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Procedure No. CET-APRS-STP-CBRN-0450	Revision: 1.1	Date: 22 December 2005
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DETERMINATION OF CHEMICAL AGENT PERMEATION AND PENETRATION RESISTANCE
PERFORMANCE AGAINST SARIN (GB) VAPOR OF THE CHEMICAL, BIOLOGICAL,
RADIOLOGICAL, AND NUCLEAR (CBRN) AIR-PURIFYING ESCAPE RESPIRATOR (APER)
STANDARD TEST PROCEDURE (STP)

1. PURPOSE

- 1.1. This document establishes the procedures for ensuring that the level of respiratory protection provided by the Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Escape Respirator (APER) performance requirements submitted for approval, extension of approval, or examined during certification product audits, meet the minimum certification standards set forth in this standard test procedure (STP) as prescribed by Title 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 APER applications against Sarin (GB) vapor, while the respirator is operated in dynamic mode by means of a breather pump connected to the breathing zone of a manikin headform. Instrumentation is integrated into the chamber for the purpose of generating and controlling challenge concentrations and detecting agent permeation and penetration of the respirator. This procedure is a separate test under the NIOSH NPPTL Respirator Branch, Certification, Evaluation and Testing Section (CET) heading of CET-APERS-STP-CBRN-0450 for challenge of Sarin (GB) vapor. This procedure is designed to test the respirator as a dynamic breathing system and generate repeatable results under laboratory conditions.

2. GENERAL

- 2.1 This STP describes the determination of chemical agent permeation and penetration against Sarin (GB) vapor of the chemical, biological, radiological, and nuclear (CBRN) air-purifying escape respirator (APER) test in sufficient detail to conduct the test and determine whether or not the product passes the test

Approvals:	<u>1st</u> Level	<u>2nd</u> Level	<u>3rd</u> Level
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- 2.2 Any laboratory using this procedure to supply certification test data to NIOSH/NPPTL is subject to the provisions of the NIOSH Supplier Qualification Program (SQP). This program is based on the tenets of ISO/IEC Procedure 17025, the NIOSH Manual of Analytical Methods (NMAM) and other appropriate NIOSH and NIOSH/NPPTL guidelines. An initial complete quality system audit and follow on audits are requirements of the SQP. Additional details of the SQP and its requirements can be obtained directly from NIOSH/NPPTL.

3. EQUIPMENT

- 3.1. **SiMulant Agent Resistant Test MANikin (SMARTMAN)**, manufactured by ILC Dover, Frederica, DE or equivalent. The **SiMulant Agent Resistant Test MANikin (SMARTMAN)** is a cast zinc, hollow shell headform representing a medium sized human male head, neck, shoulders and upper chest stature. The head features are eyes, nose, ears, mouth orifice, forehead and chin. The features are on a movable section of the head to facilitate installing and removing a peripheral front face seal, which is made of silicone rubber and fits into a channel between the face and the permanent part of the head. The seal is inflated to press against the inside of the facepiece seal area to assure against leakage. A face seal adjustment handle allows standard mechanical pressure to be exerted for securing the face seal. The surface of the face of the SMARTMAN is connected in several places to outside sampling ports by means of stainless steel tubing that is located inside the form and passes out the bottom. The largest tube, 1¼ inch in diameter, leads from the mouth area to the breather pump. Four smaller ¼" diameter tubes are present. One tube connects to the center of the left eye; it is used to sample the ocular region. A tube connects to the lower middle forehead above the bridge of the nose; it is used to supply makeup air into the respirator, if required. There are two metal tubes protruding outward from the oral/nasal region. One is used to measure differential pressure by means of a magnehelic gauge or blocked, while the second is used to sample the oronasal region. The SMARTMAN is mounted and sealed to the floor of an exposure chamber, which is raised by four legs to allow the tubing to exit and connect to the external monitoring devices. A large channel is molded at the bottom of the SMARTMAN to allow the anchoring of respirator system shrouds as they are intended per manufacturer instructions. An illustration of the SMARTMAN is shown in Picture 1.



Picture 1. SiMulant Agent Resistant Test MANikin (SMARTMAN)

- 3.2. Leak detector Model TDA-99M, manufactured by Air Techniques, Inc. or equivalent. The TDA-99M tests the respirator for leaks by generating an aerosol that challenges the respirator, while being worn on a non-contaminated SMARTMAN. The device generates an Emery 3004 poly α -olefin aerosol. With the respirator properly installed on the SMARTMAN and the breather pump operating at the specified conditions, the TDA-99M generates a liquid particulate aerosol at a concentration of $100\text{mg}/\text{m}^3$. This aerosol is introduced by the TDA 99M's pump. The respirator interior is monitored for the presence of aerosol. The leak detector compares the concentration inside with the concentration outside, and calculates a digital percent penetration value. An illustration of the TDA-99M is shown in Picture 2.



