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-0454	Revision: 1.1	Date: 22 December 2005

DETERMINATION OF HUMAN SUBJECT BREATHING GAS (HSBG) CONCENTRATIONS (CARBON DIOXIDE AND OXYGEN) FOR CHEMICAL, BIOLOGICAL, RADIOLOGICAL AND NUCLEAR (CBRN) AIR-PURIFYING ESCAPE RESPIRATOR STANDARD TESTING PROCEDURE (STP)

1. PURPOSE:

1.1. This test establishes the procedures for ensuring the level of respiratory protection provided by Chemical, Biological, Radiological, and Nuclear (CBRN) Air-purifying Escape Respirator (APER) requirements submitted for New 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 in 42 CFR, Part 84, Subpart G, Section 84.63(a)(c)&(d); Federal Register, Volume 60, Number 110, June 8, 1995.

1.2. The purpose of this STP is to describe the test conditions and procedures necessary to test and certify manufacturer submitted CBRN Air-Purifying Escape Respirator (APER) certification applications for NIOSH approval. A CBRN APER is a complete system including a tight fitting hooded respiratory device including (1) the proper designations required by NIOSH and the manufacturer's unique components and (2) a compatible negative pressure air-filtering device that is installed per the manufacturer's current user instructions. The STP is used to evaluate the concentration of inspired carbon dioxide gas at the mouth, which will be continuously monitored, calculate the average concentration during the inhalation portion of the breathing cycle, and insure that the level does not exceed the limits in paragraph 6.2.2 while worn by a human test subject breathing at a standing state and while walking briskly at 3.5 mph on a treadmill. During the walking and standing period, the inspired carbon dioxide gas and oxygen levels will be continuously monitored by medical gas analyzers remotely sensing internal levels of the tested APER and recorded on-line. The requirement for this STP is to ensure that all CBRN APER, seeking NIOSH CBRN approval, have:

1.2.1. Good self-donning face-fitting characteristics that can accommodate a wide variety of facial sizes and shapes.

1.2.2. User instructions for donning that are easily understood, applicable to all components, both visual and written, and current.

1.2.3. Achieved a pass or fail result based on completing the breathing gas trials as determined by appropriate pass criteria as stated in the APER statement of standard.

Approvals:	1st Level	2nd Level	3rd Level

1.2.4. Been evaluated on a panel of 12 test subjects having facial sizes and shapes that approximate the distribution of sizes and shapes of the general applicable statement of standard user population.

2. GENERAL:

2.1. This document describes the Human Subject Breathing Gas Concentrations for the CBRN hood type APER in sufficient detail that a team of persons knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the test, and determine whether or not the APER passes the specified test. The procedure is a separate test under the NIOSH/NPPTL Respirator Branch heading of CET-CBRN-ESCAPE-STP-0454 for the concentration of inspired carbon dioxide gas at the mouth and the calculated average concentration during the inhalation portion of the breathing cycle. The procedure is designed to rigorously test the evaluated APER on a human test subject as a dynamic respiratory protective system and generate repeatable, independent pass or fail results under defined laboratory conditions.

2.2. This test is considered a human factors test that requires participation of 12 human subjects to quantify the Human Subject Breathing Gas (HSBG) concentrations required of the CBRN APER statement of standard. The successful completion of NIOSH/NPPPTL designated Breathing Machine Test requirements specific for the type of APER being considered for breathing gas testing must be shown before HSBG testing commences on the submitted APER.

2.3. This STP shall be used to test several different types of CBRN hood type APER for satisfactory Human Subject BG performance. The hood type CBRN APER include, but are not limited to: Full Facepiece, oral/nasal cup, and mouthpiece with nose clip.

3. TEST EQUIPMENT / TEST ITEMS/ HUMAN SUBJECTS

3.1. The list of necessary test equipment and materials follows:

3.1.1. Trackmaster TM 500E treadmill (JAS Manufacturing) or equivalent. Figure 1 illustrates a treadmill machine that test subjects will use to perform the exercise indicated in this STP.

Figure 1. Trackmaster TM 500E Treadmill (JAS Manufacturing)

3.1.2. Communications. A means of providing two-way communication between the test subject(s) and the test conductor(s) shall be provided. Non-verbal communication between test subjects wearing the hood and attending laboratory technicians is acceptable.

3.1.3. Facial Size Measurement, Calipers or equivalent. Calipers and measuring tapes shall be used to measure the test participants to the requirements identified in Appendix A. Examples of calipers are sliding measurement calipers, Seritex model GPM 104, 0-200 mm length, or spreading measurement calipers, Seritex model GPM 106, 0 – 300 mm width. See figure 2, Facial Size Measurement Calipers. Measurement tape shall have millimeters as the smallest increment of measure. Figure 3 is an example of software available to manage the panel test measurements and placement of subjects.

