National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory P.O. Box 18070 Pittsburgh, PA 15236		
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DETERMINATION OF LENS FOGGING ON FULL-FACEPIECE CHEMICAL BIOLOGICAL RADIOLOGICAL AND NUCLEAR (CBRN) AIR-PURIFYING RESPIRATORS (APR), STANDARD TEST PROCEDURE (STP)

1. PURPOSE

1.1. This test establishes the procedures for ensuring that the level of protection provided by the degree of lens fogging of the Full Facepiece Chemical Biological Radiological and Nuclear (CBRN) Air-Purifying Respirators (APR) submitted for Approval, Extension of Approval, or examined during Certified Product Audits, meet 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); Volume 60, Number 110, June 8, 1995.

1.2. The purpose of this test is to subject the CBRN APR to a low temperature environmental condition in order to test the occurrence and extent of lens fogging while the item is worn by a human subject. Respirator lens fogging can be defined as the condensation of water vapor on the internal surface of the lenses to such a degree that vision becomes impaired. Factors that influence fogging of the full facepiece APR lenses or visor include environmental conditions, moisture trapping within the facepiece, work intensity, airflow dynamics within the facepiece, and the optical surface of the lenses or visor. The procedures described herein are intended to test the APR for failure of manufacturers' design characteristics for preventing obstruction of vision due to significant lens/visor fogging when subjected to potentially harsh conditions by a user. This procedure may be used for other types of Respiratory Protective Devices (RPD): Refer to the primary Statement of Standard of that RPD for the Durability Conditioning requirements.

2. GENERAL

This STP describes the Determination of Lens Fogging on Full Facepiece Chemical Biological Radiological and Nuclear (CBRN) Air-Purifying Respirators (APR) test in sufficient detail that a person knowledgeable in the appropriate technical field can conduct the test and determine whether or not the product passes testing.

3. EQUIPMENT/HUMAN SUBJECTS

3.1. Test Equipment

Approvals:			
First Level	Second Level	Third Level	Fourth Level

3.1.1. Near Vision Chart; Double-Sided, Logarithmic, Low Acuity, High Contrast (90 ± 5% Contrast) with 40 cm (16 in) cord to maintain appropriate viewing distance or equivalent. Chart measures 18 x 23 cm (7 x 9 in). Figure 1 is an illustration of the logarithmic low acuity chart.

