DETERMINATION OF BREATHING PERFORMANCE TEST FOR CBRN TIGHT FITTING POWERED AIR-PURIFYING RESPIRATOR (PAPR) STANDARD TEST PROCEDURE (STP)

1. PURPOSE:

This test establishes the procedures for ensuring the functionality of the breathing performance provided by the CBRN Breathing Performance Test, Tight Fitting Powered Air-Purifying Respirator (PAPR) requirements 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 in 42 CFR, Part 84, Subpart G, Section 84.63(a)(c)&(d); Federal Register, Volume 60, Number 110, June 8, 1995 and the Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Tight Fitting Powered Air-Purifying Respirators(PAPR) Dated ???.

2. GENERAL:

This STP describes the Determination of Breathing Performance test for the CBRN tight Fitting PAPR 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 Tight Fitting PAPR passes the specified test.

3. EQUIPMENT AND MATERIAL

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

3.1.1. Breathing Machine: Test Engineering Type BM 2-4-6-30, Breathing Machine, 40 Lpm

3.1.2. Breathing Machine: Test Engineering Type BM 2-56-6-150, Breathing Machine, 103 Lpm

3.1.3. Environmental test chamber (20-80% RH ± 5%, -30-+50 5°C) normal operating conditions. An example of an Environmental
Control System, the DataAire Model DAP-2 Environmental Control System, is shown in Figure 2.

3.1.4 Pressure Transducer: Validyne DP45-6-24 or equivalent.

3.1.5 PC-Based Data Acquisition System

3.1.6 Head Form

3.1.7 Portacount fit tester or equivalent

3.1.8 PC based audio/video monitoring system with time stamp

4. TESTING REQUIREMENTS AND CONDITIONS

4.1 This test procedure is only valid if the respirator system has first completed NIOSH Standard Test Procedure entitled Determination Of Durability Test For Environmental, Transportation And Rough Handling Conditions On Chemical Biological Radiological Nuclear (CBRN) Full-Facepiece Air-Purifying Respirators (APR) Standard Test Procedure (STP).

4.2 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).

4.3 Any laboratory using this procedure to supply certification test data to NIOSH will be subject to the provisions of the NIOSH 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 the Institute.

4.4 Precision and accuracy (P&A) must be determined for each instrument in accordance with laboratory procedures and NIOSH/NPPTL guidance. Sound practice requires, under NIOSH Manual of Analytical Methods, demonstrating a tolerance range of expected data performance of a plus or minus 25% of a 95% confidence interval of the stated standard requirement. NIOSH/NPPTL P&A tolerance can be higher but not lower.

4.5 Compressed gas cylinders must meet all applicable Department of Transportation requirements for cylinder approval as well as retesting /
4.6 Normal laboratory safety practices must be observed. This includes safety precautions described in the current NIOSH Pittsburgh Health and Safety Program.

4.6.1. Safety glasses, lab coats and hard-toe shoes must be worn at all times.

4.6.2. Workbenches must be maintained free of clutter and non-essential test equipment.

4.6.3. When handling any broken glass laboratory equipment, lab technicians and personnel must wear special gloves, which may protect against lacerations or punctures.

4.7 Please refer to Material Safety Data Sheets and the NIOSH Health and Safety Manual for the proper protection and care in handling, storing, and disposing of the chemicals and gases used in this procedure.

5. PROCEDURE:

5.1. Calibrate the pressure transducers according to SOP-003.

5.2. Set up and calibrate the breathing machine to the appropriate work rate.

5.3. Mount respirator facepiece to the headform of the appropriate size.

5.3.1. Connect remaining PAPR components including air hose, blower assembly, canisters and battery pack.

5.3.2. Perform quantitative leak test using Portacount fit tester or equivalent (Should be performed with the breathing machine functioning, but the PAPR switched off.)

5.4. Start data acquisition program.

5.4.1. Choose an appropriate file name when queried.

5.5. Set up audio/video recording equipment to monitor and record all audible and visual status messages, warnings and alarms.

5.6. Turn on PAPR.

5.6.1. Establish baseline pressure without breathing machine.
5.7. Start breathing machine.

6. **PASS/FAIL CRITERIA**

4.8.1. Temperature Range (1) = -27.5 to -32.5 °C; (2) = 22.5 to 27.5 °C.

4.8.2. Relative Humidity Range (1) = 20 ± 5 %; (2) = 50% ± 5%.

7. **RECORDS/TEST SHEETS**

7.1 All test data will be recorded on the BREATHING PERFORMANCE test data sheets (See Appendix C.).

7.2 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.

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

7.3.1 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.

7.3.2 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.

7.3.3 If a PAPR 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 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.

**RECORD OF CHANGE:**