CCER Concept Paper

Concept Requirements, Closed-circuit Escape Respirators

A. Applicable Sections of 42CFR, Part 84:

1) Subpart A - General Provisions (entire subpart)

2) Subpart B - Application for Approval (entire subpart)

3) Subpart C - Fees (entire subpart)

4) Subpart D - Approval and Disapproval (entire subpart)

5) Subpart E - Quality Control (entire subpart)

6) Subpart F - Classification of Approved Respirators; Scope of Approval; Atmospheric Hazards; Service Time - Paragraphs 84.50, 84.51, and 84.52

7) Subpart G - General construction and Performance Requirements (entire subpart)

B. Closed-Circuit Escape Respirator Requirements:

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NEW SUBPART - CLOSED-CIRCUIT ESCAPE RESPIRATORS

Section 1 - Closed-circuit escape respirator; description.

(a) A closed-circuit escape respirator (CCER), technically a subset of self-contained breathing apparatuses which are otherwise covered under 42 CFR 84, subpart H, is a type of respirator used in certain industrial and other settings in emergencies to enable persons to escape from atmospheres that can be immediately dangerous to life or health. One type of this respirator, a self-contained self-rescuer (SCSR), is relied upon by miners to escape dangerous atmospheres in underground coal mines after a mine fire or explosion. SCSRs 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, and a chemical system for removing exhaled carbon dioxide from the worker'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.

Section 2 - 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 (EFFECTIVE DATE); and

(2) All CCERs sold after (3 YEARS AFTER EFFECTIVE DATE) that were previously approved by the Institute under 42 CFR 84, Subpart H.

(b) No CCER in use or available for use shall retain a NIOSH certificate of approval after (6 YEARS AFTER EFFECTIVE DATE) unless it has been approved under the requirements of this subpart.

Section 3 - 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 that protects against impact, fogging, and

permeation by gas, vapor, and smoke, as specified in Section 9(c);

(2) Thermal exposure indicators: if the manufacturer specifies a maximum and/or minimum environmental temperature limit for storage of the CCER, then the CCER must include a component, an attribute, or other means by which the user can determine whether or not the CCER has been exposed to temperatures that exceed the limit(s);

(3) Chemical bed physical integrity: the CCER must include a component, an attribute, or other means by which the user can detect any damage or alteration of the chemical oxygen storage or chemical carbon dioxide scrubber that could diminish the NIOSH-approved performance of the CCER, as tested under this concept;

(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 pt. 107: "Hazardous Materials Program Procedures," unless exempted under Subpart B of the DOT regulation;

(5) Tamper-resistant/tamper-evident casing: if the CCER is not designed for its casing to be opened prior to the use of the unit for an actual escape (e.g., for inspection of the

components by the user, for maintenance, for escape drills, or for other purposes), the casing must include a component, an attribute, or other means to prevent a person from accidentally opening the casing and, upon opening, to either prevent the casing from being closed or to clearly indicate to a subsequent user that the casing has been previously opened;

(6) Moisture damage indication: if the CCER is not designed for its casing to be opened for inspection of its internal components, the respirator casing must include a component, an attribute, or other means by which the user can detect any ingress of water or water vapor that could degrade the performance of the apparatus, as tested under this concept.

(b) The components of each CCER must meet the general construction requirements specified in 42CFR, Part 84, subpart G, § 84.61.

(c) The manufacturer must submit evidence that the CCER will protect users from inhaling a hazardous level of any gas or vapor that is specified by the manufacturer as a gas against which the CCER would provide protection. The hazardous level of a gas or vapor, for this purpose, will be defined by the Institute's Immediately Dangerous to Life or Health (IDLH) level specified for the gas, which can be obtained from the NIOSH

Pocket Guide to Chemical Hazards, located on the NIOSH Web page: http://www.cdc.gov/niosh.

(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) The manufacturer must include with each new CCER unit instructions and a service life plan. These documents must be clearly written.

