with NIOSH, as specified under paragraph (c) of this section.

(c) ''The National Institute for Occupational Safety and Health (NIOSH) requests, but does not require, that purchasers of this respirator register each unit with NIOSH. Registration will enable NIOSH, which approved this model of respirator, to attempt to notify you if a problem is discovered that might affect the safety or performance of this respirator. Registration will also assist NIOSH in locating deployed units to periodically evaluate whether this respirator model is remaining effective under field conditions of storage and use.''

Dated: October 11, 2011.

Kathleen Sebelius,

Secretary.

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