Picture 2: Respirator Leak Detector, Model TDA-99M

- 3.3. MINIature Continuous Air Monitoring System (MINICAMS), manufactured by OI Analytical or equivalent. A Laboratory MINICAMS, as opposed to a Field MINICAMS, is used as the detector for agent penetration/permeation in a laboratory setup. It consists of a monitor, PC computer, Linear Mass Flowmeter and optional printer or recorder. The MINICAMS is a gas chromatograph equipped with a hydrogen flame emission detector and a preconcentrator tube. The preconcentrator tube is a small tube containing an adsorbent material to scrub out agent vapor contained in a sample of air drawn through it for a set time period. The tube is then heated to desorb the agent and introduce it into the column and subsequently the detector. By pre-concentrating the agent, the detection limit is lowered. The MINICAMS unique software calculates the amount of agent detected over a specified period of time. The Limit of Detection (LOD) is equal to 20% of the 8 hr Time Weighted Average for the specific chemical agent being detected. Residual contamination is the amount of challenge agent lingering in the breathing zone of the respirator when a new, clean respirator is mounted on the SMARTMAN. Residual contamination is quantified at the beginning of each test and the MINICAMS output must remain stable for a period of 60 minutes prior to the initiation of any test. Four MINICAMS are required in order to continuously monitor the oronasal and ocular regions of the interior of the respirator. An illustration of the MINICAMS is shown in Picture 3.



Picture 3: MINIature Continuous Air Monitoring System, (MINICAMS)

- 3.4. Syringe pump Model M365 manufactured by Sage or equivalent. The syringe pump is used inject liquid agent at a controlled rate into an air stream to generate a vapor challenge. The challenge concentration can be varied over a wide range to accommodate the requirements. The liquid agent is contained in a syringe connected by a flexible cannula, a small tube for insertion into a cavity or vessel, to the dilution airline. The plunger of the syringe is driven at a controlled rate by the pump to deliver a calculated constant flow of agent. The concentration of agent is adjusted by changing the speed setting of the pump. Rate Flow Range = 20.0 ml /min. to 0.3 ml/hr, Flow Accuracy = 5% Nominal. Picture 4 shows an illustration of the Sage Model M365 syringe pump.



Picture 4: Syringe pump, Sage Model M365

- 3.4. Flow-Temperature-Humidity Control System manufactured by Miller-Nelson Research, Inc or equivalent. This control system is an automated system to control the airflow,

temperature, and humidity of an air supply for an operating respirator system. Laboratory specified air and distilled water are supplied to the unit; the three sensors and controlling mechanisms are incorporated electronically, and the unit output is air of the required volume/flow (50-500 L/min), and relative humidity ($20-80 \pm 3\%$) and temperature ($20-30^{\circ}\text{C} \pm 0.3\%$). Picture 5 is an illustration of a Miller Nelson Flow-Temperature-Humidity Control System, Model HSC 401. An illustration of the Miller Nelson, Model HSC 401 is shown in Picture 5.