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

(A) An explanation of how the CCER works;

(B) A schematic diagram of the CCER;

(C) Procedures for donning and use;

(D) Procedures for inspecting the operating conditions of the CCER;

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

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

(G) Procedures for disposal; and

(H) Procedures for registration of the unit with the Institute, pursuant to Section 11 of this subpart.

(2) The service life plan must completely address the following topics:

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

(B) Any other conditions, other than that specified under paragraph (A) of this section, that should govern the removal from service of the CCER; and

(C) 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.

Section 4 - General testing conditions and performance requirements.

(a) The Institute 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 are available from the Institute upon request or from the following Web page:

http://www.cdc.gov/niosh/npptl (to be provided at a later date).

(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 with instruments capable of breath-by-breath measurement. Stressor measurements will be recorded and evaluated as one-minute averages. Operating averages will be the average of these values over the operating life of the apparatus.

Table 1: Monitored Stressors and their Acceptable Ranges

Stressor	**Acceptable Range Operating Average**	**Acceptable Range Excursion**
Average inhaled CO_2	<1.5%	≤4%
Average inhaled O_2	>19.5%	≥15%
Peak breathing pressures	$\Delta P \leq 200$ mm H_2O	$-300 \leq \Delta P \leq 200$ mm H_2O
Wet-bulb temperature[1]	<43°C	≤50°C

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

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

(1) A minute-average measurement of any stressor listed in Table 1 occurs outside the acceptable excursion range specified in Table 1; or average stressor values over the operating life exceed the operating average values specified in Table 1; or

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

[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.

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

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

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

Section 5 - Capacity test requirements.

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

(1) Three units will be tested in as received condition on a breathing and metabolic simulator;

(2) Two units will be tested on a breathing and metabolic simulator after being subjected to environmental treatments specified in Section 8;

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

(4) One as received unit 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 42 CFR, Part 84 §§ 84.99 and 84.100 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.

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

Table 2: Capacity Test Requirements

Capacity Rating	**Capacity (L)**	$\dot{V}O_2$ **(L/min)**	$\dot{V}CO_2$ **(L/min)**	$\dot{V}e$ **(L/min)**	**RF (Breaths/min)**
Cap 1	$30 \leq L \leq 59$	2.50	2.50	55	22
Cap 2	$60 \leq L \leq 79$	2.00	1.80	44	20
Cap 3	$L \geq 80$	1.35	1.15	30	18

$\dot{V}O_2$ = volume of oxygen consumed; $\dot{V}CO_2$ = volume of carbon dioxide produced

$\dot{V}e$ = ventilation rate; RF = respiratory frequency

(e) NIOSH will quantify in its test results the capacity determined through the testing specified in this section, documenting the average value achieved by the seven units tested using the breathing and metabolic simulator. Capacity will be specified in increments of 5 liters, rounding intermediate values to the nearest lower 5 liter increment. A unit must meet one of these ranges or it will not be certified.

Section 6 - Performance test requirements.

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

(1) Three as received units will be tested in new condition on the breathing and metabolic simulator; and

(2) Two units will be tested on the breathing and metabolic simulator after being subjected to the environmental treatments specified in Section 8; and

(3) One as received unit will be tested 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) CCERs with less than 50 liters of capacity, as determined by the capacity testing in Section 5, will be tested according to the work-rate test sequence specified in Table 3. The durations of each work-rate in the sequence, as specified in Table 3, will be reduced proportionally, as necessary, so that the CCER is tested by one entire cycle of the three work rates.

(d) The performance test will begin with two exhalation breaths from the simulator, at the initial ventilation rate, into the apparatus to determine the design's susceptibility to hypoxia.