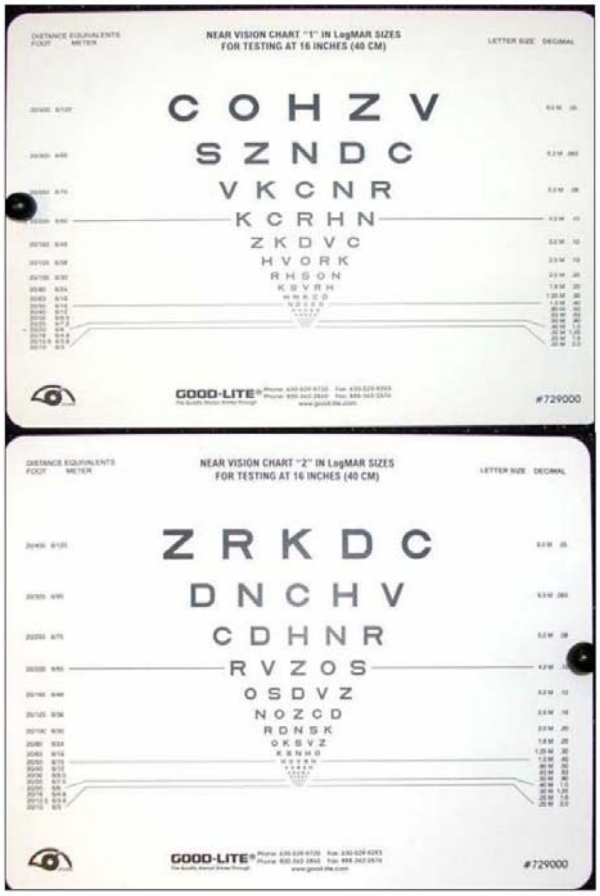

Figure 1. Good –Lite, Model # 729000: Chart 1 and Chart 2; respectively

3.1.2. Environmental Walk-In Chamber, Model D69 manufactured by Tenny Engineering, Inc. or equivalent. The Environmental Walk-In Chamber shall possess an adequate light source that will provide between 30 to 50 foot-candles of task lighting approximately 40 cm from the test subject's eyes in their line of sight. Figure 2 illustrates a Model D69 Environmental Walk-In Chamber that can attain temperatures ranging from negative 25°C (-13°F) to 35°C (95°F), adjustable humidity up to 100% RH and the adequate light source.

Figure 2. Environmental Walk-In Chamber, Model D69 manufactured by Tenny Engineering, Inc.

3.1.3. Trackmaster TM 500E Treadmill (JAS Manufacturing) or equivalent. Figure 3 illustrates a Trackmaster TM 500E Treadmill machine that test subjects will use to perform exercise during the Fogging Test.

Figure 3. Trackmaster TM 500E Treadmill manufactured by JAS Manufacturing

3.1.4. Stopwatch or timer graduated in specific increments. (photo not shown)

3.1.5. Light Meter, Model 401036, manufactured by Extech Instruments or equivalent. Model 401036 has a range of measurement between 20-20000 Foot-candles and a resolution of 0.1 foot-candles. Figure 4 is an illustration of the Light Meter.

Figure 4. Light Meter, Model 401036, manufactured by Extech Instruments

3.1.6. NIOSH or their test representative will supply the following cold weather gear: cold weather boots, cold weather trousers, cold weather parkas with permanently attached hoods, and cold weather mittens or gloves. The cold weather gear shall be available in multiple sizes to accommodate both small and large individuals, male or female, and multiple sizes in-between. (photo not shown)

3.2. Human Subjects

3.2.1. 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.

3.2.2. Both male and female volunteers between the ages of 18 – 45 years that meet the requirements of the currently and subsequently approved NIOSH *Human Subject Review Board (HSRB), Protocol No. HSRB-02-NPPTL-05XP*, will be recruited to participate in this test. Informed consent will be obtained from each volunteer upon completion of the Volunteer Agreement Affidavit and Volunteer Agreement Affidavit Explanation contained in *Protocol No, HSRB-02-NPPTL-05XP*.

3.2.3. Since the testing procedures set forth in this test require reading from visual acuity charts, volunteer recruits will be excluded from participation if they have an unaided visual acuity of 20/40 or worse. However, individuals with contact lenses will be allowed to volunteer for testing as long as visual acuity measured with their contacts meets or exceeds the 20/40 acuity requirement. See Section 5.38 for determining the subjects' visual acuity.

3.2.4. A minimum of two (2) volunteers will be used to complete visual performance testing under the low temperature lens fogging condition for each respirator system submitted for CBRN APR certification.

3.3. Required CBRN APR Test Items

3.3.1. If an APR is available in sizes of small, medium, and large, the manufacturer shall supply a minimum of four small, four medium, and four large facepieces.

3.3.2. If an APR is available in two sizes, there shall be four of each size available for the testing.

3.3.3. There shall be four CBRN APRs of each one-size mask system.

4. TESTING REQUIREMENTS AND CONDITIONS

4.1. Prior to beginning any testing, all measuring equipment to be used must 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 National Institute of Standards and Technology (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.

4.2.1. All equipment shall be in a safe operating order, and the test administrators shall comply with all equipment safety operating procedures. The treadmill must have emergency stop lanyard or other equivalent means to automatically stop treadmill movement if the human subject falls during the test.

4.2.2. All electrical equipment cables and wires must be fastened securely to the floor by tape or some form of cover to eliminate trip hazards.

5. PROCEDURES

Note: Reference Section 3. for 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 Determination of the Lens Fogging Test for ensuring that the level of protection provided by the CBRN APR meets or exceeds the performance requirements outlined in the *Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Full Facepiece Air-Purifying Respirator (APR)*, 7 March 2003 with Revision 2, April 4, 2003. Other types of CBRN Respirator Protective Devices (RPD) may be tested for Lens Fogging using this procedure: Refer to the primary Statement of Standard for the CBRN RPD being tested for the Lens Fogging performance requirements. This procedures describes the required sample size, test

equipment, test procedure and data collection methods for conducting the Determination of the Lens Fogging Test on CBRN Full Facepiece RPD.

