

Financial Officer. In addition to the Annual Report required above, all P-3 and P-4 "Private Sector" programs must file a program specific management audit (in a format approved by the Department of State).

(f) *Program participation.* A numerical count, by category, of all exchange visitors participating in the sponsor's program for the reporting year (active status).

§ 62.16 Employment.

(a) An exchange visitor may receive compensation from the sponsor or the sponsor's appropriate designee for employment when such activities are part of the exchange visitor's program.

(b) An exchange visitor who engages in unauthorized employment shall be deemed to be in violation of his or her program status and is subject to termination as a participant in an exchange visitor program.

(c) The acceptance of employment by an accompanying spouse or dependant of an exchange visitor is governed by Department of Homeland Security regulations. An exchange visitor must report to his or her sponsor the Employment Authorization Document (EAD) number and the validation and expiration dates of the authorized period of employment for any accompanying spouse and each dependant. As required by 62.10(d)(6), sponsors must report accompanying spouse and dependant EAD information in SEVIS.

Dated: December 4, 2008.

Stanley S. Colvin,

Deputy Assistant Secretary, Office of Private Sector Exchange, Bureau of Educational and Cultural Affairs, Department of State.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

RIN 0920-AA10

Approval Tests and Standards for Closed-Circuit Escape Respirators; Notice of Proposed Rulemaking

AGENCY: Centers for Disease Control and Prevention (CDC).

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes updated requirements that the Department of Health and Human Service's (HHS), Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health

(NIOSH) would 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 mines. NIOSH and MSHA jointly review and approve this type of respirator used for mine emergencies under 42 CFR pt. 84, Approval of Respiratory Protective Devices. NIOSH also approves these respirators used in other work environments where escape equipment may be provided to workers, such as vessels operated by U.S. Navy and Coast Guard personnel. The proposed rule would replace only those technical requirements in 42 CFR Part 84—Subpart H that are uniquely applicable to closed-circuit escape respirators (CCERs), a subset of the variety of escape respirators presently covered by Subpart H. All other applicable requirements of 42 CFR Part 84 would remain unchanged. The purpose of these updated requirements is to enable NIOSH and MSHA to more effectively ensure the performance, reliability, and safety of CCERs.

DATES: CDC invites comments on this proposed rule from interested parties. Comments must be received by February 9, 2009.

ADDRESSES: You may submit comments, identified by RIN: 0920-AA10, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* niocindocket@cdc.gov. Include "RIN: 0920-AA10" and "42 CFR pt. 84" in the subject line of the message.

- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking, RIN: 0920-AA10. All comments received will be posted without change at the NIOSH docket Web page: <http://www.cdc.gov/niosh/docket>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document. Background information on this rulemaking is available at the NIOSH Web page: <http://www.cdc.gov/niosh/npptl>.

FOR FURTHER INFORMATION CONTACT: Tim Rehak, NIOSH National Personal Protective Technology Laboratory (NPPTL), Pittsburgh, PA, (412) 386-6866 (this is not a toll-free number). Information requests can also be submitted by e-mail to niocindocket@cdc.gov.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments are invited on any topic related to this proposal.

Comments submitted by e-mail or mail should be titled "Docket #005 Public Comments", addressed to the "NIOSH Docket Officer", and identify the author(s), return address, and a phone number, in case clarification is needed. Comments can be submitted by e-mail to niocindocket@cdc.gov as e-mail text or as a Word or Word Perfect file attachment. Printed comments can be sent to the NIOSH Docket Office at the address above. All communications received on or before the closing date for comments will be fully considered by CDC.

All comments submitted will be available for examination in the rule docket (a publicly available repository of the documents associated with the rulemaking) both before and after the closing date for comments. A complete electronic docket containing all comments submitted will be available after the closing date at <http://www.cdc.gov/niosh/docket>. Comments will also be made available in writing upon request. NIOSH includes all comments received without change in the docket, including any personal information provided.

II. Background

A. Introduction

A closed-circuit escape respirator (CCER) technically defined as a closed-circuit, self-contained breathing apparatus (SCBA) 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 (SCSR), is primarily used by miners to escape dangerous atmospheres in mines. It is also used by certain Navy personnel, such as crews working below decks on vessels, to escape dangerous atmospheres. To a lesser extent, it is also used by other industries involved in working

underground or in confined spaces, such as tunneling operations in the construction industry and in the maritime 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, that employ either compressed oxygen or a chemical source of oxygen, plus a chemical system for removing exhaled carbon dioxide from the breathing circuit. 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. Certification of CCERs

NIOSH certifies CCERs under 42 CFR pt. 84, Approval of Respiratory Protective Devices. NIOSH and MSHA jointly review and approve such respirators for use by miners to escape hazardous atmospheres generated during emergencies in underground coal mines.¹ In those regulations, Subpart H, Self-Contained Breathing Apparatus, specifies testing and certification requirements for these respirators, identified in the regulations as closed-circuit apparatus for "escape only." The subpart 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

Storage of CCERs in harsh environmental conditions, such as extreme heat, cold, and humidity, and the daily wearing of the respirators during physical work and on and around vibration-generating equipment and tools, can result in damage that degrades the respirators' performance, despite their protective cases. NIOSH

field evaluations of certified 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 certified.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 are not governed by current regulations and do not exist in some of the respirators currently available.

Furthermore, current performance testing requirements for CCERs rely on a non-uniform testing regime, which does not control for differences between human subjects involved in the testing. This can produce variation in test results. The proposed improvements would establish a consistent testing regimen for evaluating the life support capability of CCERs.

Finally, the current certification requirements might be contributing to a risk communication and risk management problem. NIOSH is currently required to approve these respirators as providing protection for a specific duration³ 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 and less physically fit 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 certification. While such incidents could have resulted from the respirator

failing to perform as certified, they might also reflect limitations of understanding about the testing criteria regarding duration.

This rulemaking proposes to eliminate the duration-specific approval, replacing it with a capacity rating system based on the quantity of usable oxygen supplied by the model. NIOSH would also assist MSHA and other agencies to foster the use of effective practices by which employers can select the model of certified respirator best suited to the physical sizes of their employees and the particular escape contingencies their employees might encounter. Effective practices would include selecting a maximum capacity model of CCER or empirically testing different models in simulated escapes to determine which models provide an adequate breathing supply and are suitable in terms of other practical concerns.

In addition, over the last several decades, the mining community has encountered various problems with particular CCER designs, some of which could be prevented through additional certification requirements. These issues are identified and addressed in the discussion of the new provisions for testing the safety features and the "wearability" of CCERs.

Persons interested in a detailed examination of issues concerning the current use, limitations of, and opportunities for improving CCERs may wish to review the report of an interagency task force led by the Department of Labor, which included representatives from the mining industry, labor, and respirator manufacturers. The report, entitled "Joint Government, Labor, Industry Task Group on Person Wearable, Self-Contained, Self-Rescuers," is available from the NIOSH Web page: <http://www.cdc.gov/niosh/npptl> or upon request to NIOSH.