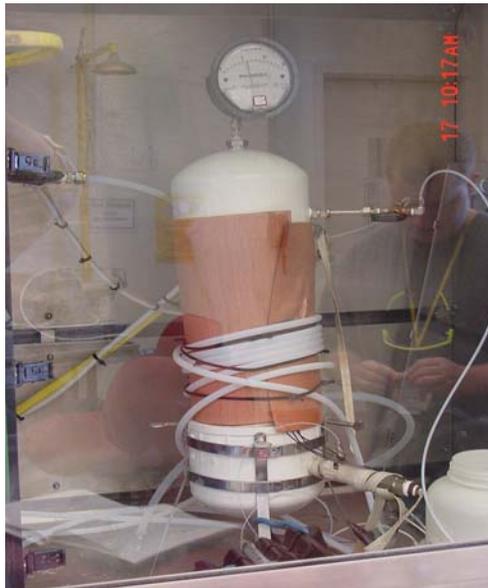
Picture 5: Miller Nelson, Model HSC 401

- 3.6. Exposure Chamber or equivalent. The respirator exposure chamber is constructed of clear, chemical resistant material (Plexiglas® or Lexan®) or other equivalent material. The floor must be constructed efficiently to support the 85-pound SMARTMAN. The front panel is removable and is held in place with clamps on each edge. The dimensions are approximately 2 ft. cubed. Four Plexiglas legs are attached to the bottom to elevate the chamber above the floor of the exhaust hood to allow room for laboratory tubing and the face adjustment handle. A M12A1 military air-purifying filter is installed on top of the chamber to filter the air that passes out of the chamber. There are ports in the sides to accommodate tubing for challenge concentration and clean purge air mixtures. An electric fan is installed near the top front to achieve a mixed challenge concentration. An Exposure Chamber is used to perform a fit and leak test on a respirator test unit. Picture 6 is an illustration of the Exposure Chamber.



Picture 6: Exposure Chamber

- 3.7. Agent Mixing Chamber or equivalent. The chamber is made of PVC with caps and three baffles for mixing of Chemical Warfare Agent (CWA) and air. A pressure gauge indicates internal mixture pressure and serves as a safety indicator. Pressure limits are indicated per laboratory SOP. A heating blanket is around the chamber to facilitate vaporization. The chamber is the primary mixing area for the agent syringe pump flow and the regulated airflow controller and generates a specified concentration of agent. When the mixture is not being passed into the exposure chamber for a test, it is passed through a scrubber M18 Filter or equivalent. Picture 7 is an illustration of a Mixing Chamber.



Picture 7: Agent Mixing chamber

- 3.8. Breather Pump, Model E1R1 manufactured by Jaeco Fluid Systems, Inc., or equivalent. The breather pump is used to replicate a constant human breathing pattern. It employs a double pump, operated by a single electric motor. The pump design is a modified variable speed motor generating varied strokes per minute. Planetary gears and a Scotch Yoke, producing a sinusoidal breathing pattern, control the pump. The sinusoidal pattern starts at zero flow rate, rises to peak flow of approximately π (3.1416) times the rated test certification flow rate in liters per minute and drops back to zero. The exhalation stroke of the pump is the same sinusoidal pattern. The volume per breath /tidal is adjustable up to 1.5 liters. Picture 8 is an illustration of the Model E1R1 Breather Pump.



Picture 8: Model E1R1 Breather Pump

- 3.9. Mass Flow Controllers, manufactured by Tylan Electronic or Brooks Instruments or equivalent. Mass flow controllers are used to control the flow of sample to the MINICAMS and the flow of laboratory air to flush out the exposure chamber when the agent challenge is removed. The mass flow controllers are sized to meet the flow requirements. Flows are controlled to $\pm 2\%$ of set point.
- 3.10. Ambient Air Analyzer, MIRAN® Model 1A or equivalent, manufactured by Thermo Environmental Instruments Inc or equivalent. The MIRAN® Model 1A is an infrared absorption based detector that uses a long path length cell up to 20 meters, into which the air sample is introduced. This analyzer is used to monitor GB challenge concentration.
- 3.11. Quantities Required for Live Agent Testing (LAT) Respirator Systems Required for Testing.
- 3.11.1. Respirator Systems Required:

Three respirators are required for this Live Agent Testing (LAT) per NIOSH Statement of Standard For Chemical, Biological, Radiological and Nuclear (CBRN) Air-Purifying Escape Respirator, September 30, 2003. One respirator shall be tested as a pre-qualifier in the “as received condition”, and two respirators shall be tested after undergoing the required Environmental Conditioning. The entire APER system shall be exposed to the GB vapor.

- 3.11.2. GB Live agent respirators should be labeled prior to actual live agent testing with the following administrative information:
- NIOSH Task Number (TN Number) from NIOSH DEIMS.
 - Model of AEPR from NIOSH DEIMS.
 - Other routine information that will allow the lab to accurately track receipt, time in test, test results, noted observations, required retest, status of testing,

disposal and trend analysis is required to be managed and available for review upon request by current representative of NIOSH/NPPTL.

- Accurate labeling of post- tested respirators is mandatory in support of post-test incident investigations.

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.

4.2. System Test Conditions:

4.2.1. Breathing Machine:

Airflow = 40 liters per minute

Respirations = 36 \pm 2 strokes per minute

Tidal Volume = 1.1 liters

4.2.2. Miller-Nelson airflow settings into exposure chamber:

Airflow Rate: The actual value here is experiment/method dependent. The value eventually used must be documented. Determine an appropriate airflow rate based upon obtaining a stable concentration, the known volume of the exposure chamber, considering the agent challenge concentration desired, volume of chamber, breather air flow, and dilution air exhaled from the APER.