Table 3: Performance Test Requirements

Work-Rate Test Sequence	Duration per cycle	$\dot{V}O_2$ (L/min)	$\dot{V}CO_2$ (L/min)	$\dot{V}e$ (L/min)	RF (breaths/min)
1. Peak	5 min.	3.00	3.20	65.0	25
2. High	15 min.	2.00	1.80	44.0	20
3. Low	10 min.	0.50	0.40	20.0	12

$\dot{V}_{O_2}$ = volume of oxygen consumed; $\dot{V}_{CO_2}$ = volume of carbon dioxide produced

$\dot{V}e$ = ventilation rate; RF = respiratory frequency

Section 7- Wearability test requirements.

(a) NISOH will conduct the wearability test on a total of three of the units submitted for approval. Three human subjects of differing physical characteristics, one subject per unit, will conduct the test. All CCERs tested must meet all conditions specified in this section to receive approval.

(b) The Institute 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 to the point of having isolated the lungs within 30 seconds[1]; and

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

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

(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 Section 4(b), without harming or hindering a user. To be certified, the use of each unit during these activities must not indicate to the Institute any potential for the CCER to harm or hinder a user or to fail to provide an adequate and uninterrupted breathing supply to a user during reasonably anticipated conditions of an escape.

Section 8 - Environmental treatments.

(a) Four units submitted for approval will be tested for capacity and performance, pursuant to the requirements of Section 4 - 6, after exposure to environmental treatments simulating extreme storage temperatures, shock, and vibration that the CCER must be designed and constructed to withstand.

(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.

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.

(c) The units will be subjected to physical shock according to the following procedure:

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

(2) Each drop of the unit will test a different axis of impact with respect to the orientation of the CCER.

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

(1) Each unit will be will be vibrated for 180 minutes per axis using a shaker table with motion along a single axis;

(2) The unit will be vibrated along each of three axes, for a total of nine hours; and

(3) The vibration 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

Section 9 - 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) NISOH 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 manufacturer must submit fifteen additional new units, which will be subjected to a battery of tests to evaluate fire and explosion hazards. These tests are 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 the Institute upon request.

(c) NISOH will perform the following tests on the eye protection (gas-tight goggles or escape hood lens) of one or more of the units 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) and will be regarded as satisfactory if the reflectance after the test is not less than 80% of its value before testing.[2]

(2) The Institute will test the effectiveness of the eye protection against gas using the method specified in Clause 14 of

[2] Clause 13 of ISO 4855 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

ISO 4855; the test must not result in staining of the area enclosed by the eye-protection.[3]

(3) The Institute will test the durability of the eye protection using the method specified in Sub-clause 3.1 of ISO 4855.[4]

(4) The Institute will test resistance to fogging of the eye protection in accordance with the method specified in European Standard EN 168: 2002.[5]

Section 10 - Post-certification testing.

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

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

(c) The Institute will conduct such testing pursuant to the methods specified in Sections 4 - 6, except as provided under paragraph (d) of this section.

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[3] Clause 14 of ISO 4855 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

[4] Sub-clause 3.1 of ISO 4855 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

[5] European Standard EN 168:2002 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(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 Sections 5 and 6.

(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) The Institute will replace deployed units obtained for testing with new units at no cost to the employer.

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

Section 11 - Registration of CCER units upon purchase.

(a) The manufacturer shall include with each CCER unit sold, within the user instructions, a copy of procedures for registering each unit with the Institute. The manufacturer can obtain a copy of these procedures from the Institute upon request or from the following Web page: http://www.cdc.gov/niosh/npptl (to be provided at a later date).

(b) The manufacturer of the CCER shall notify in writing each purchaser of the purpose of registering a unit with the Institute, as specified under paragraph (c) of this section. If the purchaser is a distributor of the CCER, the manufacturer must request in writing that the distributor voluntarily notify in writing each of its purchasers of the purpose of registering a unit with the Institute, 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. It will also assist NIOSH in locating deployed units of this respirator to periodically evaluate whether this respirator is remaining effective under field conditions of storage and use."