5.2. Test Material/Items

5.2.1. Test Items

Indicate on the Lens Fogging of Full Facepiece CBRN Air-Purifying Respirators Data Sheets in Appendix A the following general pretest information about the APR on the test record documentation:

- NIOSH Application Number
- Name of Manufacturer
- Type of RPD being Tested (APR, PAPR, ETC):
- Model Number of CBRN RPD
- Model Number of Canister (If Applicable)
- Date Arrived
- Date of Fogging Test
- General Condition of Packaging
- Appearance of CBRN RPD and Canisters
- Any Specific Physical Anomalies
- Type of Test being Conducted

5.2.2. Number Test Items

All test items shall be individually numbered without affecting form, fit or function using an indelible pen or tagged in a sequence that the number can be correlated to the NIOSH application number, manufacturer, and model number so it can be tracked throughout the series of tests. For example, the number sequence can be LFTS1, LFTS2…; LFTM1, LFTM2…; or LFTL1, LFTL2….. In this example, the LFTS1 would indicate a Small sized CBRN APR # 1 that is subjected to the Lens Fogging test and LFTL2 would indicate a Large sized CBRN APR #2.

5.3. Low Temperature Environment

5.3.1. The environmental test chamber shall be set at minus 21 ^{o}C +/- 1^{o}C (-6 ^{o}F +/- 2 ^{o}F) and be allowed to equalize before preconditioning any of the CBRN APR.

5.3.2. The Treadmill machine shall be set at a speed of 4.8 kilometers per hour and at a grade setting of level ground.

5.3.3. There shall be 2 CBRN APR of each size preconditioned in the chamber at the specified temperature [minus 21 ^{o}C +/- 1^{o}C (-6 ^{o}F +/- 2 ^{o}F)] for 4 hours.

5.3.4. Before any visual acuity tests are administered, the antechamber room and environmental chamber shall possess an adequate light source that will provide between 30 to 50 foot-candles of task lighting approximately 40 cm (16 in) from

the test subject in their line of sight. Measurements shall be taken with the Light Meter's light sensor being placed approximately 40 cm (16 in) from the human subject's eye position in their line of sight. Measurements shall be taken in the absence of the Visual Acuity Chart. The foot-candle values shall be recorded on the Test Data Sheet 2 of 2.

5.3.5. Using an APR that isn't undergoing conditioning, each volunteer will be sized and fitted in an air-conditioned antechamber room maintained at approximately 22.2°C ±1.1°C (72°F ±2 °F) prior to the fogging test in accordance with the APR manufacturer's instructions. Where an individual is qualified to wear multiple sizes of the APR, the subject shall select the respirator size that provides the most comfortable fit. The test subjects shall be trained in the donning and usage of the APR per manufacturer's instructions and be given time to perfect donning techniques under the guidance of a test administrator. The subject shall self-don their assigned CBRN APR in accordance with the manufacturer's instructions. Once a confirmed seal is attained by the test subject during the pre test procedure, test procedure and post test procedure, the test administrator or an observer shall not touch the test APR in order to adjust the fit or comfort of the APR on the test subject. Standard practice involving hair line infractions, nose cup distortion, improper head harness orientation etc must be addressed by the applicant's user instructions since this is a self-donning and not an expert donning test. The volunteer will doff the APR and prepare to enter the environmental chamber.

5.3.6. Subjects will dress in clean, serviceable, cold weather gear in an air-conditioned antechamber room maintained at approximately 22^{o}C (72^{o}F). Test administrators will be available to assist with the donning of the cold weather clothing and will ensure that it has been properly donned. Volunteers will wear their own clothing under the cold weather gear for testing.