Relative Humidity: 50 \pm 5% RH.

Temperature: 25 \pm 3°C

4.2.3. SMARTMAN Sampling Points:

4.2.3.1. Oronasal region sampling point is a single SMARTMAN nasal port. The tubing from the sample point is run outside the chamber, then teed to allow sequential dual MINICAMS detections.

4.2.3.2. Ocular region sampling point is similar to the oronasal region sampling configuration allowing sequential dual MINICAMS detections.

4.2.4. GB Vapor Test:

4.2.4.1. GB VAPOR: GENERAL.

- Vapor Challenge Concentration = 210 mg/m³ \pm 10%
- Vapor Challenge Time = X minutes, but no longer than X + 1 minute

X = Manufactured Rated Time of Respirator

Total Test Time = 2X.

- 4.2.4.2. Sarin (GB) agent is required to be Chemical Agent Standard Analytical Reference Material (CASARM) grade. Agent purity analysis must be NIST traceable, documented and meet CASARM agent purity requirements. Proper CASARM storage requirements per local regulation are required to be adhered to.
- 4.2.4.3. Test time will start immediately upon detection of agent in the test chamber. MINICAMSs are required to be sampling at the start of the test. GB vapor challenge time of X minutes plus X minutes of decay (no GB generation) equals the total test time (2X).
- 4.2.5. Test Termination Parameters: The termination of the GB application test is in accordance with the total vapor test duration time 2X plus the before and after test check shots. The test will be terminated to protect the detectors from over-saturation. The termination point should be set at or above the highest calibration point for each one of the MINICAMSs in use.
- 4.3. Safety and Training: Normal laboratory safety practices are required. Laboratory specific regulations such as US Army Regulation 50-6, Chemical Surety apply as required. The practices includes all safety precautions described in the current Occupational Safety & Health Facility Laboratory Safety Manual, the applicable US Army Regulations, the U.S. Army Soldiers and Biological Chemical Command Laboratory Safety Procedures, and any other equivalent manuals/periodicals.
- 4.3.1. Safety glasses, lab coats, assigned respirator and butyl gloves are required be available/worn as laboratory standard operating procedures apply.
- 4.3.2. Work and walking surfaces must be maintained free of clutter and non-essential test equipment.
- 4.3.3. When handling any laboratory glassware, laboratory personnel must wear approved gloves, which are rated appropriate in accordance with current safety and hygiene plans.
- 4.3.4. Laboratory personnel are required to be trained on this STP and documentation is required to be available for review of said training. Personnel are required to be trained and qualified per local requirements in all applicable standard operating procedures (SOP) appropriate for the test.
- 4.3.5. The laboratory personal shall be knowledgeable about the specific CBRN APER being tested. The laboratory personal must be able to properly align and fit the respirator system on the SMARTMAN headform without malformation or destruction of the APER.
- 4.3.6. All APER systems exposed to agent during testing shall be treated as hazardous materials in accordance with local laboratory testing procedures and methods. Disposal

of contaminated CBRN APER materials is the responsibility of the testing laboratory. Respirator manufacturers shall not be held accountability for APERs exposed to agent during this test in accordance with local testing lab test equipment procedures per Department of Defense HAZMAT protocol.

- 4.3.7. Surety lab procedures outlined in applicable SOPs and a controlled copy of this STP are required to be on hand. Refer to appropriate Material Safety Data Sheets, manufacturer's instructions and available current Health and Safety manuals, or other appropriate documentation for the proper protection and care in handling, storing, and disposing of the contaminated respirators, canisters, subassemblies and chemicals used in this procedure.