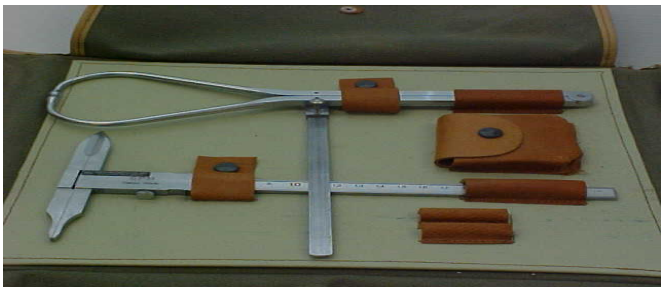


Figure 2, Facial Size Measurement Calipers

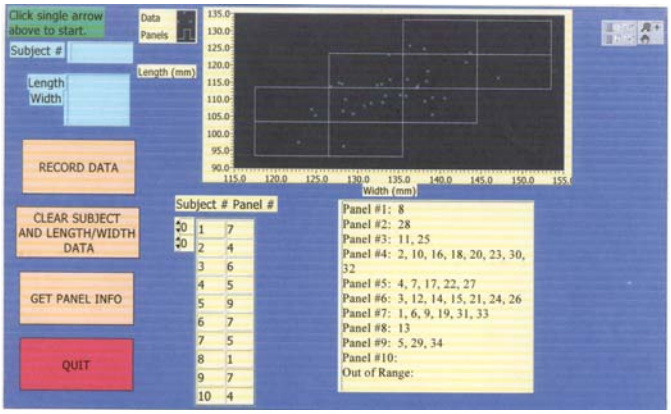


Figure 3, Sample LANL Panel Calibration Software

3.1.4. PC-Based Data Acquisition System: A PC-based data acquisition system consisting of a National Instruments AT-MIO-16E-2 DAQ board, an SCXI-1122 isolated analog multiplexer module and a customized LabVIEW software application will be used to record breath-by-breath fractional concentrations of respired carbon dioxide and oxygen. The system records1500 samples/channel at a rate of 50 Hz. Equivalent data acquisition hardware and software products, as well as hardcopy recordings of breath-by-breath samples with high-speed chart recorders, are permitted as long as an equivalent resolution of the data is achieved.

3.1.5. Perkin-Elmer MGA model 1100 or equivalent. Medical Gas analyzer with calibrated sampling line used to measure fractional concentrations of respired carbon dioxide and oxygen levels. Oxygen level range- 0-100%. Carbon dioxide level range- 0-20%. Figures 4 and 5 represent a typical gas analyzer.

Figure 4. MGA-1100 Gas Analyzer, close up

Figure 5, MGA-1100 Full View

3.1.6. Facepiece Probes. TSI fit test probes model 8025-N95 or equivalent. The probes shall not interfere with the fit or function of the respirator. Figure 6a, below is an interior view of a sample APER probed using alternative probes and location due to respirator design. Figure 6b, below is an interior view of a sample APER probed in the oral nasal region of the nose cup.

Figure 6a, Sample Exterior APER Probe (alternative method)

Figure 6b, Sample Exterior APER Probe

Figure 7, Sample Interior APER Probe

3.2. Required CBRN APER Test Items:

3.2.1. Test APER Hoods. Each applicant shall provide 12 hooded APER of production quality for HSBG testing, in the NIOSH agreed configuration, in each size according to the testing requirements set forth in Appendix A of this STP. An additional 12 APER units will also be required for submission for user training. User instructions for self-donning and system attachments or other hardware are required for each APER submitted for testing. Test factors such as weight of accessories, weight of critical components, type of head harness used and identical LAT configuration tested must be adhered to. A total of Twenty-four (24) APER are required if one universal size is tested, Twenty-four (24) APER if two sizes (12 Small/Medium and 12 Medium/Large) are tested, and Twenty-four (24) APER if three sizes (8 Small, 8 Medium and 8 Large) are submitted per manufacturer sizing instructions specified in applicable APER user instructions.

3.3. Human Factors:

3.3.1. Test Subjects. Twelve human test subjects are required for this test. All procedures and requirements specified in the NIOSH Human Subject Review Board (HSRB) Protocol HSRB-04-NPPTL-01XP entitled, “Determination of Breathing Gas Concentrations for Chemical, Biological, Radiological and Nuclear (CBRN) Air-purifying Escape Respirator (APER) Submitted for NIOSH Certification” shall be followed and met. 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-04-NPPTL-01XP. The test subjects shall be subjected to medical assessments as defined in HSRB-04-NPPTL-01XP and supplemental facial measurements. The caliper and measuring tape facial/neck measurements shall be used to determine facial size and panel placement prior to each test subject donning a new type of

APER or new manufacturer application.

3.3.2. Test Administrator(s). Shall have successfully completed the CDC/ATSDR Scientific Ethics Training, the DHHS/NIH Human Participant Protections Education for Research Teams or an equivalent NIOSH sanctioned course. Note: The NIOSH Human Subject Review Board will determine if specific courses not stated above are equivalent.

4. TESTING REQUIREMENTS AND CONDITIONS:

4.1. Calibration. Prior to beginning any testing, all measuring equipment utilized for final measurements as part of this testing must have been calibrated within the preceding 12 months, or as specified by the equipment manufacturer, using a method traceable to the National Institute of Standards and Technology (NIST). Equipment calibration records shall be available for examination at each testing facility. Laboratory technicians will check calibration prior to the conduct of the testing. A statement that all test equipment is within calibration shall be attested by the lab technician on each NIOSH test report.

4.2. Safety. Normal laboratory safety practices must be observed. This includes safety precautions described in the current NIOSH Bruceton Research Center Laboratory Safety Manual or site-specific procedures that are applicable to health and safety requirements.

4.3. Certification Inventory. Test facility personnel will confirm that the model of APER hood submitted for HSBG testing is the same model and configuration as submitted under the NIOSH application for certification with the required accessories as defined by the manufacturer and successfully live agent tested. Part number inspection, location and referencing must be accurate and complete before test begins. Any accessories that affect form, fit, function, or provide a protective quality shall be installed on the APER hood and subject to HSBG testing. Facility personnel are required to keep a certification inventory, when complete, prior to HSBG commencing. Individual manufacturer APER equipment stocks are required to be separated & covered between manufacturers.

4.4. Probing. Each APER hood shall be probed and verified functional prior to issue to test subjects by lab personnel for purposes of measuring concentrations of carbon dioxide and oxygen inside the oral nasal region in accordance with paragraph 3.1.6 of this STP. For those APER without nose cups defining the oral nasal region, the sampling probe must still extend into the breathing zone or directly in the path of the inhaled air. The test facility administrator or the facility staff shall be responsible for probing all the APER. The APER sampling location shall be in the oral/nasal region if the APER has a nose cup. The optimum sampling oral/nasal probe position is approximately 1/4 inch from the skin at the point of quadrilateral symmetry of the mouth and nose, i.e. midway between the nose and upper lip. The exact final position of the sample probes will depend upon the design of the APER being evaluated and will be as close as practically possible to the optimal location as stated above. The testing personnel will ensure that the probe is not in contact with the subject or any part of the APER. A second probe will be installed in the same general area to monitor the pressure in the respirator to facilitate the determination of the beginning of the inhalation portion of each breath.