5.3.7. The wear trial will be completed by one subject at a time and will begin as the test participant enters the chamber. Upon entering the chamber, the subject shall self-don their assigned CBRN APR in accordance with the manufacturer's instructions and a visual acuity test shall be immediately administered using the near vision chart or an equivalent method.

5.3.8. Subjects will be asked to identify and read aloud all letters of the smallest line of letters that they are able to see when properly positioned 40 cm (16 in) from the test eye chart by using the distance cord. If a subject correctly identifies all five letters on the chosen line, they will be asked to attempt to read the next smallest line of letters on the chart. The line is considered read when more than half (eg, three of five) are read correctly and total credit (5 points) is given for that line. When a subject is unable to correctly identify three or more letters, the administrator will discontinue the visual acuity test and obtain the Visual Acuity Score (VAS). The VAS method initially assigns a score of 50 points for the 20/200 line and 5 points per line thereafter if the line is read correctly. The VAS method awards one point for each letter read on the visual acuity chart with five letters per line after the 20/200 Line. If the 20/20 line is read correctly and two

letters in the 20/16 Line, a 102 point score shall be assigned for the VAS. Record the actual VAS score on the respective test data sheet. Table 1 is a Scoring Table that can be used as an aid in the VAS scoring system. The Visual Acuity Score shall be recorded on the test data sheet 2 of 2 for the respective test subject and test contained in Appendix A.

Table 1.

Scoring Table

Line	Letters	Distance Equivalent in Feet	Line Score
1.	**C O H Z V**	20/200	50
2.	**Z R K D C**	20/160	5
3	**D N C H V**	20/125	5
4.	**O K S V Z**	20/100	5
5.	**H S N Z V**	20/80	5
6.	**V C S Z H**	20/63	5
7.	**S O V N Z C**	20/50	5
8.	**R H S D N**	20/40	5
9.	**K C R H N**	20/25	5
10.	Z R K D C	20/20	5
11.	R N D V K	20/16	5
12.	R H S C N	20/12.5	5

5.3.9. The test subject shall be constantly monitored during the test to determine that the CBRN APR is functioning satisfactorily and that they are not experiencing undue discomfort because of air-flow restrictions or other physical changes in the operation of the APR.

5.3.10. The test participant shall then exercise for five minutes by walking on the treadmill at the specified settings.

5.3.11. Immediately after the exercise, the test participant shall rest for two minutes in the standing position at which time a visual acuity test shall be administered using the same VAS scoring methods described previously in paragraph 5.3.8. The VAS (VAS #2) shall be recorded on the Test Data Sheet.

5.3.12. The test participant shall then exercise for an additional five minutes by walking on the treadmill at the specified settings.

5.3.13. Immediately after the exercise, the test participant shall remain on the treadmill in the standing position at which time another visual acuity test shall be administered. Again, the VAS (VAS #3)shall be recorded on the Test Data Sheet.

5.3.14. After completion of the visual acuity test, the subject shall remove the CBRN APR and then exit the environmental chamber with the CBRN APR.

5.3.15. The CBRN APR shall normalize in the ambient room temperature for 1 hour and then be cleaned and sanitized in accordance with instructions provided by the manufacturer.

5.3.16. Record remarks concerning unit operation and test subject's comments on the test data sheet for the respective subject.

5.3.17. A second fogging test shall be performed in the low temperature chamber by repeating the steps of Section 5.3.5. through 5.3.15. using a different volunteer and a different APR.

5.4. Data Analysis

5.4.1. The average VAS shall be calculated from the VAS obtained after initial chamber entry don, after five minutes of exercise, and at the end of final exercise period for each individual subject.

$$\text{Average VAS} = \frac{\text{Initial VAS + Post 5-min walk VAS + End of Exercise VAS}}{3}$$

5.4.2. Record the average VAS (VAS #1, VAS #2, and VAS #3) for each individual on the Test Data Sheet and assess a pass or fail rating.

5.4.3. Record remarks concerning unit operation and test subject’s comments on test data sheet.

6. Pass/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.

(b) 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.

