National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory P.O. Box 18070 Pittsburgh, PA 15236		
Procedure No. CET-APRS-STP-CBRN-0499	Revision: 1.1	Date: 23 December 2005

STANDARD TEST PROCEDURE (STP) FOR DETERMINING THE DONNING TIME OF THE CHEMICAL, BIOLOGICAL, RADIOLOGICAL AND NUCLEAR (CBRN) ESCAPE RESPIRATOR (AIR-PURIFYING AND SELF-CONTAINED)

1. PURPOSE

1.1. This test establishes the procedures for determining the time to don a chemical, biological, radiological, and nuclear (CBRN) escape respirator (ER) for approval, extension of approval, or examined during certified product audits, meets the minimum certification standards set forth in this standard test procedure (STP) as prescribed by *42 CFR, Part 84, Subpart G, Section 84.63(a)(c)(d)* and *Federal Register*, Volume 60, Number 110, June 8, 1995.

1.2. The purpose of this test is to qualify the donning effectiveness of a CBRN ER by measuring the time at which a respirator can be properly donned in accordance with the manufacturer's user's instructions. This STP outlines the test procedures to test the donning effectiveness for both types of CBRN ER: air-purifying and self-contained. It is important that a CBRN ER possess the intrinsic feature to be quickly and properly donned from the ready-to-use configuration by the general working population. The ready-to-use configuration is the operational packaging state prior to use such that immediately upon opening allows the user to don the respirator. The CBRN ER will be worn by the general population to provide protection against CBRN materials resulting from a possible terrorist attack. This test method objectively measures the donning effectiveness to ensure that a CBRN ER can be properly donned within the required time by the general population after reading the respirator manufacturer's user's instructions.

2. GENERAL

This STP describes the determination of donning effectiveness of the CBRN ER (air-purifying and self-contained) test in sufficient detail that a person knowledgeable in the appropriate technical field can conduct the test and determine whether or not the product meets the test requirements.

Approvals:	1st Level	2nd Level	3rd Level

3. EQUIPMENT AND MATERIALS

3.1. Test Equipment

3.1.1. Fisher Scientific, Model # 06-662-3 Stop Watch or Equivalent. Figure 1 illustrates a Fisher Scientific, model # 06-662-3 stop watch. Equivalent brands can be used that are traceable to the National Institute of Standards and Technology (NIST) calibration.

Figure 1. Fisher Scientific, model # 06-662-3 stop watch

3.2. Human Subjects

3.2.1. Eight (8) volunteers will be used to complete the donning effectiveness test of the CBRN ER. The volunteers shall be used immediately before conducting the following tests:

- Two (2) volunteers before the *Determination of Lens Fogging on Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirators Test.*
- Six (6) volunteers before the *Determination Of Laboratory Respirator Protection Level (LRPL) Quantitative, Medium Flow, Deep Probe, Corn Oil, Fit Factor Performance Test For Chemical, Biological, Radiological And Nuclear (CBRN) Full Facepiece Respiratory Protective Devices (RPD) Test.*

NOTE: The recruitment of the eight (8) volunteers does not necessarily have to exclusively come from the participants of the fogging and LRPL

tests. If the situation merits a change, volunteers may be recruited from other human factor tests being conducted, and the number of volunteers from either the fogging test or the LRPL test may be altered. The important thing is that the test
obtained from each volunteer occurs upon completion of the Volunteer Agreement Affidavit and Volunteer Agreement Affidavit Explanation outlined in the human use protocol for that particular human factor test.

3.2.2. Each human subject shall be assigned a subject number to be used during the actual donning effectiveness test in the following sequence: DTS1, DTS2, DTS3…etc. meaning donning test subject #1, donning test subject #2, donning test subject #3.

3.2.3. Test administrator(s): Shall have successfully completed the Centers for Disease Control and Prevention (CDC)/ Agency for Toxic Substances and Disease Registry (ATSDR) *Scientific Ethics Training*, the Department of Health and Human Services (DHHS)/National Institutes of Health (NIH) *Human Participant Protections Education for Research Teams* or an equivalent course. **Note:** The NIOSH Human Subject Review Board will deem if courses are equivalent.

3.3. Required CBRN ER Test Items

3.3.1. If a CBRN ER is available in sizes of small, medium, and large, the manufacturer shall supply a minimum of three (3) small, four (4) medium, and three (3) large escape respirators.

3.3.2. If a CBRN ER is available in two sizes, there shall be five (5) of each size available for the testing.

3.3.3. There shall be ten (10) CBRN ER of each one-size mask system.

4. TESTING REQUIREMENTS AND CONDITIONS

4.1. Before testing, all test equipment shall have been calibrated in accordance with the manufacturer's calibration procedure and schedule. At a minimum, all measuring equipment utilized for this testing must have been calibrated within the preceding 12 months using a method traceable to the NIST.

4.2. Normal laboratory safety practices must be observed. This includes safety precautions described in the current *Centers for Disease Control and Prevention (CDC) General Laboratory Health and Safety Manual* or site-specific procedures that are applicable to the health and safety requirements.