4.4. EQUIPMENT PRE-TEST CONDITIONS: MINICAMS

- 4.4.1. Background Reading: Once the APER is placed on the SMARTMAN, the MINICAMS are required to show steady state background readings lower than 3% of the Maximum Peak Excursion (0.522ng or 0.00261 mg/m³ {MPE=0.087 mg/m³}). This is accomplished by rinsing the head form with isopropanol or using a clean escape hood mounted on the SMARTMAN head form then allowing the test system to breathe. The live agent test (LAT) for certification is not authorized to start without the background readings of the assigned SMARTMAN system (tested respirator and headform) being within the limits specified above.
- 4.4.2. Unit of Measure. A small volume of air is drawn through a pre-concentrator tube containing an adsorbent material. GB sample volume is a laboratory determined value. Agent in the sample is adsorbed on the material. Later in the cycle the tube is heated to desorb the agent, which then flows through a gas chromatograph column to a flame emission detector. Because the total agent in the sample is detected at one time instead of continuously, the detection limit is much lower. The total quantity of agent detected is calculated back to the sample volume and is expressed as ng/L.
- 4.4.3. Sample Cycle. Operation of the MINICAMS requires the use of compressed house air, hydrogen, and nitrogen, of a high purity. The operating manual recommends operating parameters (temperature, timing, pressures, etc.) and cycle times (3, 5, 10 or 15 min.), depending on the laboratory application. CBRN APER GB analysis requires a total 4-minute cycle (2 minute sample followed by 2 minute purge per detector). The two MINICAMS are required for each of the two sampling sites and each pair must be synchronized so that one MINICAMS sampling begins when the other MINICAMS sampling ends. Raw data results confirm this requirement.
- 4.4.4. GB Detection Principle. The MINICAMS shall be installed in accordance with the operating manual and local lab SOP. The appropriate optical filter for GB must be installed in front of the photomultiplier tube. In principle, when GB burns in a hydrogen flame, a phosphorous moiety is formed that emits radiation at a unique wavelength. The optical filter isolates the radiation and allows it to

pass into the photomultiplier tube (PMT), whose output voltage is correlated with the quantity of agent burned in the flame.

4.4.5. Standardization. MINICAMS are configured in accordance with the operating manual and the specific method for the chemical warfare agent that is being used. In order to quantify the agent in the sample, the MINICAMS must be standardized. Standardization is accomplished by injecting a small quantity (1.0 or 2.0 microLiter) of a known standard solution of the agent onto the preconcentrator tube during the INJECT segment of the test cycle in accordance with MINICAM calibration SOP. The standard solutions of agent are made in isopropanol, spectrophotometric grade. At least three injections of each quantity of agent should be injected per LAT sequence.

4.4.6 Pretest activities for the MINICAMS are as follows:

- Set or verify operational parameters for appropriate agent
- Perform standardization
- Record ASCII file name on Data Sheet
- Standby for start of testing

4.5. EQUIPMENT PRE-TEST CONDITIONS: SMARTMAN GB Vapor Generation.

4.5.1. Vapor Concentration. The vapor challenge for SMARTMAN testing is generated by injecting the required quantity of liquid agent into the volume of air that passes through the exposure chamber to give the challenge in mg/m^3 . This is accomplished by a combination of controlled airflow from the Miller-Nelson Air controller and a syringe pump for injecting the agent through a heated “tee” into the air stream. Determine the volume of air needed to pass through the exposure chamber per minute (flow rate) and the quantity of agent necessary to give the specified challenge concentration for this flow rate, taking into account the volume of air discharged into the chamber from the exhalation air of the APER.

Ramp-Up Time: Conditions for each individual system will have to be determined for each laboratory setup to achieve the required ramp up time for CBRN APER exposure concentration. The ability to accurately detect and quantify this agent ramp up time is a requirement for the testing laboratory and ramp up time and agent duration exposure time graphs should be available to confirm agent exposure duration in accordance with the procedures of this STP.

Challenge Concentration Verification.

Step 1. GB Setup (Mass Balance Analysis Concept or Demonstrated Equivalent)

Exposure Chamber size = $6\text{-}8 \text{ ft}^3$

Target Vapor Challenge Concentration = $210.00 \text{ mg}/\text{m}^3 \pm 10\%$.

Ramp Up Time = 2-4 minutes (time from initial start of injection of GB air mixture to $210 \text{ mg}/\text{m}^3 \pm 10\%$, the lowest acceptable challenge concentration)

Dilution Air from Breather Pump = 40 l/m

Miller-Nelson Challenge Mixing Air = 50-90 l/m
Syringe Rate for Challenge Injection = 0.34 ml/m
Total GB expected in 15 minutes = 5.1 ml liquid

Step 2. GB test chambers are equipped with Miniature Infrared Analyzer® (MIRAN®) portable gas analyzers that measure the challenge concentrations. A MIRAN® is a single-beam infrared spectrophotometer that operates at a selected wavelength. It features a 5.6 liter gas cell that is supplied with chamber air from the recirculation system with the aid of a small air pump. MIRAN® Model 1A Setup:

Pathlength = 0.75 meters

Wavelength = 9.8 microns

Slit Width = 2.0 millimeters

Response Meter = 4 seconds

Course Zero = 1X

Range = 0 –1 Absorbance units

Note: Setting may be different depending on calibration

4.5.2. Agent Dispersion. From the pump operating manual select the syringe size and pump rate that will inject the required amount of agent per unit time. Draw up the total amount of agent needed into the syringe, with a small excess, connect one end of the cannula (the small flexible tube that is inserted into the air duct) to the syringe, and the other end to the heated tee in the air duct. Clamp the barrel of the syringe onto the pump and move the plunger drive until it contacts the end of the plunger. Turn on the power to the pump. The plunger will be activated and agent will be steadily injected into the air stream as a vapor from the heated tee. The mixture passes into the mixing chamber where it is thoroughly mixed, ready to be introduced into the exposure chamber for the test.

4.6. EQUIPMENT PRE-TEST CONDITIONS: Miller-Nelson (MN) Controller.

4.6.1. The Miller-Nelson unit receives compressed air from the laboratory house air supply system. Operate the Miller-Nelson according to the manufacturer's instructions. The sensors for relative humidity and temperature must be calibrated, as well as the flow controller, since it is important that the total flow through the test system be known in order to supply the requisite amount of agent from the syringe pump. Insure the total flow, temperature value and relative humidity values are logged in the laboratory's notebook prior to commencing each actual live agent test.

4.6.2. Set the readout panels on the Miller-Nelson according to paragraph 4.2.2. Ensure the Miller-Nelson is properly configured for current test procedure and all required airlines are secure to inlet ports of SMARTMAN and Miller Nelson systems. Allow the clean air to flow through the mixing chamber and the scrubber M18 filter until it is time to start the test.

4.7. EQUIPMENT PRE-TEST CONDITIONS: Syringe Pump.

- 4.7.1. A syringe pump is used to inject liquid agent into the dilution air stream at a controlled rate such that the concentration of agent in air is that required for the challenge specified for the test. Manual setting of the syringe pump controls allows the pump rate to be changed by using a turn knob.
 - 4.7.2. Select the size syringe that will hold sufficient agent for the challenge period and the total volume of air required. Fill the syringe to the volume determined and attach the syringe to the fitting on the flexible cannula. The cannula is normally made of plastic with Luer locks on each end. One end of the cannula is attached to the heated tee in the dilution airline. Set the syringe in the holder and clamp it in place. Move the drive block until it is firmly against the end of the plunger.
 - 4.7.3. Set the switch on the pump to the setting required for the size syringe and the injection rate. Turning on the power switch will start the drive block pushing the plunger of the syringe to begin generating the agent challenge concentration. Turning off the power switch will stop the drive block from pushing against the plunger and stop the challenge agent concentration flow at the predetermined time.
- 4.8. EQUIPMENT PRE-TEST CONDITIONS: TDA-99M Aerosol Leak Detector
- 4.8.1. The TDA-99M leak detector is used to detect liquid particulate aerosol leaks into the APER after it has been installed on the SMARTMAN headform in accordance with manufacturer's instructions. The APER is operated under negative pressure using air supplied to the APER from the Miller-Nelson. Ensure the seal, threaded interface, inlet and outlet areas and canister housing are not changed in any manner prior to or during the live agent test. Do not make any corrections for APER deformities at this time. Document all APER deformities in the laboratory notebook and take digital photos for follow up incident review if necessary.
 - 4.8.2. Turn on the power and let the leak detector equilibrate, according to the manufacturer's instructions. Then turn on the breather pump to activate the negative pressure test respirator. Connect the detector inlet to a sample line from the SMARTMAN. When aerosol is being generated, direct the probe to various portions of the APER and all mechanical seals or joints to detect any leak paths. If no localized leaks are found, replace the front panel of the exposure chamber and start the actual TDA 99M test.
 - 4.8.3. Connect the TDA-99M to a port into the exposure chamber and fill the chamber with aerosol. Maintain a constant aerosol concentration inside the exposure chamber for 30 minutes. Check the display on the TDA-99M for detection of aerosol inside the facepiece. When the detector indicates a maximum penetration of less than 0.0010 % for 30 minutes which indicates no leakage, continue with the next item in the LAT procedure; however, if 0.0010% cannot be obtained and there are TDA-99 reading fluctuations due to residual particles from the APER manufacturing process, the laboratory manager shall make a determination

whether a true leak exists or residual particles are being detected. If there is evidence of leakage, attempt to find and eliminate the leak. If leakage or contamination is detected. It is at the laboratory manager's discretion whether or not to continue with the test. Annotate the Lab Book with description and decision.