D. Scope of the Rulemaking

This rulemaking is intended to apply only to CCERs. It would establish new testing and certification requirements for these respirators, replacing all testing and certification requirements of 42 CFR pt. 84, Subpart H, that are uniquely applicable to closed-circuit SCBAs used only for escape. This rulemaking would not alter the testing and certification requirements applicable to the other types of respirators included under Subpart H.

E. Impact on Rulemaking and Other Activities of MSHA

The proposed rule might require MSHA to promulgate limited, non-

² Kyriazi N, Shubilla JP [2002]. Self-contained self-rescuer field evaluation: seventh-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, DHHS (NIOSH) Publication No. 2002-127, RI 9656.

³ These certifications are defined in four discrete durations ranging from 15 minutes to one hour.

¹ See 42 CFR 84.3.

substantive changes to incorporate the terminology of this rule, *i.e.*, “CCER” versus “SCSR,” and to reflect the new capacity rating system being proposed. As discussed and documented in the summary of the new rating system presented in Section 84.304, the proposed capacity rating of “Cap 3” is equivalent to the “60-minute” duration rating currently certified by NIOSH and referenced as a requirement in MSHA regulations.⁴

In addition, MSHA would modify relevant MSHA training programs to incorporate the use of respirators approved under the proposed new rating system and the proposed phasing-in of these respirators, discussed under § 84.301.

F. Public Meetings for Discussion and Comment

NIOSH held public meetings to discuss technical issues addressed in this proposed rule in Arlington, Virginia on April 10, 2003, and Golden, Colorado, on April 24, 2003. NIOSH held a second set of public meetings at these two locations on September 19th and September 28th of 2006 respectively, to provide the public with an opportunity to address any new perspectives resulting from Sago and other recent mine disasters.⁵ Official transcripts of the meetings are available from the NIOSH Docket Office at the address provided above in the Summary.

NIOSH will convene public meetings to provide stakeholders with an opportunity to provide oral comment on this rulemaking during the comment period. The meetings will be in the vicinities of Washington DC and Denver, CO and are announced in a separate notice in this issue of the **Federal Register**.

III. Summary of Proposed Rule

This proposed rule would establish new requirements for testing and certification of CCERs under a new Subpart O of 42 CFR pt. 84—Approval of Respiratory Protective Devices. The new subpart would replace all current requirements for testing and certification of CCERs found under Subpart H. The following is a section-by-section summary which describes and explains the provisions of the rule. The public is invited to provide comment on any aspect of the proposed

rule. The complete, proposed regulatory text for the proposed rule is provided in the last section of this notice.

Subpart O

Section 84.300

This section provides a general description of CCERs 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 certification program.

Section 84.301

This section would establish a schedule for phasing-in the implementation of the testing and certification requirements of the proposed rule. A phase-in process would allow 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 will also ensure that during the interim, there is a constant supply of CCERs approved under the current regulations. Upon promulgation, the new requirements would be immediately applied to all new CCER designs that are submitted for approval. Manufacturers and distributors could continue to sell CCERs with current approvals for up to three years after promulgation of the new requirements. CCERs with current approvals could remain in use or be available for use as approved devices for up to six years after promulgation of the new requirements. The only exception would be for individual units that exceed their manufacturer-designated service life within this time period.

The phase-in period would also substantially reduce the potential economic costs⁶ to employers of replacing or retrofitting any respirators that remain in use at their worksite, but do not pass the new certification tests. Designations of service life for currently approved CCERs range from 10 to 15 years.⁷ However, 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 less than

designated, due to wear and tear and damaging environmental conditions.⁸

NIOSH is seeking public comment on the proposed phase-in schedule. NIOSH believes this schedule allows sufficient time for the continued use of currently approved devices to ensure a constant, adequate supply while providing substantial incentives to manufacturers for bringing improved technology to market as quickly as possible. The phase-in would also require employers to replace deployed devices, including those with remaining service life, that cannot pass the proposed new requirements within a reasonable transition period. NIOSH expects that newly approved devices would become available soon after the final rule becomes effective since current technology, with relatively minor design improvements, can meet the proposed new requirements. Manufacturers have substantial incentive to bring to market as quickly as possible devices that meet the new requirements since employers are likely to prefer to purchase such devices for their improved performance and to minimize the potential economic costs of the six-year approval limitation in the proposed rule.

NIOSH also seeks public comment on an alternative to the proposed phase-in, which would be to retain the proposed three-year limit on sales of devices approved under the current standard, but eliminate the six-year limit on the approval status of devices purchased after the effective date of the final rule. The argument for this alternative is that employers would be able to use the full service life of devices purchased (which were approved under the current requirements). This would minimize any economic impact of the proposed rule on employers. However, under this alternative, it is conceivable that a substantial number of devices approved under the current requirements could remain deployed in workplaces for as long as 13 to 18 years following the effective date of the final standard, given the current service life range of 10 to 15 years.

NIOSH invites public comment on reasons that it might be unlikely that large numbers of older devices would in fact remain deployed for such an extensive period, particularly in mining. For example, one reason may be that the deployment conditions in mining are

⁸ 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 NIOSH internal reports, and actionable findings provide the basis for remedies addressed by NIOSH and the applicant.

⁴ See 30 CFR 75.1714(a).

⁵ Notice of these meetings was published in the **Federal Register** on March 20, 2003 (68 FR 13712) and August 31, 2006 (71 FR 51829). NIOSH also sent a letter announcing the meeting to known stakeholders and posted it on the NIOSH Web page: <http://www.cdc.gov/niosh/nppt1>.

⁶ See Section IV.A of this preamble for a discussion of these potential economic costs.

⁷ 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.

especially damaging, as discussed above, making it unlikely that a unit would remain deployed for 13 to 18 years. Second, it is in the interest of employers to provide their employees with the best available protective equipment; this is especially important in the mining industry, where concerns about the performance of CCERs are particularly salient. Finally, MSHA and OSHA have authority to require employers to provide employees with devices approved under the proposed new requirements, should the agencies determine such a regulatory measure were necessary to assure safe and healthful working conditions. NIOSH believes that none of these reasons provide assurance of a rapid replacement of devices that are not approved under the proposed new requirements. NIOSH lacks adequate information to predict how quickly devices that cannot pass the proposed new requirements would be fully replaced.

Another alternative is establishment of a time-limit different from the proposed six years for the continued use of the CCERs certified under the current requirements. NIOSH seeks public comment on whether to establish a different balance between providing the best possible protective equipment to employees and controlling the potential economic impact on employers of replacing deployed equipment, recognizing that in any case manufacturers will require time to develop and bring new products to market. NIOSH judges that six years represents a reasonable balance between public health and economic concerns, allowing more than half of the service life⁹ of devices purchased up to the effective date of the final rule to pass before requiring their replacement (even if they're still operational).

NIOSH also invites comment on an alternative to the proposed phase-in that would allow a specific exception for the Department of Defense (DoD). Under this alternative, for all uses other than for the DoD, the proposed three year limit on sales of devices approved under the current standard would be retained, and would also set the six-year limit on the approval status of devices after the effective date of the final rule. However, this alternative would permit the DoD to use the full service life of devices, which were approved under the current requirements, based on the DoD deployment plan where CCERs are retained in conditions of storage.