4.5. User Instructions. Prior to conducting the test, the Users Instructions provided with the test equipment shall be reviewed by the test facility personnel and the test subjects. Test subjects will be taught by the principal investigator or a facility representative on the areas of manufacturer's size selection, donning, fit check, doffing, and other fitting procedures for the APER hood, in order to represent any training prescribed or offered by the manufacture's instructions. Any clarifications or supplemental instructions provided by manufacturer representatives at the time of certification inventory, during the test or after the test must be NIOSH reviewed prior to incorporation into revised User Instructions before final NIOSH approval is granted.

4.6. Self Donning. Each test subject shall perform an unassisted donning of the APER hood in accordance with the manufacturer's instructions prior to beginning the HSBG test. Each test subject conducting self –donning under supervision of test facility personnel is permitted time to make the appropriate adjustments to the hood until they are satisfied that they are wearing the hood in compliance with the manufacturer's Users Instructions prior to testing. Self-Donning relies on the clarity of the user instructions addressing, if applicable, head harness pull-tab sequence, faceblank orientation and other APER component orientations.

4.7. Air Flow Sampling. Air shall be sampled out of the respirator oral nasal region at a minimum rate of 240ml/min. The method in which the sampling probe is installed shall not interfere with APER performance and shall minimize sampling biases.

4.8. HSBG Exposure Conditions:

4.8.1. Temperature Range = 68-80 ^{o}F

4.8.2. Relative Humidity Range = 50 $\pm$ 10 %

5. PROCEDURE:

Note: Paragraph 3 of this STP contains examples of HSBG test equipment and select manufacturer's APER. Review the manufacturer's operation and maintenance manuals for calibration instructions, operational use, and maintenance procedures prior to commencing this STP.

5.1. General. This procedure describes the Human Subject Breathing Gas (HSBG) performance test for ensuring that the level of carbon dioxide retained in the breathing zone of the CBRN hood type Air-Purifying Escape Respirator (APER) meets or exceeds the requirements defined in the Statement of Standard for that particular CBRN APER being tested. Refer to the current Statement of Standard for the CBRN APER being tested for specific data. This procedure describes the required sample size, test equipment, data collection methods, human use protocol requirements, and the specific performance requirement for APER being tested.

5.2. Number of Test Samples.

5.2.1. See paragraph 3.2.1 and Appendix A of this STP for specific subject quantity and

test panel requirements.

5.2.2. All CBRN APER shall be individually numbered with an indelible pen or tagged in a sequence that the number can be correlated to the NIOSH application number (TN), manufacturer, and administrative sequence number so it can be tracked throughout the HSBG test.

5.2.3. The administrative sequence numbers are replicated in the test summary data sheets and indicate product performance per the stated requirement.

5.3. Test Equipment:

5.3.1. Test facility staff will install the sampling probe, in accordance with paragraph 4.4 of this STP, in each facepiece submitted under the applicable NIOSH TN and verify the integrity of probes before physical testing is initiated. A calibrated length of tubing specific to the MGA will be used to connect the sample probe in the APER to the gas analyzers.

5.3.2. Probes that do not clearly enter the oral nasal region, penetrate just the eye lens without penetrating the oral/nasal nose cup, penetrate through a faceblank molded seam creating a possible seal leak, or enter the nose cup but are blocked by internal respirator parts are considered inadequate test probes.

5.3.3. Electronic or manual caliper measurements shall be used to determine facial size and panel placement prior to each test subject donning a new type of APER or starting a new manufacturer APER application. Additionally the subject's neck and head circumference will be taken for panel placement prior to testing using a measuring tape in millimeters.

5.4. Conducting the BG Test:

5.4.1. Panels: Test subjects shall be selected to cover all the cells within the panel referenced in Appendix A. Each HSBG test shall consist of one trial per exercise, standing or walking at 3.5 mph. A minimum of 4 data points shall be collected from the self-donnings by test subjects of each facepiece size of each APER submitted to NIOSH, as prescribed in Appendix A. At a minimum, anthropometrical measurements of face length (Menton-Nasal Root Depression or Menton-Sellion), face width (Bizygomatic diameter), head circumference, and neck circumference shall be taken for facepiece size determination per HSBG. The test subject anthropometrical panel results must fall into the panel box requirements outlined in Appendix A. These results determine what size APER is issued to the test subject, if multiple sizes are available. Those test subjects that are determined to be on the border line between various indicated panel cells must be re-measured prior to HSBG testing starting and confirmed what panel box they fall into. For those cases, were a test subject is rated in a dual size category panel box (M/L or S/M), the use of expert sizing by test facility personnel is required to determine what size is initially tested twice. If test subjects fail one dual size category twice, test facility personnel are authorized to

resize the individual if panel test subject availability is in demand.

5.4.2. Training. The training APER hoods shall be properly sized, if applicable, and assigned to clean-shaven test subjects by trained test facility personnel. Prior to BG testing, test subject training will be conducted by test facility personnel based on the manufacturer's NIOSH recognized Users Instructions. Procedures for doffing, trouble shooting, negative seal checks, and head harness tightening must be taught to test subjects by test facility personnel if the manufacture's instructions provide for or require training. Manufacturers may request the opportunity to observe HSBG testing of their equipment, with prior notification to NIOSH/NPPTL. After initial instruction each test subject shall practice donning (15 minutes) and wearing the training APER continuously for a minimum of ten (10) minutes. Test subjects do not attach critical components to the APER. Test facility personnel attach all critical components, per the manufacturer's user instructions. The instruction period will be a minimum of 10 minutes and a maximum of 30 minutes. All test subjects shall be trained in accordance with the manufacturer's instructions. Monitoring of training time and training subjects is required to ensure effective instruction and follow on actions are performed correctly.