4.9. EQUIPMENT PRE-TEST CONDITIONS: Quality Control Measures

- 4.9.1. SMARTMAN Leak Test Without Respirator Mounted: Because the SMARTMAN is made of cast zinc, it is possible for leak paths, after extensive LAT or incorrect assembly, to form through the metal casting, allowing chemical warfare agent vapor to pass through the headform cavity into the interior of the respirator mounted on the headform. To check for these invisible leak paths, install a clean peripheral seal on the headform and inflate it to the recommended static pressure value. Flood the interior of the headform with a known helium concentration. Use the probe of the helium leak detector to check the entire surface and the seal for presence of helium. Any leak found by the helium leak probe procedure must be diagnosed and eliminated, if possible. The leak test is to be performed initially on each new or reconditioned SMARTMAN and monthly on the SMARTMAN headforms when they are in continuous daily use.
- 4.9.2. Standardization of Instrumentation: Standardize the MINICAMS by using liquid standard solutions of the agents at various concentrations. These solutions are to be made in accordance with US Army, ECBC CAT IOP #214: Preparing Standard Agent Solutions for Instrumentation, or equivalent laboratory procedures. A stock solution is the primary solution made by weighing a quantity of agent into a volumetric flask and diluting to volume. Stock solution may be used for two weeks, unless deterioration is noted before that time. The stock solution is diluted further to make a series of standard solutions that are used to standardize the MINICAMS. The standard solutions may be used for one week, unless MINICAMS analyses indicate that the solutions are deteriorating. Class A glassware must be used for all volumetric work. Calibration curves should have a minimum correlation of $r^2 = 0.999$ for GB. Agent solutions must be stored at recommended surety storage temperatures.
- 4.9.3. Calibration of Flows: Since flow rates are used in several aspects of this test, it is necessary to use calibrated flow meters to set the flows used in the instruments. Flow meters are calibrated by the US Army Test Methods & Development Equipment (TM&DE) and Metrology Laboratory, in accordance with ISO 17025 procedures or equivalent using instruments traceable to NIST. Flow meters to be checked against calibrated meters are the Miller-Nelson Air Flow Controller, all electronic flow meters used for the MINICAMS preconcentrator tube and the flow meters from the breather pump and the syringe pump agent injector.
- 4.9.4. Aerosol Leak Testing: APER leak testing using the TDA-99M Aerosol Tester is performed on the facepiece after installation on the SMARTMAN and while the breather pump is operating. Allow the TDA-99M to stabilize in its initial detection procedure. When readings are stable within ± 2 end place digits of

0.0000, the TDA-99M Aerosol Tester is ready to begin detecting potential leak paths. If there is no leak, the display on the TDA-99M should read 0.0000 % penetration. Values of 0.0009 to 0.0001% penetration of particulate are acceptable. If leakage or contamination is detected. It is at the laboratory manager's discretion whether or not to continue with the test.

- 4.9.4 MINICAMS Detector Response: Check the response of the MINICAMS detector, before and after each LAT. This is done by injecting an aliquot of standard solution that contains a known concentration of agent near the mid-range of the standard curve. Inject the aliquot into the end of the heated sample line from the oronasal sampling port; it is necessary to disconnect the line from the bottom of the chamber to do this. This is called a "check shot". Repeat it at the end of the test to assure that the detector response has not changed during the test. The response of the detector should fall on the standard curve at the value expected for the amount of agent in the aliquot, or within 10% of that value. Record results of check shot in Laboratory Notebook. If the check shot does not reproduce a verifiable result, repeat the check shot. If the second check shot is not within the 10% parameter, the test is invalid. A quantifiable check shot should be made at the maximum, within 3 hours of the start of the actual test and at the end of test.