NIOSH also seeks public comment specifying and characterizing the

particular burden (financial or otherwise), if any, that would be imposed on specific affected parties by the proposed phase-in periods; whether there is an unsupportable or serious burden that would be imposed on any affected parties; and whether there are other interests that NIOSH should consider in deciding this matter.

In seeking public input on the concepts underlying the proposed rule, NIOSH received comments from two respirator manufacturers and a representative of the Navy opposing the six-year limit on the deployment of devices approved under the current requirements. The commenters objected to the imposition of costs that would be incurred by employers who would have to replace deployed devices with remaining service life at the end of the six-year limit. No comment was received objecting to the three-year limit for the sale of devices approved under the current requirements.

Section 84.302

This section specifies the components, attributes, and instructions that would be required to be included with 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 (b)).

Paragraph (a)(2) would require the manufacturer to 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) would require the manufacturer to 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.¹⁰ 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 pt. 107: "Hazardous Materials Program Procedures," unless exempted under Subpart B of the DOT regulation.

Paragraph (a)(5) would require the manufacturer to 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.¹¹

Paragraph (a)(6) would require the manufacturer to include a means to detect the ingress of any water or water vapor that could degrade the performance of the unit, unless the CCER were designed for its casing to be opened for frequent inspection. Because the chemical 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 (c) would require manufacturers to 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 available from the NIOSH Web page <http://www.cdc.gov/niosh/npptl>. The test will be conducted on a single CCER unit.

¹⁰ Same as footnote 2.

¹¹ 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, DHHS (NIOSH) Publication No. 2000-128, RI 9451.

⁹ See note 7.

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 would not be new. It is included under Subpart H of this part (§ 84.85) for all SCBAs currently approved by NIOSH.

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

Paragraph (f) would require manufacturers to provide users with instructions and a service life plan to accompany each unit. These requirements generally reflect current practice. It is important that users receive comprehensive guidance concerning the use and service life of CCERs.

Section 84.303

This section would establish the general testing conditions and requirements for the certification of CCERs.

Paragraph (a) specifies that NIOSH would use the breathing and metabolic

simulator tests specified in this subpart for all quantitative evaluations of the performance of a CCER. NIOSH would 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.¹² 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.¹³ These studies, which include side-by-side comparisons of respirator testing using three-person panels of human subjects on treadmills against testing using a breathing and metabolic simulator, 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. The advantage of the simulators, as discussed in II.C. of the preamble, is that their performance for all metabolic parameters can be calibrated and replicated, whereas each human test subject performs uniquely, making the testing less repeatable.

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 page: <http://www.cdc.gov/niosh/npptl>.

Paragraph (b) specifies that four stressors would 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 sensed by the CCER user’s trachea). Paragraph (d) establishes that CCERs must perform within the acceptable ranges of measurement specified in the table below.

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	DP ≤ 200 mm H ₂ O	· 300 ≤ DP ≤ 200 mm H ₂ O.
Wet-bulb temperature ¹⁴	<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.¹⁵ Decision-making was slightly impaired in some subjects after breathing 4 percent carbon dioxide

for one 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 would require the CCER to maintain the inhaled levels of carbon dioxide below 4 percent (as a one-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% for inhaled oxygen that NIOSH would require 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

¹² Kyriazi N (1986). Development of an automated breathing and metabolic simulator. Pittsburgh, PA: U.S. Department of the Interior, Bureau of Mines, IC 9110.

¹³ Kyriazi N, Kovac JG, Shubilla JP, Duerr WH, Kravitz J [1986]. Self-Contained Self-Rescuer Field Evaluation: First-Year Results of 5-year Study. Pittsburgh, PA: U.S. Department of the Interior, Bureau of Mines, RI 9051.

Kyriazi N, Shubilla JP [1992]. Self-Contained Self-Rescuer Field Evaluation: Results from 1982–1990. Pittsburgh, PA: U.S. Department of the Interior, Bureau of Mines, RI 9401.

Kyriazi N, Shubilla JP [1994]. Self-Contained Self-Rescuer Field Evaluation: Fourth-Phase Results.

Pittsburgh, PA: U.S. Department of the Interior, Bureau of Mines, RI 9499.

Kyriazi N, Shubilla JP [1996]. Self-Contained Self-Rescuer Field Evaluation: Fifth-Phase Results. Pittsburgh, PA: U.S. Department of Energy, RI 9635.

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, DHHS (NIOSH) Publication No. 2000–128, IC 9451.

Kyriazi N, Shubilla JP [2002]. Self-Contained Self-Rescuer Field Evaluation: Seventh-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, DHHS (NIOSH) Publication No. 2002–127, IC 9656.

¹⁴ 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.

¹⁵ Kamon E, Deno S, Verduyven M [1984a]. 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, p. 13.

level of oxygen for protecting the health and safety of workers. However, the technology used in CCERs requires NIOSH to permit brief excursions on the oxygen supply to above 15% for up to one minute. 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.¹⁶ Therefore, NIOSH would require the CCER to provide levels of oxygen above 15 percent (as a one-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-bulb¹⁷ temperature are based on physiological research at Pennsylvania State University. Researchers found the highest tolerable wet-bulb temperature of inhaled air was approximately 50 °C.¹⁸ Based on such research and NIOSH findings from testing escape respirators, NIOSH proposes 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 one-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 millimeters of H₂O for only a short period of time.¹⁹

¹⁶ Fowler, B., Paul, M., Porlier, G., Elcombe, D.D., Taylor, M. 1985. A reevaluation of the minimum altitude at which hypoxic performance decrements can be detected. *Ergonomics*, 28(5): 781-791.

¹⁷ 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 et al., 1984b).

¹⁸ Kamon E, Deno S, Vercruyven M [1984b]. 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, p. 117, 119.

¹⁹ Hodgson JL [1993]. Physiological costs and consequences of mine escape and rescue. University Park, PA: The Pennsylvania State

University. U.S. Bureau of Mines contract No. J0345327, p. 19.

Based on NIOSH findings from testing escape respirators, the 200 millimeter 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 would provide 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 relinquish 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 would 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 would threaten the successful use of the CCER for an escape.

Section 84.304

This section specifies the testing regime that would 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 would ensure the CCER provides the certified quantity as a constantly adequate supply of breathing gas, in terms of the stressors addressed in Section 84.303 of this Part. The capacity would be evaluated in terms of 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 physically or chemically 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 one hundred and ninety 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.²⁰

A three capacity ratings system would be established: "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 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.

The Cap 3 rating is equivalent to the current NIOSH-certified 60-minute rating for CCERs. 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 4.²¹ 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. It would help prevent misunderstandings that could lead employers to select a CCER model that is inadequate for a particular set of escape contingencies and that could mislead an employee regarding the amount of breathing supply remaining during an escape. Using the hypothetical example of the one hundred and ninety pound man in the previous paragraph, 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

²⁰ Kamon E, Bernard T, Stein R [1975]. Steady state respiratory responses to tasks used in Federal testing of self-contained breathing apparatus. *AIHA J* 36:886–896.