5.4.4. BG Exercises. The HSBG test consists of two exercises. The first is standing in place for ten minutes. Upon Completion of the first exercise the subjects will take an intermission, until the subject is prepared to continue, with the respirator doffed. Prior to beginning the second exercise the subjects will re-don the same respirator. The second test is walking briskly at 3.5 mph for ten minutes on a treadmill. The exercise routine listed below shall be used to determine the levels of carbon dioxide and oxygen in the breathing zone of the APER while the respirator is worn. Either of the two exercises may be performed first.

5.4.4.1. Standing in Place: In a normal standing position, the subject shall breathe normally while wearing the APER for ten (10) minutes.

5.4.4.2. Rest: The APER shall be removed and the subject shall rest quietly in a seated position for a period of at least one minute or until subject is prepared to continue with the test.

5.4.4.3. Walking at 3.5 mph: The subject shall don the APER and walk briskly at a pace of 3.5 mph for 10 minutes. Test staff will ensure sample lines are not restricting movement during the walking.

5.4.5. At the conclusion of a complete exercise session of standing and walking, test subjects shall doff the APER. Standing and walking conditions shall be randomly administered and always be separated by a ten minute resting period.

5.4.6. All comments and observations by test subjects, which are voluntary, will be written on the test data sheet.

5.4.7. If an APER is identified as a failure upon trial termination, prior to data analysis, test facility personnel will conduct failure assessment protocol of the APER in two phases. First phase is to inspect the APER while it is still donned on the test subject. Second phase is to inspect the APER when it is doffed. Post test failure analysis should consist of inspection of the test subjects eye to eye lens positioning, head harness positioning, head harness strap twists, nose cup scrunched up on face, hair in the faceblank seal area, canister not on securely, probe lose, missing or on a molded seal or surface causing seal gap or any other case dependent situations. If noted deficiencies are confirmed with the APER being improperly probed, reassign another like, but serviceable APER to the test subject and retest for two complete trials. If the APER has a serviceable probe but continues to fail, log it as a HSBG failure. Probe failures such as ripped faceblank material or inadequate probe sealing areas are cause for reanalysis of the determined probe entry point. If an APER is identified as a failure after data analysis the APER will be inspected according to the second phase of the post test analysis as well as a possible redonning of the respirator by the subject if still available.

6. PASS/FAIL CRITERIA

6.2. This test establishes the standard procedure for ensuring the following:

6.2.1 The criterion for conduct of this test is set forth in 42 CFR, Part 84, Subpart G, Section 84.63 (a, c, and d) Volume 60, Number 110, June 8, 1995 and applicable RPD current statement of standards in final approved form. Each respirator and respirator component shall when tested by the applicant and by the Institute, meet the applicable requirements set forth in 42 CFR Part 84, subparts G, I, K, and applicable portions of L, N and KK. All applicable manufacturer user instructions that address seal enhancement kits and other critical seal components/tasks must be clearly depicted in final NIOSH approved documents and present during testing.

6.2.1.1 In addition to the stated requirements NIOSH/NPPTL 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 CBRN atmospheres.

6.2.1.2 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.

6.2.1 CBRN ESCAPE APER: The average inhaled carbon dioxide level recording at each minute of testing during minutes six (6) through ten (10) shall not exceed 0.025 (or 2.5%) for a hood with a service life of 15 or 30 minutes and 0.020 (or 2.0%) for a hood with a service life of 45 or 60 minutes. The measured oxygen

levels at the end of inspiration will not fall below 0.195 (or 19.5%) during the same measurement periods for carbon dioxide assessment. For 95% of the tests the preceding two trials must be evaluated as passing. Should a group of test subjects result in a BG tests where less than 95% of trials have passing results, one additional run of test trials consisting of 12 test subjects may be preformed to increase the total number of trials; the total number of trials will be the sum of trials from the first and second run of subjects. All trials shall be considered in the practical performance criteria, see STP CET-CBRN-ESCAPE-STP-0456 entitled "Practical performance level test."

6.2.2 Data analysis will be conducted following the test in the following method. The data will be collected for the final 30 seconds of each of the last 5 minutes in each portion of the test, walking and standing. The inhalation portion of each complete breathe in the collection period of each minute will be averaged. Then the averages for each minute will be averaged and the final value must pass the pass/fail criteria for each exercise, standing and walking.

7. RECORDS\TEST SHEETS

7.1. All test data will be recorded on the HUMAN SUBJECT BREATHING GAS (CO_2 O_2), PERFORMANCE TEST FOR CBRN HOOD TYPE AIR-PURIFYING ESCAPE RESPIRATOR test data sheets (See Appendix C.)

7.2. All test data will be recorded on the PRACTICAL PEFORMANCE LEVEL TEST data sheets (See Appendix C.). For evaluation methods of the PP Level test refer to STP CET-CBRN-ESCAPE-STP-0456 titled "Practical Performance Level test."

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

7.4. All equipment failing any portion of this test will be handled as follows;

7.4.1. If the failure occurs on a new certification application, or extension of approval application, the Test Facility Manager (Principal Investigator or designee) will send a test report to the NIOSH Certification Evaluation and Testing (CET) Section Chief and prepare the hardware for return to the manufacturer.

7.4.2. If the failure occurs on hardware examined under an Off-the-Shelf Audit, the hardware will be examined by a laboratory technician and the CET Section 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 CET Section Chief, or his designee, following the standard operating procedures outlined in Procedure for Scheduling, and Processing Post-Certification Product Audits, RB-SOP-005-00.

7.4.3. If an APER fails the criteria specified in Para 6.0 of this STP, ensure all measures are taken to ascertain the reason/cause for failure, conduct all post test

inspections in accordance with Para 5.8 of this STP that support the accuracy of the reported failure and provide NIOSH with written Test Incident Reports (TIR), digital photos of assessment and recommendations as required.