4.3. Work benches must be maintained free of clutter and non-essential test equipment.

5. PROCEDURE

NOTE: Reference Section 3. for test equipment, model numbers and manufacturers. For calibration purposes, use those described in the manufacturer's operation and maintenance manuals.

5.1. This procedure describes the donning effectiveness test for ensuring that the level of protection provided by the donning effectiveness of a CBRN ER meets or exceeds the requirements outlined in the *Statement of Standard For Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator*, 30 September, 2003 and the *Statement of Standard For Chemical, Biological, Radiological, and Nuclear (CBRN) Self-Contained Escape Respirator*, 30 September, 2003. Other types of CBRN respiratory protective devices (RPD) may be tested for donning effectiveness using this procedure: refer to the primary statement of standard for the CBRN RPD being tested for the donning requirements. This procedure describes the required sample size, test equipment, test procedure, data collection methods and the pass or fail criteria for the type of CBRN ER being tested.

5.2. Test Items

5.2.1. Test Items

Indicate on the attached test data sheet 1 of 2 the following general pretest incoming inspection information about the CBRN ER:

- NIOSH application number:
- Type of ER being tested (APR, self-contained or other):
- Name of manufacturer:
- Model number of RPD:
- Model number of canister (if applicable):
- Date arrived:
- Test Date:
- General condition of packaging:
- Appearance of RPD and canisters (if applicable):
- Any specific physical anomalies:
- Type of test being conducted:
- Type of test it is being conducted before (fogging, LRPL or other):

5.2.2. Number Test Items

Prior to performing the donning effectiveness test, all test item packages shall be individually numbered with an indelible pen in two (2) places in a sequence that the number can be traced to the NIOSH application number, manufacturer, and model. For example, the number sequence can be S1, M1, and L1. The S1 will mean a small CBRN ER #1, M1 will mean a medium CBRN ER #1 and L1 will mean a large CBRN ER #1. After the donning effectiveness test has been completed, the ER shall be marked in two (2) places on the exterior hood (non-lens and non-component region) with the same number that was originally marked on the respective packaging.

5.3. Familiarization of Respirator Manufacturer's User's Instructions

Prior to testing, each human subject shall be provided with training that is in accordance with the training requirements that are specified in the manufacturer's application for certification. The applicant's training materials shall be used as the basis for preparing the test subjects. The respirator training requirements as a minimum shall include a user's instruction manual that shall address sizing, donning procedures, system use, maintenance (care and useful life), and cautions and limitations. If the respirator user's instruction manuals are not available or accessible and the instructions are printed on the respirator packaging, then the human subjects shall be provided with the unopened packaged respirator so the subjects can read the user's instructions directly from the packaging.

5.4. Assigning Respirator Sizes and Human Subject Number

The test administrator shall provide the proper size respirators to the human subjects in accordance with the respirator manufacturer's user's instruction manual. Also, the test administrator shall assign a human subject number in accordance with Section 3.2.2. of this STP.

5.5. Performing the Donning Effectiveness Test

After the human subjects have been properly trained on wearing the respirator and have been provided with a proper size respirator in accordance with the respirator manufacturer's user's instruction manual, the test administrator shall perform the donning effectiveness test individually with the human subjects by using the following procedures:

5.5.1. The test administrator shall document on the attached test data sheet 2 of 2 the following general pretest information [GPI] and specific human subject information before conducting any tests:

- NIOSH application number [GPI]:

- Manufacturer of the CBRN ER [GPI]:
- CBRN ER type (APR, self-contained, PAPR, etc.) [GPI]
- Human subject number [specific human subject]
- Respirator number and respirator size [specific human subject]
- Test date [specific human subject]
- Test time [specific human subject]

5.5.2. The test administrator shall test the functioning of the stop watch by initializing the time reading to zero (0:00), depressing the start button, allowing it to time for 30 seconds and depressing the stop button. If the stop watch is functioning properly, initialize the reading on the stop watch to (0:00) in order to be ready to obtain the donning time of the first human subject.

5.5.3. The test administrator shall instruct the human subject to remove the respirator from the ready-to-use configuration packaging and properly don the respirator in accordance with the manufacturer's user's instructions upon hearing the word, "Begin". The test administrator shall also instruct the human subject to hold their hands up while saying the word, "Done" after properly donning the respirator. The human subject shall be informed that they have 30 seconds to properly don the respirator.

5.5.4. The donning effectiveness test shall be performed with one human subject at a time out of view and undisturbed from other human subjects.

5.5.5. The human subject shall hold their assigned respirator in their hands by their waist and wait for the test to begin.

5.5.6. The test administrator shall begin the test by saying the word, "Begin" to the human subject and simultaneously starting the stop watch by depressing the start button. At this point, the human subject shall begin removing the respirator from the ready-to-use configuration packaging with the intent to don the respirator.

5.5.7. Once the human subject properly dons the respirator and holds their hands up while saying the word "Done", the test administrator shall depress the stop button on the stop watch.