²¹ See 42 CFR 84.100, Table 4 for the specific requirements of Man test 4.

durations achieved by users in actual or simulated escapes.

CAPACITY VERSUS WORK ACTIVITY

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

NIOSH is seeking information on the capacity versus work activity information provided in the table to determine if the provided information is useful to users for developing escape respirator deployment plans. NIOSH is also seeking opinions on whether a table, such as described above, should be required to be provided by the CCER manufacturer in the CCER user instructions.

In addition to having a capacity rating system to categorize products, manufacturers would be able to use the actual tested capacity of approved respirator models, which NIOSH would report to the manufacturer in increments of 5 liters, to specify more precisely the capacity of each product. This would 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 would evaluate seven CCER units using the breathing and metabolic simulator. Three would be tested in the condition received from the applicant (i.e., "new" condition), two would receive environmental treatments prior to capacity testing, and the remaining two units would be tested at the cold-temperature limit specified by the manufacturer, after being stored at the specified temperature.

Each unit would be tested at the work rate identified in the table 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.²² As the table 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. To further evaluate these proposed test parameters, NIOSH invites the public to submit comparable data on physiological

monitoring of worker populations at varied levels and durations of exertion.

In December 2006, NIOSH received comments from a respirator manufacturer regarding the use of different work rates to test CCERs of different capacities. The manufacturer recommended that NIOSH apply the same work rate irrespective of the capacity of the device being evaluated.

The Navy, which is the principal consumer of low capacity CCERs, has specifically requested that NIOSH test at a high work rate the CCERs used by Navy personnel. This is consistent with the premise that 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 has specified such an approach in this proposed rule. NIOSH welcomes further comment and information regarding this matter.

One of the units submitted would 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.

CAPACITY TEST REQUIREMENTS

Capacity rating	Capacity (L of O ₂)	VO ₂ (L/min)	VCO ₂ (L/min)	V _e (L/min)	RF
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

VO₂ = volume of oxygen consumed/min; VCO₂ = volume of carbon dioxide produced/min.
V_e = 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 approved for use in coal mines under the Cap 3 rating, NIOSH would also continue to

conduct the one-hour Man test 4 discussed above, as required under the current 42 CFR Part 84 regulations. Although the proposed capacity system and tests using the breathing and

metabolic simulator represent a substantial improvement over the existing Man test 4, the Federal Mine Safety and Health Act requires that "no mandatory health or safety standard

²² Kamon E, Bernard T, Stein R [1975]. Steady state respiratory responses to tasks used in Federal

testing of self-contained breathing apparatus. AIHA J 36:886-896.

* * * shall reduce the protection afforded miners by an existing mandatory health or safety standard.” 30 U.S.C. 811(a)(9). Since NIOSH would no longer approve CCERs as one-hour devices under this proposed rule, NIOSH must be able to demonstrate that the use of the Cap 3 rating and associated tests to approve equipment for use in underground mines would not constitute a reduction in protection or a reduction in the duration of breathing supply regulated under the current MSHA one-hour requirement for SCSRs. NIOSH believes that the continued use of the Man test 4, as a supplement to the proposed new testing requirements and capacity rating system, would be the most practical method of accomplishing such a demonstration. NIOSH invites public comments on this or any alternative approaches that might effectively address this legal requirement.

In addition, NIOSH invites public comment on the oxygen consumption rate associated with breathing and metabolic simulator testing for the Cap 3 rating. As discussed above, the oxygen consumption rate associated with this rating would be the average rate demonstrated through NIOSH testing of the 50th percentile miner by weight (191 pounds) performing the 1-hour Man test 4. NIOSH could require a more stringent testing parameter, such as the oxygen consumption rate associated with the 95th percentile miner by weight (220 pounds). The effect of a more stringent standard would be to increase the minimum quantity of adequate breathing gas supplied under a Cap 3 rating. This increased minimum supply would be accompanied, however, by a commensurate increase in the minimum sizes of CCERs that could be designed under the Cap 3 rating. This

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

Section 84.305

This section specifies the performance testing regimen that would 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 would 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) 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.

In December 2006, NIOSH received comments from a respirator manufacturer recommending that NIOSH test devices in compliance with the manufacturer’s user instructions. This recommendation would mean that NIOSH would not evaluate the potential for hypoxia when testing a CCER that uses compressed rather than chemical oxygen, since users are not instructed to exhale into such respirators upon donning them.

NIOSH performance testing assumes that some CCER users will not comply with manufacturer’s instructions. 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. 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 has proposed a generic performance testing protocol, irrespective of CCER design, that includes the hypoxia testing procedure. NIOSH welcomes further comments and information from the public concerning this matter.

The performance testing would evaluate five CCER units using the breathing and metabolic simulator. Of these, three units would be tested in new condition, and two would receive environmental treatments prior to performance testing. The testing regimen would 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 the table below.

PERFORMANCE TEST REQUIREMENTS

Work-rate test sequence	Duration per cycle (min.)	VbO ₂ (L/min)	VCO ₂ (L/min)	V _e (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

VO₂ = volume of oxygen consumed/min; VCO₂ = volume of carbon dioxide produced/min. V_e = 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.²³

²³ “Evaluation of Proposed Methods to Update Human Testing of SCBA,” Turner, Beeckman, and Hodous, AIHA Journal, Volume 56, December 1995, pp 1195–1200. “Cardiorespiratory strain in jobs that require respiratory protection,” Louhevaara, V., T. Tuomi, J. Smolander, O. Korhonen, et al., Int. Arch.

The test would be started by the exhalation of two large breaths into the unit before donning it. This would

Occup. Environ. Health. 55:195–206, 1985. “The human energy cost of fire fighting,” Lemon, P.W. and T.T. Hermiston, J. Occup. Med. 19:558–562, 1977.

determine the susceptibility of the CCER to hypoxia.

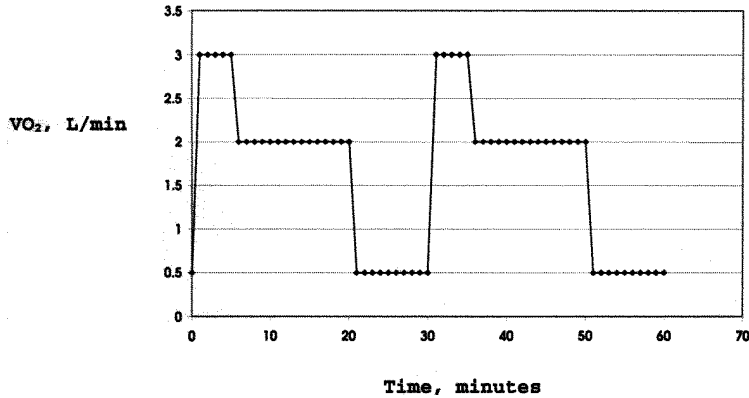
Since the testing cycle requires 50 liters of oxygen, CCERs that have less than a 50 liter capacity would exhaust their capacity prior to completing a full cycle as specified. To accommodate this limitation, if a unit contains less than 50 liters of useable oxygen (as determined by the capacity test 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 would repeat the cycle until the oxygen supply is

exhausted, as indicated in the graph below.