Appendix A
CBRN APER and SCER BG STP-0454

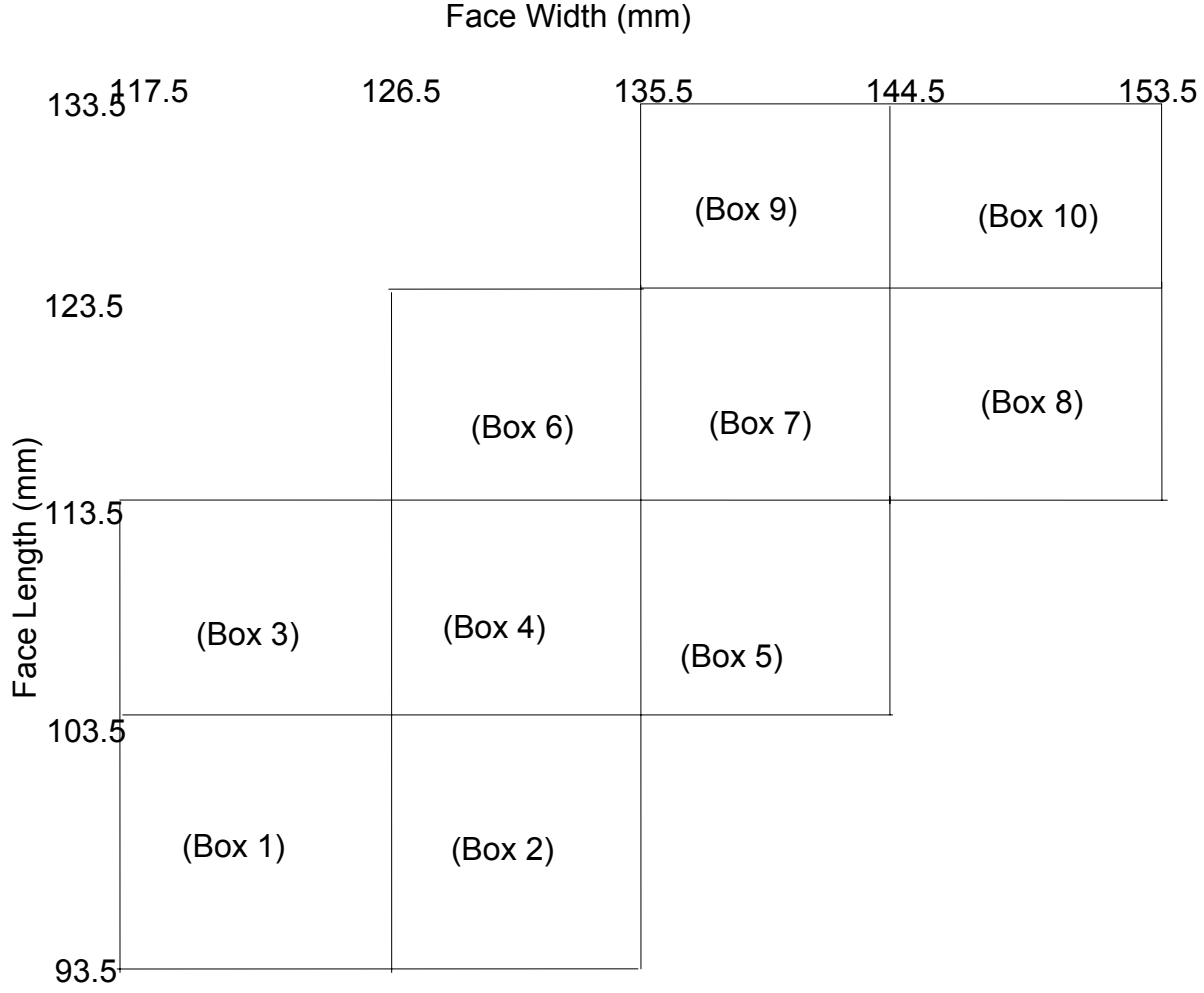
APER Human Subject Breathing Gas (HSBG) Test Panel

	Small	Medium	Large
Face Length and Face Width	**Cell A** **Use LANL boxes 1, 2, 3, 4 (2 or 3 subjects each box, 2 trials per subject)** Subjects= 4 Tests= 8	**Cell D** **Use LANL boxes 3, 4, 5, 6, 7, 8; panel size 17 (2 or 3 subjects each box, 2 trials per subject)** Subjects= 4 Tests= 8	**Cell G** **Use LANL boxes 7, 8, 9, 10; panel size 11 (2 or 3 subjects each box, 2 trials per subject)** Subjects= 4 Tests= 8
Head Circumference	**Cell B** **N/A** Subjects= 0 Tests= 0	**Cell E** **N/A** Subjects= 0 Tests= 0	**Cell H** **570-603 mm** Subjects= 2 min Tests= 4 min
Neck Circumference	**Cell C** **306-378 mm** Subjects= 2 min Tests= 4 min	**Cell F** **355-403 mm** Subjects= 2 min Tests= 4 min	**Cell I** **378-451 mm** Subjects= 2 min Tests= 4 min

Table 1.—Test sizing criteria

Test Subject, Member Panel for
HSBG Testing of NIOSH CBRN Hood Type APER

One Size Fits All/Universal LANL Panel



25 Test Subject, One Size/Universal LANL, Member Panel for
Testing of NIOSH CBRN APER

Appendix B
CBRN HSBG PASS/FAIL CRITERIA

Where the service time is	Maximum time-weighted average fractional concentration of inspired carbon dioxide
15 min or 30 min	0.025 (or 2.5%)
45 min or 60 min	0.020 (or 2.0%)

Table 2.—Inspired carbon dioxide limits

PASS/FAIL Criteria: Whenever a full panel of sizes 1 through 10 is used to evaluate a one-size-fits-all CBRN APER hood, 0 failures will be allowed, depending on number of subjects. The same number of failures will be allowed for the two facepiece sizes and three facepiece sizes. This is because, when a 12 person panel size is used consisting of all 10 facial sizes, one failure would not meet the 95% pass rate. When a small sample size is used (<30), statistical analysis is not practical. If more than three sizes are submitted, NIOSH will determine which sizes to test based on manufacturer recommendations. If sizing enhancement tools or products are used to maintain user seal, these products must demonstrate LAT passing criteria in accordance with applicable APER LAT STP. NOTES: Some panel members may be the same individuals in a dual role filling the cell requirements of 2 panels for the facepiece sizes. The data for each test subject donning (sample) are judged individually against the pass/fail criteria.