5.5.8. The time to properly don the respirator shall be recorded on data sheet 2 of 2 in the donning time (DT) column for that particular test subject.

5.5.9. After the human subject removes the respirator, the test administrator shall label the respirator in two (2) places on the exterior hood (non-lens and non-component region) with the same number that was originally marked

on the respective ready-to-use configuration packaging.

5.5.10. Repeat the steps indicated in Sections 5.5.1. through 5.5.9. of this STP to obtain the donning test times for the remaining human subjects.

5.6. Data Analysis

The test administrator shall count the following on test data sheet 2 of 2:

1.) Total number of human subjects whose donning time is less than or equal to 30 seconds; and

2.) Total number of human subjects whose donning time is greater than 30 seconds.

6. PASS OR FAIL CRITERIA

6.1 The criterion for passing this test is set forth in *42 CFR, Part 84, Subpart G, Section 84.63(a)(c)(d).*

6.2 This test establishes the standard procedure for ensuring that:

84.63 Test requirements; general.

(a) Each respirator and respirator component shall when tested by the applicant and by the Institute, meet the applicable requirements set forth in subparts H through L of this part.

(c) In addition to the minimum requirements set forth in subparts H through L of this part, the Institute reserves the right to require, as a further condition of approval, any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres.

(d) Where it is determined after receipt of an application that additional requirements will be required for approval, the Institute will notify the applicant in writing of these additional requirements, and necessary examinations, inspections, or tests, stating generally the reasons for such requirements, examinations, inspections, or tests.

6.3 A candidate CBRN ER must comply with either the *Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Air-Purifying Escape Respirator*, 30 September, 2003 or the *Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Self-Contained Escape Respirator*,

30 September, 2003. Both standards state, "The time to don the respirator from the ready-to-use configuration shall be no greater than 30 seconds. The ready-to-use configuration is the operational packaging state prior to use such that immediately upon opening allows the user to don the respirator".

6.3.1 For the applicant's respirator to successfully pass the donning effectiveness requirement, the total number of subjects whose donning time is less than or equal to 30 seconds shall be greater than or equal to six (6).

6.4 Other types of CBRN RPD may be tested for donning effectiveness using this procedure: refer to the primary statement of standard for that particular CBRN RPD being tested for the donning performance requirements.

7. RECORDS AND TEST DATA SHEETS

7.1. All test data shall be recorded on the attached Determination of Donning Effectiveness Test of The CBRN Escape Respirator (Air-Purifying and Self-Contained) Test Data Sheets.

7.2. All videotapes and photographs of the actual test being performed, or of the tested equipment shall be maintained in the task file as part of the permanent record.

7.3. All equipment failing any portion of this test shall be handled as follows:

7.3.1. If the failure occurs on a new certification application, or extension of approval application, send a test report to the Respirator Branch; Certification, Evaluation and Testing (CET) Team Leader and prepare the hardware for return to the manufacturer.

7.3.2. If the failure occurs on hardware examined under an off-the shelf audit, the hardware will be examined by the test administrator and the CET Team Leader for cause. All equipment failing any portion of this test may be sent to the manufacturer for examination and then returned to NIOSH. However, the hardware tested shall be held at the testing laboratory until authorized for release by the Respirator Branch Chief, or designee, following the standard operating procedures outlined in the *Procedure for Scheduling, and Processing Post-Certification Product Audits, RB-SOP-0005-00.*

Appendix A

General Pretest Incoming Inspection Information
(Test Data Sheet 1 of 2)

NIOSH application number:_____

Type of ER being tested (APR, self contained or other):_____

Name of manufacturer:
_____

Model number of RPD:_____

Model number of canister (if applicable):_____

Date arrived:_____

Test Date:_____

General condition of packaging:_____

Appearance of RPD and canisters:_____

Any specific physical anomalies:_____

Type of test being conducted:_____

Type of test that is being conducted before donning effectiveness: fogging, LRPL or other human factor tests:_____

Donning Effectiveness Test Of The CBRN Escape Respirator-
(Air-Purifying and Self-Contained) Data Sheet
(Test Data Sheet 2 of 2)

NIOSH application number: _____

Manufacturer of the CBRN ER:_____

CBRN ER Type (APR, self-contained, PAPR, etc.):_____

Requirement: For the applicant's CBRN ER to successfully pass the donning effectiveness requirement, the total number of subjects whose donning time is less than or equal to 30 seconds shall be greater than or equal to six (6).

Pass _____ Fail _____

Results:

Test #	Human Subject Number and Gender (F/M)	Donning Time	Respirator Number and Size	Test Date	Time of Test
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

NOTE: A minimum of 8 tests shall be performed, but above chart allows 12 data points to be entered

Total number of subjects whose donning time is less than or equal to 30 Seconds: _____

Total number of subjects whose donning time is greater than 30 Seconds: _____

Comments: _____
_____
_____

Test administrator signature: _____ Date: _____

Laboratory supervisor signature: _____Date: _____

Revision History

Revision	Date	Reason for Revision
0	17 September 2004	Historic document
1.1	23 December 2005	Update header and format No changes to method