One unit would 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



Section 84.306

This section specifies the testing regimen that would 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 would not physically harm or significantly hinder the user and would provide an adequate and uninterrupted supply of breathing gas. Testing would be conducted using three human subjects of differing heights and weights,²⁴ as specified, to provide reasonable assurance that the results would be representative of most potential CCER users.

Subsection (b) would require 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,²⁵ is reasonably protective in the case of emergency scenarios involving an explosion or sudden detection of a hazardous breathing environment. This subsection would allow 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 would 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 would 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.

WEARABILITY TEST REQUIREMENTS

Activity	Minimum duration
Sitting	1 min.
Stooped walking	1 min.
Crawling	1 min.
Lying on left side	1 min.
Lying on right side	1 min.
Lying on back	1 min.
Bending over to touch toes	1 min.
Turning head from side to side	1 min. (at least 10 times).
Nodding head up and down	1 min. (at least 10 times).
Climbing steps or a laddermill	1 min. (1 step/sec).

²⁴The size range is intended to be representative of respirator users. See: Zhuang Z and Bradtmiller B [2005]. Head-and-face anthropometric survey of

U.S. respirator users. Journal of Occupational and Environmental Hygiene 2: 567-576.

²⁵Vaught C, Brnich MJ, and Kellner HJ (1988). 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, RI 9208.

WEARABILITY TEST REQUIREMENTS—Continued

Activity	Minimum duration
Carrying 50-lb bag on treadmill at 5 kph	1 min.
Lifting 20-lb weight from floor to an upright position	1 min. (at least 10 times).
Running on treadmill at 10 kph	1 min.

Section 84.307

This section specifies the environmental treatments that would 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 the temperature associated with storage in the trunks of vehicles. The shock test specified in subsection (c), which is a series of one 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. The vibration test specified in subsection (d) is a composite test based on the reported vibration levels measured on the frames of underground longwall and continuous mining machines and on underground and surface haulage vehicles.²⁶

Section 84.308

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

Under subsection (b), NIOSH would 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 one-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 would 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. The tests proposed for dust and gas were established by the International Organization for Standardization (ISO), a globally recognized consensus standard setting organization.²⁷ The test for fogging was established by the European Committee for Standardization (CEN), a consensus standard-setting organization within the European Union.²⁸ NIOSH has also proposed an ISO test for the robustness of the construction of the eye protection.²⁹ These specified tests, which are widely accepted by the safety and manufacturing communities, would be incorporated by reference into this rule.

NIOSH received comments from one respirator manufacturer indicating that these standards for the safety and durability of eye protection might not be appropriate for eye protection included with CCERs.

It is reasonable to question whether eye protection that is stored within the protective cover of a CCER and used only during a one-time escape requires the same durability as eye protection worn daily. At this time, NIOSH lacks other alternative standards, but considers it important that eye protection provided with a CCER be able to endure the rough handling of CCERs in mines and be adequate for various escape scenarios. This would include all of the potentially degrading conditions addressed by the consensus standards that NIOSH has proposed to include by reference. NIOSH welcomes public comments and information concerning this matter.

Section 84.309

This section would 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 2006.³⁰

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

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

Paragraph (c) provides that NIOSH would 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 would not be taken into account in rating the capacity of the CCER.

Paragraph (d) provides that NIOSH would 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 would also provide for appropriate labeling to specify the capacity of the resupply unit and its compatibility with the CCER.

Paragraph (e) provides that NIOSH would 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.

²⁶ Dayton T. Brown, Inc. Environmental Test Criteria for the Acceptability of Mine Instrumentation. USBM contract J0100040, Phase 1, Final Report DTB2GR80-0643, June 1980, 131 pp., Table 2, p. 72.

²⁷ See clauses 13 and 14 of ISO 4855, (1981-04-01). 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/store.htm>.

²⁸ See European Standard EN 168:2002, (28 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://www.bsigroup.com/en/Standards-and-Publications>.

²⁹ Sub-clause 3.1 of ISO 4885, (1981-04-01). Copies are available from NIOSH. 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/store.htm>.

³⁰ "The Sago Mine Disaster: A preliminary report to Governor Joe Manchin III", McAteer, J. Davitt et al., July 2006, p. 14, Buckhannon, West Virginia, <http://www.wv.gov.org>.

Paragraph (f) provides that NIOSH would 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 certified by NIOSH as dockable.

Section 84.310

This section would provide for NIOSH to conduct periodic testing of deployed units of approved CCERs. The purpose of such post-certification 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 would obtain such units from employers in exchange for new units, substituted at no cost to the employer. NIOSH would 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-certification testing program. 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 would request remedial actions by the applicant. NIOSH would 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 would work with the relevant regulatory agencies and industry and labor organizations to notify users of the revocation.

A program of post-certification testing is important for assuring users of the effectiveness of their equipment. Simulations of environmental conditions conducted in a laboratory during the certification 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-certification testing also can serve to identify potential problems of quality control in the manufacturing process.

For such testing to occur, NIOSH must be able to purchase a sufficient number of units of a CCER to replace deployed units selected for testing. 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. The regulatory

requirements of this section would ensure the feasibility of a post-certification testing program and would establish specific legal authorities and obligations in connection with the results of such testing.

Section 84.311

This section would require manufacturers to provide each purchaser of a CCER unit with copies of procedures for registering purchased units with NIOSH. NIOSH would also work with relevant agencies and industry and labor associations to publicize the registration program. It would be 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 would 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.

Subpart G

Sections 84.60, 84.63–84.65

These sections of Subpart G, which provide general construction and performance requirements for respirators certified under 42 CFR pt. 84, are presently limited to covering respirator types specified under Subparts H through L. Since this rule would remove CCERs provisions from under Subpart H and would place them under a newly created Subpart O, Subpart G needs to be 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. NIOSH would extend 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 certified. This change will also provide coverage under Subpart G for respirator types that might be distinguished under newly created sections in the future.

Subpart H

Section 84.70

This section would exclude CCERs from coverage under any provisions of Subpart H. The provisions of Subpart H concerning respirators used for escape from hazardous environments would be applicable solely to those with an open-circuit design.

IV. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether a regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the executive order. Under Section 3(f), E.O. 12866 defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

This proposed rule is being treated as a "significant regulatory action" within the meaning of E.O. 12866. In particular, the proposed rule would limit the applicability of current MSHA requirements under 30 CFR 75.1714–1 that mine operators provide miners in underground coal mines with CCERs (referred to in the mining community as "SCSRs") 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 canisters; 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."

The proposal would eliminate the practice by NIOSH and MSHA of approving CCERs on the basis of the duration of breathing supply provided

by the CCER. Hence, paragraphs (a) and (b) of the MSHA regulation would no longer have effect.