(c) 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 APR in accordance with the Statement of Standard for Chemical Biological Radiological and Nuclear (CBRN) Full-Facepiece Air-Purifying Respirators (APR), March 7, 2003 with Revision 2, April 4, 2003 must obtain an Average Visual Acuity Score of greater than or equal to 75 points for each participant to meet the Low Temperature/ Fogging requirement. In addition, no individual VAS score shall be less than 70 points for any of the participants.

6.4. Other types of CBRN RPD may be tested for Lens Fogging using this procedure: Refer to the primary Statement of Standard for that particular CBRN RPD being tested for the Lens Fogging requirements.

7. RECORDS/TEST SHEETS

7.1. All test data shall be recorded on the Lens Fogging Of Full Facepiece CBRN Air-Purifying Respirators 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 follow:

7.3.1. If the failure occurs on a new certification application, or extension of approval application, send a test report to the Technology Evaluation Branch Chief 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 a technician and the Technology Evaluation

7.3.3. Branch Chief 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 Technology Evaluation 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.

8. ATTACHMENTS

8.1. Lens Fogging, Full Facepiece CBRN Air-Purifying Respirators Data Sheet 1

8.2. Lens Fogging, Full Facepiece CBRN Air-Purifying Respirators Data Sheet 2

Attachment 8.1, Lens Fogging, Full Facepiece CBRN Air-Purifying Respirators Data Sheet 1

Lens Fogging of Full Facepiece CBRN Air-Purifying Respirators Data Sheet 1 of 2

NIOSH Application Number _____

Name of Manufacturer _____

Type of RPD being Tested (APR, PAPR, ETC): _____

Model Number of CBRN RPD _____

Model Number of Canister _____

Date Arrived _____

Date of Fogging Test_____

General Condition of Packaging _____

Appearance of CBRN APRs and Canisters_____

Any Specific Physical Anomalies _____

Type of Test being Conducted _____

Requirements:

For the CBRN Full Facepiece APR, An Average visual acuity scores for each participant shall be greater than or equal to 75 points. In addition, no individual VAS score shall be less than 70 points for any of the participants.

Other types of CBRN RPD may be tested for Lens Fogging using this procedure: Refer to the primary Statement of Standard for that particular CBRN RPD being tested for the Lens Fogging requirements.

Attachment 8.2, Lens Fogging, Full Facepiece CBRN Air-Purifying Respirators Data Sheet 2

Lens Fogging of Full Facepiece CBRN Air-Purifying Respirators Data Sheet 2 of 2

NIOSH Application No._____ Date: _____

Name of Manufacturer: _____

Respirator Type/Model Number: _____

Requirement: Average visual acuity scores for each test participant shall be greater than or equal to 75 points. In addition, no individual VAS score shall be less than 70 points for any of the participants.

Results:

1. Subject: _____; Test Item #_____; Chamber Temp._____ ^{o}C; RH_____%

Task Lighting Requirement:30-50 foot-candles	
Area	Foot-candles
Antechamber Room	
Environmental Chamber	

Time	Visual Acuity Score
Initial Chamber Entry don (VAS #1)	
Post 5-min walk (VAS #2)	
End of exercise (VAS #3)	
Average VAS	

Comments: _____

_____

2. Subject: _____; Test Item #_____; Chamber Temp._____ ^{o}C; RH_____%

Task Lighting Requirement:30-50 foot-candles	
Area	Foot-candles
Antechamber Room	
Environmental Chamber	

Time	Visual Acuity Score
Initial Chamber Entry don (VAS #1)	
Post 5-min walk (VAS #2)	
End of exercise (VAS #3)	
Average VAS	

Comments:

_____

_____

Overall Comments_____

PASS ☐ FAIL ☐

Test administrator signature: _____ Date: _____

Laboratory supervisor signature: _____ Date: _____

Revision History

Revision	Date	Reason for Revision
0	21 September 2004	Historic document
1.1	22 December 2005	Update header and format No changes to method
1.2	25 July 2006	Section 7.3 Clarifications to identification of Technology Evaluation Branch Chief, requirement for no individual VAS to fall below 70 added to both data sheets, minor editorial corrections
1.3	12 November 2008	Document renamed from CET-APRS-STP-CBRN-0314, Format changes including addition of Section 8 – No changes to method