National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory P.O. Box 18070 Pittsburgh, PA 15236		
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EVALUATION OF DONNING OF CLOSED CIRCUIT ESCAPE RESPIRATORS (CCER)

1. PURPOSE

This procedure establishes the test for ensuring that the level of protection provided by donning a Closed-Circuit Escape Respirators (CCER) submitted for Approval, Extension of Approval, or examined during Certified Product Audits, meet the minimum certification standards set forth in Section 84.306 (b) (1), and (2) of Subpart O−Closed Circuit Escape Respirators updated requirements to 42 CFR, Part 84, Volume 60, Number 110, June 8, 1995 as published in Federal Register / Vol. 77, No. 46 / Thursday, March 8, 2012 / Rules and Regulations pp. 14168-14197.

2. GENERAL

This STP describes the Donning test for closed circuit escape respirators in sufficient detail such that a person knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the test, and determine whether or not the product passes the test.

3. EQUIPMENT AND MATERIALS

Timer, Digital stopwatch, calibrated to hundredths of a minute (Cronus Precision Products, Inc.) or equivalent.

4. TEST REQUIREMENTS AND CONDITIONS

4.1. Test subjects must meet requirements of the NIOSH Institutional Review Board approved Protocol. Refer to HSRB-12-NPPTL-04, "PROTOCOL FOR TESTS WITH HUMAN SUBJECTS OF CLOSED-CIRCUIT ESCAPE RESPIRATORS IN CERTIFICATION, QUALITY ASSURANCE AND DEVELOPMENT" for the proper consent form and complete details on the use of human test subjects in respirator certification testing.

4.2. Prior to beginning any testing, all measuring equipment must have been calibrated using a method traceable to the National Institute of Standards and Technology (NIST) in accordance with the manufacturer's calibration procedure and schedule.

4.3. Any laboratory using this procedure to supply certification test data to NPPTL will be subject to the provisions of the NPPTL Supplier Qualification Program (SQP). This program is based on the tenets of ISO/IEC 17025, the NIOSH Manual of Analytical Methods and other NIOSH guidelines. An initial complete quality system audit and follow on audits are requirements of the Program. Additional details of the Program and its requirements can be obtained directly from NPPTL.

Approvals: First Level	Second Level	Third Level	Fourth Level

4.4. Normal laboratory safety practices must be observed. These include safety precautions given in the current *NIOSH-Pittsburgh Health and Safety Manual*, Job Hazard Analysis (JHA), work instruction documents and test equipment manufacturer recommended practices.

4.5. Procedures will be conducted at the following ambient conditions:

4.5.1. Ambient temperatures of 23ºC ± 3ºC; and

4.5.2. Atmospheric pressures of 735 mm Hg ± 15 mm Hg.

4.6. The donning test will be conducted on a total of three units submitted for approval, each with a different human subject.

4.6.1. Three human subjects, two males and one female, one subject per unit, will conduct the test.

4.6.2. The three subjects will range in height and weight as follows: one subject of height ≥ 174 cm and weight ≥ 90 kg; one subject of <u>either</u> 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.

4.7. Prior to performing the CCER donning, each subject will receive training in how to don, operate and doff the CCER.

4.7.1. The training will cover procedures indicated and/or recommended in the CCER instructions, as contained in one or more of the following required topics:

4.7.1.1. Procedures for donning and use (§ 84.302 (h) (1) (iii))

4.7.1.2. Procedures for inspecting the operating condition of the CCER (§84.302 (h) (1) (iv))

4.7.1.3. Any procedure by which the user should inspect the CCER and determine when the CCER should be removed from use (§ 84.302 (h) (2) (iii))

4.7.2. Training may involve use of a training unit(s).

5. <u>PROCEDURES</u>

5.1. Prior to performing the CCER donning evaluation test, the CCER will be put in the "as ready" condition specified by the manufacturer.

5.2. The CCER in the "as ready" condition will be placed on a table or bench.

5.3. All test subjects will receive the consent form and procedures included in HSRB 12-NPPTL-04 for wearability test.

5.4. The subject will stand in front of the table or bench within an arm's length of the CCER.

5.5. The tester will indicate to the subject to begin donning the CCER and simultaneously begin timing.

5.5.1. A countdown may be used.

5.6. The tester will stop timing when the subject has completed donning which includes:

5.6.1. Isolating his/her lungs:

5.6.1.1. In the case of mouth-bit devices, isolation includes inserting the mouth-bit into the mouth, and applying the nose clip to the nose.

5.6.1.2. In the case of facepiece devices, isolation includes achieving a face seal.

5.6.2. Activating the oxygen supply system.

5.6.3. The donning time **does not** include any additional steps that might be required after the lungs are protected to adjust the unit for wear.

6. PASS/FAIL CRITERIA

6.1. The device passes if the donning time recorded in the procedure is 30 seconds or less.

6.2. The device fails if the donning time recorded in the procedure exceeds 30 seconds.

7. RECORDS AND TEST SHEETS

CCER: Manufacturer: Model: Sample or serial number:

Test subject: Sex: Height: Weight:

Training: Date: Training type:

Test: Date: Donning time:

Comments/notes:

Technician:

8. ATTACHMENTS

None

Revision History

Revision	Date	Reason for Revision
00	15 September 2011	Initial Review
1.0	8 March 2012	Administrative changes – Document number changed
2.0	3 April 2012	Administrative changes were made to include information from the release of the proposed rule
		Former document number - STP-00001-PSDB-0012
0.0	7 April 2014	New document number to reflect numbering in the approval library, normalization of format. No changes to procedure from historical document.