As discussed above, categorization of a CCER's capacity according to the duration of its breathing gas supply during testing can be misleading to purchasers and users because testing results may not reflect actual performance for varied users under actual escape conditions. The most reliable practice to ensure that miners are adequately provisioned for escapes would be to empirically test "worst-case" escape scenarios for a particular mine site using respirators likely to have sufficient capacity and then to make selections accordingly. The MSHA rule would have to be modified to either replace the current duration denominations with capacity ratings pursuant to the rating system in this proposed rule or require mine operators to conduct empirical tests to select appropriate CCERs.

The proposed rule is not considered economically significant, as defined in § 3(f)(1) of the E.O. 12866. Respirator manufacturers will probably have to modify existing CCER designs to meet the proposed new capacity and performance testing requirements. However, these changes are not expected to require manufacturers to use fundamentally different or substantially more costly technology. Benchmark testing of currently approved technology using the capacity and performance requirements of the proposed rule shows that at least one current CCER product is likely to pass these new tests without any change in design. Similarly, NIOSH does not expect the proposed 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 would have to engage in new manufacturing processes (to meet the requirements under this proposed rule) that would substantially increase manufacturing costs or product prices.

Moreover, the scope of the market for CCERs is presently very limited. According to data from the Bureau of Labor Statistics, in 2003 there were fewer than 45,000 U.S. miners and other workers in underground extractive occupations (such as mining machine operators; excavating machine operators; and loaders, roof bolters, and their helpers) who might use CCERs. According to MSHA, there are

approximately 37,000 underground coal miners, the principal users of CCERs in the private sector. The service life of current CCER models ranges from 10 to 15 years, although some units may be damaged or used for an escape or escape simulation and used sooner. Assuming that each CCER unit is replaced, on average, every ten years and taking into account that approximately 203,000 units will be deployed under the current MSHA emergency standard,³¹ the mining industry would purchase an average of 20,300 units annually. Since the average cost of CCERs is \$665³² and is not expected to increase substantially as a result of the proposed rule, these data suggest that this principal component of the current CCER market represents less than \$14.0 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 and anticipated average annual purchases of approximately \$20 million.³³

Mine operators and other employers would be most significantly impacted by the one-time costs associated with potentially having to replace CCERs approved under the existing standard with CCERs approved under the final rule, upon promulgation and expiration of the phase-in period. As proposed, these purchasers would have to replace any currently deployed CCERs that are not re-approved under the proposed rule within six years after the final rule is promulgated. Assuming that 40 percent, or 81,200 units, would have to be replaced by mine operators prior to the end of their service life³⁴ at the

³¹ MSHA estimates there were approximately 45,000 CCERs deployed for coal mining prior to the MSHA emergency temporary standard for emergency mine evacuation, one unit for each underground miner or mine contractor, and MSHA estimates an additional 168,000 units would be deployed in compliance with the Final Emergency Mine Evacuation standard.

³² *MSHA Regulatory Economic Analysis, Emergency Mine Evacuation, Final Rule, December 2006* (RIN: 1219-AB46), p. 57.

³³ Estimated from information provided by the Naval Surface Warfare Center, Panama City, Florida, December 20, 2004.

³⁴ This assumption is conservative. It supposes that CCERs deployed in mines would last for a service life of 10 years. It is the experience of NIOSH researchers that CCERs do not typically remain in approved condition this long, due to the harsh physical conditions to which they are subjected in and outside of the mine while donned, worn, stored, and transported on mine vehicles. It also assumes that mine operators will purchase newly approved devices once the NIOSH final rule is promulgated and becomes effective, despite the three year grandfather period during which respirator manufacturers could continue to sell devices that would not be approved under the final rule.

assumed 10 percent annual replacement rate,³⁵ the proposed rule would cost all mine operators combined a maximum of \$8 million. This estimate represents the present value of the remaining service life of deployed units that would have to be replaced at the end of the six-year grandfather period. The replacement cost for the Navy would be approximately \$12 million in terms of the present value of deployed units that would have to be replaced.³⁶

The cost of replacing deployed units whose service life has not expired would be incurred only once since this rule includes no provisions that would force respirator manufacturers to design CCERs with shorter service lives than are achieved by currently certified models of these respirators.

The new requirements would likely produce economic benefits. First, they would provide more product performance information to purchasers, which would serve to produce a more efficient market. Respirators would 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 would allow purchasers to match respirators more closely to their particular needs. As a result, the new requirements would provide an incentive for manufacturers to innovate and possibly produce more diverse products. Having specific NIOSH-certified capacity levels would 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.

Second, the new requirements for safety features (which provide for the detection of units that have undergone

³⁵ MSHA estimates that approximately 45,000 CCERs were deployed in mines prior to promulgation of the MSHA final standard and that approximately 168,000 units will be deployed as a result of the final standard. The 81,200 units would have an average of 2.5 years of remaining service life at the end of the 6-year grandfather period, if NIOSH promulgates a final rule in 2008. The present value of the remaining service life years of deployed units was calculated by using a 7 percent discount rate and an average cost of a CCER of \$665.

³⁶ The Navy has approximately 400,000 units in service and is replacing them at a rate of approximately 40,000 per year and a cost of approximately \$500 per unit. This means 160,000 units would have to be replaced at the end of the 6-year grandfather period, being replaced an average of 2.5 years prior to their planned replacement.

excessive environmental stresses or mishandling) has potential for increasing the ability of purchasers, users, inspectors, and others to contribute to assuring the reliability of deployed CCER units.

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 would derive from the improvements in this rule, costs associated with death and disability could be avoided. In addition, costs associated with rescue operations could be averted if workers escape independently.

The proposed rule would not interfere with State, local, and 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 proposed rule would not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

The proposed rule establishes new testing and certification requirements for the particular type of respirator, the CCER, used by workers in mines and other settings to escape hazardous atmospheres. MSHA and Occupational Safety and Health Administration (OSHA) regulations require that when employers provide respirators to their employees, the respirators must be NIOSH/MSHA-certified or NIOSH-certified respirators. Hence, the proposed rule would impose new requirements on the manufacturers of CCERs, who may have to design new products and make related changes to their manufacturing process for such products. However, such new designs would not require substantial technological innovation and any additional costs incurred by the manufacturers would be passed on to consumers since there is essentially no demand elasticity for these products, which are required by Federal safety and health regulations.

Furthermore, CCERs are presently manufactured by only two U.S. companies: CSE Corporation of Monroeville, Pennsylvania, and Ocenco Incorporated of Pleasant Prairie, Wisconsin. While these manufacturing companies are small businesses as defined under the Small Business Act (Pub. L. 85-536) for this industry sector (NAICS 339112—Surgical and Medical Instrument Manufacturers), employing fewer than 500 employees, HHS proposes that two companies do not represent a substantial number of entities under the RFA.