Appendix C

CBRN APER HSBG Test Data Sheet
CBRN APER PP Observation Sheet

Human Subject BG for CBRN APER Test Data Sheet

Task Number: **STP No:** CET-CBRN-ESCAPE-STP-0454

Manufacturer: **Reference No:**

Test: Human Subject Breathing Gas Test
for CBRN Air-Purifying Escape Respirators (SCER)

Model Number:

Trade Name:

Facepiece/
Part Number:

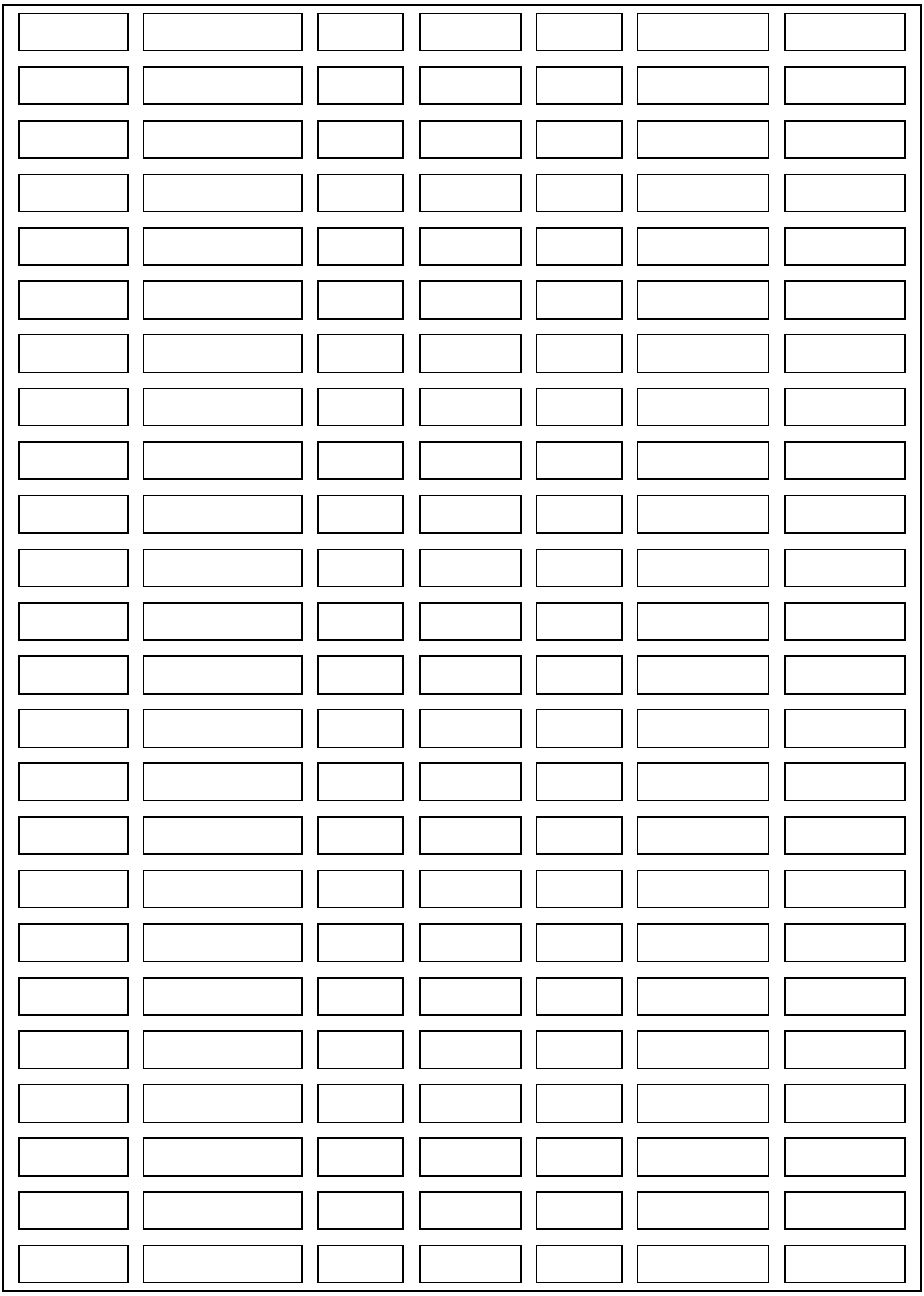
Test Temperature:

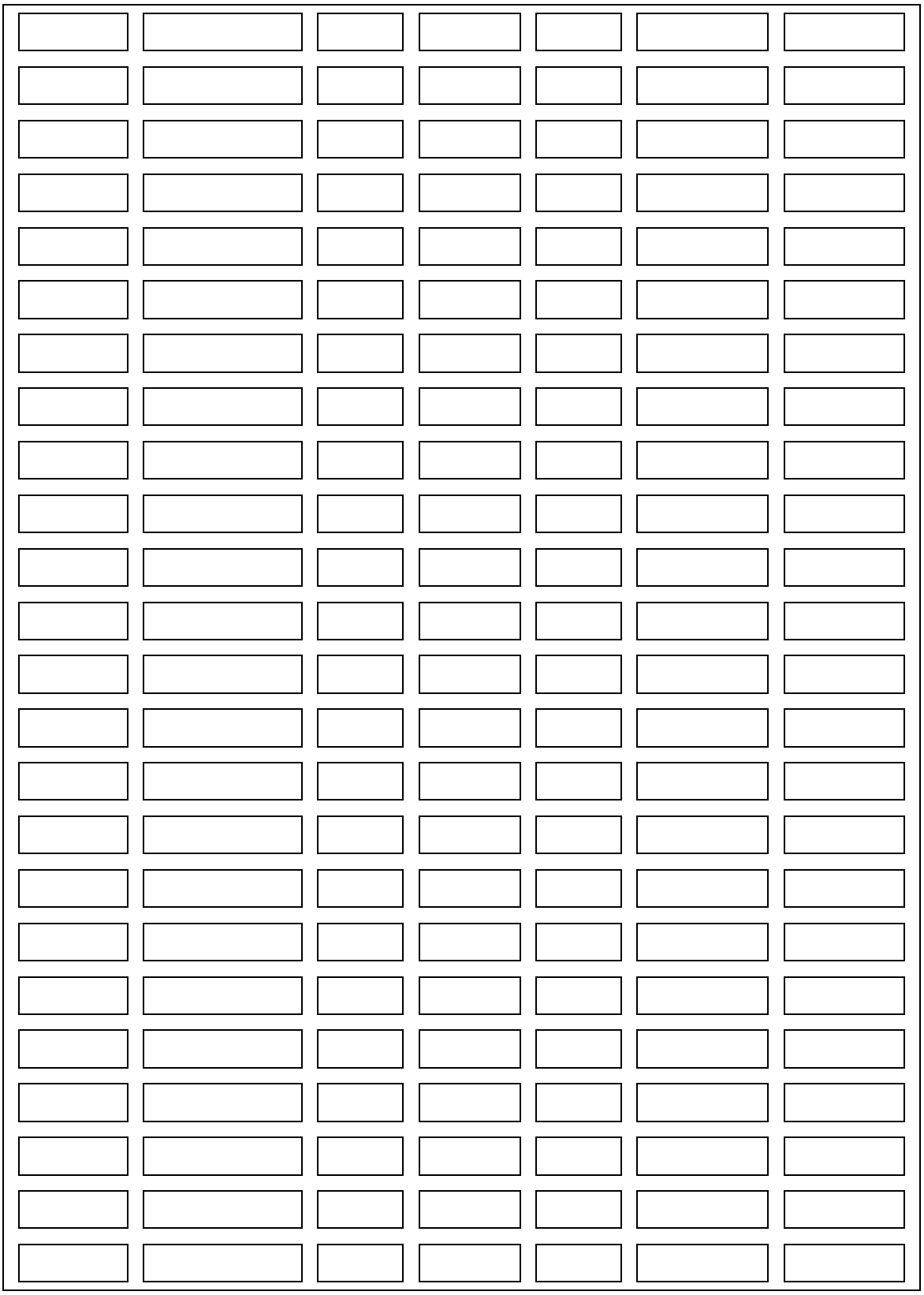
Relative Humidity:

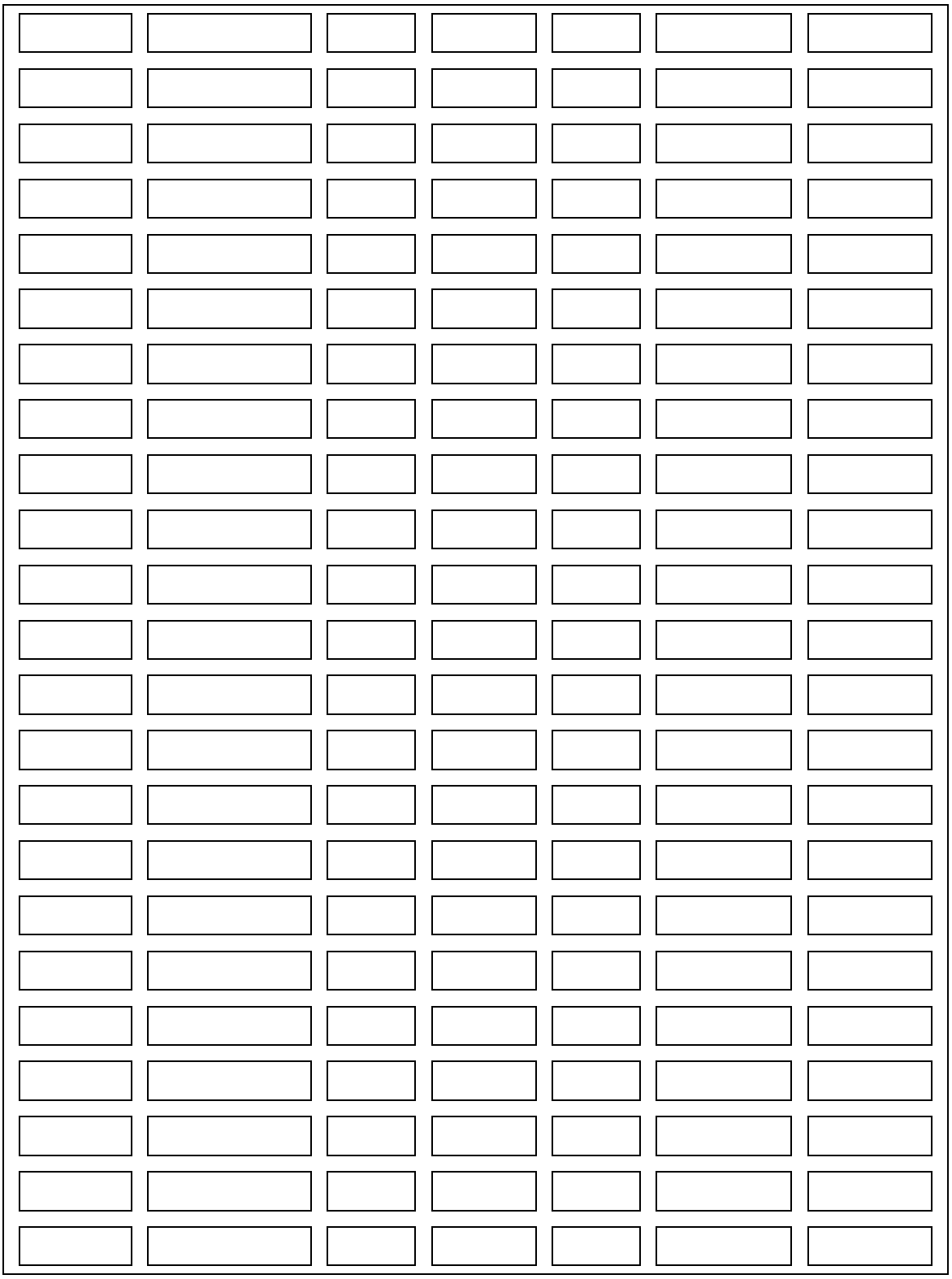
Facepiece Size:

NIOSH Approval Numbers	

Test Subject No	Test Subject Identification & Hood Size	BG Box #	O_2 Level	CO_2 Level	Practical Performance Pass/Fail	Reason for Failure







Overall Pass Percentage: % **Overall Result:**

Practical Performance: **Total Pass--____** **Total Fail--____**

Requirement:

Each CBRN Air-Purifying Escape Respirator (APER) will be worn in an atmosphere resembling a standard atmosphere's oxygen and carbon dioxide levels, while completing the specified exercises. The minimum Oxygen level in the breathing zone is 19.5% and the maximum Carbon Dioxide level in the breathing zone is 2.5% for 15-30 minute respirators and 2.0% for 45-60 minute respirators throughout the entire test. The breathing gas quantities will be evaluated in accordance with Procedure No. CET-CBRN-ESCAPE-STP-0454. Each wearer shall not be subjected to any undue discomfort or encumbrance because of the fit, air delivery, or other features of the respirator during the testing period.

Was all equipment verified to be in calibration throughout all testing?	Yes	No

Were the part numbers verified against the hardware?	Yes	No

(NAR – Non-Applicable Research Data)

Pass Percentages	**BG Levels**	**Results**
=> 19.5/19.5%	O_2	
<= 0.025/0.02%	CO_2	

Comments:

Signature: _____ Date: _____

Laboratory Technician

Concurrence:

Laboratory Supervisor

Data Sheet A, Practical Performance Level Observation Data Sheet (Page 1 of 2)

NOTE: (Use this sheet during the LRPL TEST and THE HUMAN SUBJECT BREATHING GAS TEST)

NIOSH Procedure Number: _____

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: _____ **STP No.:** CET-CBRN-ESCAPE-STP-0456

Manufacturer: _____ **Reference No.:** 42 CFR 84.63 (a)(c)(d)

Test: Determination of Practical Performance Level for Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator (APER) and Self-Contained Escape Respirator (SCER) Standard Testing Procedure (STP)

During which test is Practical Performance being evaluated (circle)?

LRPL Human Subject Breathing Gas Testing

Model Number: _____

Trade Name: _____

NIOSH Approval Numbers	

Escape Hood Respirator Type (circle):
APER SCER

Date of Evaluation_____

Test Subject Number	Test Subject Identification	Hood Size	LRPL Panel Cell #	Human Subject Breathing Gas Testing LANL Panel Cell #	Check here if Practical Performance Passed	Check here if Practical Performance Failed	Reason for Practical Performance Failure

Data Sheet A, Practical Performance Level Observation Data Sheet (Page 2 of 2)

Test Subject Number	Test Subject Identification	Hood Size	LRPL Panel Cell #	Human Subject Breathing Gas Testing LANL Panel Cell #	Check here if Practical Performance Passed	Check here if Practical Performance Failed	Reason for Practical Performance Failure

Total Pass	Total Fail

Enter Total Pass and Total Fail Results on Data Sheet B, Master Practical Performance Data Sheet

Requirement:

The Practical Performance Level of the respirator shall evaluate human interface issues associated with the use of the escape respirator. As a minimum, contributing factors (if applicable based upon the respirator design) are: the use of mouth bits and nose clips; seal of the hood around the respirator wearer's neck; seating of inner masks; position of the hood on the respirator wearer's head; and strength required to don the respirator.

The pass criteria for the Practical Performance requirement shall be that ≥ 95% of the total trials from the Human Subject Breathing Gas Test and Laboratory Respirator Protection Level (LRPL) Test demonstrate acceptable Practical Performance.

If the ≥ 95 % requirement is not met for Practical Performance, the Human Subject Breathing Gas test and / or the LRPL test may be run a second time to increase the total amount of trials for evaluating the Practical Performance Level.

1) Each test (the Human Subject Breathing Gas Test and / or the LRPL Test) may be rerun only one time.
2) If tests are rerun, the total number of trials used to evaluate the Practical Performance Level will be the total number of trials from all Human Subject Breathing Gas tests and LRPL tests. Total trials will include both the number from the original tests plus the rerun tests.
3) If the Human Subject Breathing Gas test and / or the LRPL test are rerun, the number of trials used to evaluate those individual tests will be the sum of trials from the original test plus the rerun test.

Was all equipment verified to be in calibration throughout all testing? Yes No

Were all part numbers verified against the hardware? Yes No

Appendix D

Breathing Gas Performance Evaluation

For Chemical, Biological, Radiological and Nuclear RPD Evaluations

Medical Screening and Test Subject Consent Forms

To be Published

Revision History

Revision	Date	Reason for Revision
0	3 August 2004	Historic document
1.1	22 December 2005	Update header and format No changes to method