The proposed rule will have an economic impact on the operators of the 580 underground coal mines in the United States in 2003³⁷, the majority of which are defined as small businesses by the Small Business Administration. Underground coal mine operators are required to supply each underground coal miner with NIOSH/MSHA-certified CCERs. These mine operators might have to replace some of their stock of CCERs that have remaining service life if the CCERs have not been re-approved by NIOSH under the new requirements of the final rule. This economic impact would not be significant, however. The present value of respirators that might have to be replaced as a result of this rule would not exceed \$8 million, as discussed above. This represents less than 0.1 percent of the estimated annual revenues for underground coal mine operators.³⁸

In addition to costs for replacing any respirators with remaining service life that are not re-approved by NIOSH, any change in the cost of respirators would also be borne by mine operators.

Although NIOSH is not able to forecast whether the prices of CCERs would indeed be affected by the new certification testing requirements, it is unlikely that any increase in costs would prove substantial. Respirator manufacturers would probably have 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

new manufacturing processes that would substantially increase product prices.

Moreover, even if product prices were to increase substantially, it would not produce a substantial economic impact on mine operators. Currently, the average price of a CCER is \$665.³⁹ Assuming that each unit requires replacement every 10 years and that the prices of CCERs were to increase by 50 percent as a result of this rule, the annualized additional costs of \$26 per underground coal miner⁴⁰ would not be significant in the context of the total per capita labor costs of underground coal mine operators.⁴¹

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

C. What Are the Paperwork and Other Information Collection Requirements (Subject to the Paperwork Reduction Act) Imposed Under This Rule?

The Paperwork Reduction Act is applicable to the data collection aspects of this rule. Under the Paperwork Reduction Act of 1995, a Federal agency shall not conduct or sponsor a collection of information from ten 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.

OMB has approved NIOSH's collection of information from applicants under this rule (OMB Control # 0920-109, "Respiratory Protective Devices," which covers all information collection under 42 CFR pt. 84). The information NIOSH would collect pursuant to this rulemaking does not differ substantially from the information presently collected by NIOSH from applicants who presently hold NIOSH approvals of their CCER products. Furthermore, NIOSH is aware of only three manufacturers (two that are U.S. companies) intending to continue manufacturing CCERs.

³⁹ MSHA Regulatory Economic Analysis, *Emergency Mine Evacuation, Final Rule, December 2006* (RIN: 1219-AB46), p. 57.

⁴⁰ \$665/unit × 0.5 cost increase × 203,000 units × 0.1 annual replacement rate × 0.1424 annualization factor ÷ 37,000 underground miners = annual costs per underground miner.

⁴¹ According to the National Mining Association, coal miners have average annual earnings of \$50,000. *Profile of the U.S. Coal Miner 2003*; http://www.nma.org/pdf/c_profile.pdf; updated October 2004.

³⁷ Table 2: Coal Production and Number of Mines by State, County, and Mine Type, 2003. Annual Coal Report 2003. Energy Information Administration.

³⁸ MSHA estimates revenues of underground coal mine operators at \$9,488,466,936. See Can this be put in quotes? Previous footnote documents are not underlined. *MSHA Regulatory Economic Analysis, Emergency Mine Evacuation, Final Rule, December 2006* (RIN: 1219-AB46), p. 106.

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 would 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 proposed 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 proposed 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 would apply uniformly to all applications from manufacturers of CCERs. This proposed rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

HHS has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The proposed 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 proposed rule on children. HHS has determined that the proposed rule would 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 proposed rule on energy supply, distribution, or use because it applies to the underground mining sector. The proposed rule would not result in any yearly costs to mines and could result in one-time costs of \$8 million associated with the replacement of deployed CCERs that do not pass the tests in this proposed rule and have not reached the end of their service life. Relative to the annual revenues of the underground coal mining industry, which were \$11.1 billion in 2004, these one time costs are not "likely to have a significant adverse effect on the supply, distribution, or use of energy" and hence this proposed 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.

List of Subjects in 42 CFR Part 84

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

Text of the Rule

For the reasons discussed in the preamble, the Department of Health and Human Services proposes to amend 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".

§ 84.64 [Amended]

4. Amend § 84.64(b) to remove the phrase "in Subparts H through L" and add in its place the phrase "in Subparts H through KK".

§ 84.65 [Amended]

5. Amend § 84.65(a) to remove the phrase "in Subparts H through L" and add in its place the phrase "in 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 from hazardous atmospheres. Such respirators are covered under the provisions of Subpart O—Closed-Circuit Escape Respirators.

* * * * *

7. Amend Part 84 to add Subpart O 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-certification testing.

84.311 Registration of CCER units upon purchase.

Subpart O—Closed-Circuit Escape Respirators

§ 84.300 Closed-circuit escape respirator; description.

A closed-circuit escape respirator (CCER), technically a subset of self-contained breathing apparatuses (SCBA) 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-rescuer (SCSR)s, CCERs are relied upon by miners to escape dangerous atmospheres in underground coal mines after a mine fire or explosion. CCERs are commonly worn on workers' belts or stored in close proximity to be

accessible in an emergency. They are relatively small respirators that employ either compressed oxygen or a chemical source of oxygen, plus a chemical system for removing exhaled carbon dioxide from the user's recirculated air. 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.

(a) This subpart applies to the following CCERs:

(1) All CCERs submitted to NIOSH for a certificate of approval after [DATE RULE BECOMES EFFECTIVE]; and

(2) All CCERs sold after [DATE 3 YEARS AFTER DATE RULE BECOMES EFFECTIVE].

(b) After [DATE 6 YEARS AFTER DATE RULE BECOMES EFFECTIVE], NIOSH certificates of approval are rescinded, without further action or notification by NIOSH, for all CCERs certified by NIOSH prior to [DATE RULE BECOMES EFFECTIVE].

§ 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) of this subpart;

(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:* 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.

(b) The components of each CCER must meet the general construction requirements specified in Subpart G, § 84.61.

(c) 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 page at <http://www.cdc.gov/niosh/npptl/resources/certpgmspt/default.html>, 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.

(d) 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.

(e) 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.

(f) Each new CCER unit must be accompanied by instructions and a service life plan. These documents 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 of this subpart.

(2) The service life plan must completely address 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 certified by NIOSH, due to reasonably foreseeable degradation of materials used in its construction;

(ii) Any other conditions, other than that specified under paragraph (f)(2)(i) of this section, that should govern the removal from service of the CCER; 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.

§ 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 page at <http://www.cdc.gov/niosh/npptl/resources/certpgmspt/default.html>.

(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 one-minute averages. The operating averages of each stressor will be calculated upon the completion of each test as the average of the one-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 one-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	DP ≤ 200 mm H ₂ O	· 300 ≤ DP ≤ 200 mm H ₂ O.
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 one-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 23C ± 3C; 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 eight to ten 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(f)(1)(F) of this subpart, 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 under a Cap 3 rating for use in coal mines, two units will also be tested by a human subject under the specifications of §§ 84.99 and 84.100 of this part that are applicable to a one-hour 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 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 ≤ 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

VO₂ = volume of oxygen consumed/min; VCO₂ = volume of carbon dioxide produced/min.
 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 of this subpart; 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 to determine the design's susceptibility to hypoxia.

TABLE 3—PERFORMANCE TEST REQUIREMENTS

Work-rate test sequence	Duration per cycle (min)	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

VO₂ = volume of oxygen consumed/min; VCO₂ = volume of carbon dioxide produced/min.
 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 (2) males and one (1) 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 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) of this subpart, 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 the user during reasonably anticipated conditions and activities of an escape.

TABLE 4—WEARABILITY TEST REQUIREMENTS

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

§ 84.307 Environmental treatments.

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

(b) The units will be stored for sixteen hours at a temperature of · 45 °C and for forty-eight hours at a temperature of 71 °C. 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 will be subjected to physical shock according to the following procedure:

- (1) The unit will be dropped six times from a height of one meter onto a concrete surface; and
- (2) Each drop will test a different orientation of the unit, with two drops along each major axis.

(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 nine hours; and

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

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.

§ 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 §§ 84.304–84.307 of this part. These units will be evaluated for fire and explosion hazards using the tests specified in the following reports published by the Bureau of Mines: Reports of Investigations 9333 (1991), pages: 4–18; 8890 (1984), pages 6–62; and PRC Report No. 4294 (1980), pages: 18–62. These reports are available from NIOSH upon request; to request a copy, call 1–800–CDC–INFO (232–4636).

(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 Clause 13 of International Standards Organization (ISO) 4855 (First edition, 1981). The result will be satisfactory if the reflectance after the test is equal to or greater than 80% of its value before testing.

(2) NIOSH will test the effectiveness of the eye protection against gas using the method specified in Clause 14 of ISO 4855. 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 Sub-clause 3.1 of ISO 4855 of ISO 4855.

(4) NIOSH will test the eye protection's resistance to fogging in accordance with the method specified in European Standard EN 168: 2002.

(5) 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 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. A copy is also available for inspection at NIOSH, National Personal Protection

Technology Laboratory, Bruceston Research Center, 626 Cochran Mill Road, Pittsburgh, PA 15236. To arrange for an inspection at NIOSH, call 412–386–6593. Copies of the ISO standard 4855 are also available for purchase from the International Organization for Standardization (ISO) Web site at: <http://www.iso.org/iso/store.htm>. Copies of the European Standard 168 are available for purchase from BSI British Standards Web site at: <http://www.bsigroup.com/en/Standards-and-Publications>.

§ 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) of this part, 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 of this part, 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-certification 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 §§ 84.303–84.305 of this subpart, 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 §§ 84.304–84.305 of this subpart.

(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 units 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 three 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-certification testing.

§ 84.311 Registration of CCER units upon purchase.

(a) Each CCER unit sold will include, within the user instructions, a copy of procedures for registering the unit with NIOSH. The applicant can obtain a copy of these procedures from from the NIOSH Web page: <http://www.cdc.gov/niosh/npptl/resources/certpgmspt/default.html>.

(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 each purchaser of this respirator register all units purchased with NIOSH. Registration will enable NIOSH, which certified 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 is remaining effective under field conditions of storage and use.”

Editorial Note: This document was received at the Office of the Federal Register on December 5, 2008.

Dated: July 23, 2008.

Michael O. Leavitt,

Secretary, Department of Health and Human Services.

[FR Doc. E8–29235 Filed 12–9–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

RIN 0920–AA04

Quality Assurance Requirements for Respirators; Notice of Proposed Rulemaking

AGENCY: Centers for Disease Control and Prevention.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS) proposes to update existing quality assurance requirements under 42 CFR Part 84 for the manufacture of all respirators approved by the National Institute for Occupational Safety and Health (“NIOSH”) of Centers for Disease Control and Prevention (CDC), HHS. The proposed new requirements would require respirator manufacturers to be compliant with a widely adopted voluntary consensus standard for quality management systems, would update technical requirements particular to quality assurance for manufacturing of NIOSH-approved respirators, and would establish requirements governing the related quality assurance oversight activities of NIOSH.

DATES: CDC invites comments on this proposed rule from interested parties. Comments must be received by February 9, 2009.

ADDRESSES: You may submit comments, identified by RIN: 0920–AA04, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *E-mail:* niocindocket@cdc.gov. Include “RIN: 0920–AA04” and “42 CFR pt. 84” in the subject line of the message.
- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676

Columbia Parkway, Cincinnati, OH 45226.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking, RIN: 0920–AA04. All comments received will be posted without change to <http://www.cdc.gov/niosh/docket>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Public Participation” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.cdc.gov/niosh/docket>.

FOR FURTHER INFORMATION CONTACT:

William Newcomb, NIOSH National Personal Protective Technology Laboratory (“NPPTL”), Pittsburgh, PA, (412) 386–4034 (this is not a toll-free number). Information requests can also be submitted by e-mail to niocindocket@cdc.gov.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments are invited on any topic related to this proposal.

Comments submitted by e-mail or mail should be addressed to the “NIOSH Docket Officer”, titled “NIOSH Docket #109”, and should identify the author(s), return address, and a phone number, in case clarification is needed. Comments can be submitted by e-mail to: niocindocket@cdc.gov. E-mail comments can be provided as e-mail text or as a Word or Word Perfect file attachment. Printed comments can be sent to the NIOSH Docket Office at the address above. All communications received on or before the closing date for comments will be fully considered by CDC.

All comments submitted will be available for examination in the rule docket (a publicly available repository of the documents associated with the rulemaking) both before and after the closing date for comments. A complete electronic docket containing all comments submitted will be available on the NIOSH Web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in

the docket, including any personal information provided.

II. Background

A. Introduction

Under 42 CFR Part 84, “Approval of Respiratory Protective Devices” (“Part 84”) NIOSH approves respirators used by workers in mines and other workplaces for protection against hazardous atmospheres. The Mine Safety and Health Administration (“MSHA”) and the Occupational Safety and Health Administration (“OSHA”) require U.S. employers to supply NIOSH-approved respirators to their employees whenever the employer requires the use of respirators. In addition, MSHA co-approves with NIOSH all respirators used in mine emergencies and mine rescue.

As provided under Subpart E of Part 84, NIOSH presently requires, as a condition of approval, that the manufacturer of a NIOSH-approved respirator maintain a quality control plan designed to ensure that the products manufactured are of adequate quality and perform to the specifications under which they were approved by NIOSH. To provide quality assurance oversight, NIOSH conducts audits of manufacturing facilities (site audits) and of finished products (product audits). Additionally, NIOSH investigates complaints from employers and users concerning the performance of approved respirators in their workplaces. These audits and investigations can result in a variety of compliance actions by NIOSH, including requesting product recalls, stop-sale orders, retrofits, advisories, and various remedial quality control actions.

B. Background and Significance

Employers rely upon NIOSH-approved respirators to protect their employees from airborne toxic contaminants and oxygen-deficient environments. More than 3.3 million private sector employees in the United States wear respirators for certain work tasks. The most effective and reliable means of protecting workers from airborne contaminants is to prevent the workplace air from substantial contamination in the first place through enclosed processes and ventilation engineering. Similarly, the most effective and reliable means of protecting workers from oxygen-deficient environments is to prevent their causes or entry into them by workers. However, it is not technologically or economically feasible in all workplaces and operations to reduce airborne concentrations of