5. PROCEDURE

- 5.1. Connect the detector inlet to a sample line from the SMARTMAN, allow the APER to breath, and create a stable value on the TDA-99M. When the aerosol is being generated, direct the probe to various portions of the hood and all mechanical seals and joints to detect any leaks. The aerosol will be detected inside the hood if it finds a leak path. If any leaks are found, authorized laboratory personnel may make corrections in accordance with APER manufacturer's user instructions.
- 5.1.1. If leakage persists, laboratory manager shall be notified and the testing laboratory is authorized to perform artificial sealing methodology between neck dam and the neck of the SMARTMAN using the duct tape. Test report must indicate which respirators were duct taped and which were not.
- 5.1.1.1. Duct Tape Method consists of one layer of duct tape uniformly adhered to the end point of the neck dam material interfacing with the SMARTMAN neck area. The duct tape used will be approximately 1 inch wide. The duct tape will be placed on the neck dam and the neck area so that approximately 1/2 of the tape will be on the neck dam and 1/2 on the neck area. Slippage of the adhesive sealing material is not permitted. The tape must lie flat on the neck area. Neck Dam seal must be confirmed prior to start of test and supported by TDA-99M passing % prior to start of test. Documentation of sealing methodology verification testing and results are required to be available for review upon request by NIOSH. See figure XX for an example of artificial sealing method and equivalent equipment.

- 5.1.1.2. If TDA 99M results still indicate percent leakage greater than 0.0009% after neck dam is artificially sealed with duct tape, use the aerosol wand to isolate potential gross leak areas on the respirator. If gross leaks are identified even with neck dam duct tape in place, advise NIOSH and the applicant that a gross leak is identified with the TDA 99M and the potential exists for the respirator to fail certification live agent testing if permitted to proceed on with the conduct of STP-CBRN- 0450. Annotate TDA-99M readings attained with neck dam duct taped in laboratory notebook. Once the applicant acknowledges test laboratory TDA-99M findings, the applicant advises NIOSH to withdraw application or continue certification testing. If applicant decides to withdraw, all current and future testing on that application terminates immediately. The applicant can request on site visit of follow on TDA 99M confirmation tests to see for themselves the failing results of the TDA 99M.
- 5.1.1.3. If the applicant requests to continue despite the high TDA 99M readings, testing laboratory manager has the option to continue the test or terminate the test based upon the inability of the respirator to pass the TDA 99M indicator screening test. If the testing laboratory manager authorizes the test to continue, the laboratory continues the LAT. Testing laboratory must attain failing Ct value or three maximum peak excursions before ending the LAT. If the respirator passes in LAT, the applicant must submit a MSDS to NIOSH identifying the particulates prior to a letter of approval being issued.
- 5.1.2. If no localized leaks are found, replace the front panel of the exposure chamber. Connect the TDA-99M to a port into the exposure chamber and fill the chamber with the aerosol challenge. Maintain the aerosol challenge inside the chamber for 30 minutes of continuous TDA-99M operations below 0.0010% penetration.
- 5.1.2.1. If penetration exceeds 0.0010%, stop the 30 minute test and reanalyze the system then restart a new 30 minute test. The APER must pass a continuous 30 minute test at ≤ 0.0009 % penetration parameters in the exposure chamber. If after repeated attempts a successful leakage test cannot be achieved, the laboratory manager may use alternative means to seal the hood to the headform. See section 5.5.1. for alternative means of sealing. Other methods such as allowing the respirator to purge itself of internal off gassing particulates are acceptable provided the purge time is not excessively long. If 0.0010% cannot be obtained and there are TDA-99 reading fluctuations due to residual particles from the APER manufacturing process, the laboratory manager shall make a determination whether a true leak exists or residual particles are being detected. If the respirator continues to fail the TDA 99M by

exceeding 0.0010%, the APER manufacturer shall provide NIOSH upon request the Material Data Safety Sheet (MSDS) of the identified particles being detected by the TDA 99M. If leakage or contamination is detected. It is at the laboratory manager's discretion whether or not to continue with the test.

- 5.2. Take digital photographs of the assembled unit prior to start of LAT.
- 5.3. If batteries are required, ensure they are properly installed.
- 5.4. Start the breathing machine and the Miller Nelson temperature and humidity controller.
- 5.5. Connect the detector inlet to a sample line from the SMARTMAN, allow the APER to breathe, and create a stable value on the TDA-99M. When the aerosol is being generated, direct the probe to various portions of the hood and all mechanical seals and joints to detect any leaks. The aerosol will be detected inside the hood if it finds a leak path. If any leaks are found, authorized laboratory personnel may make corrections in accordance with APER manufacturer's user instructions. If leakage persists, laboratory manager shall be notified and appropriate action taken. If no localized leaks are found, replace the front panel of the exposure chamber. Connect the TDA-99M to a port into the exposure chamber and fill the chamber with the aerosol challenge. Maintain the aerosol challenge inside the chamber for 30 minutes of continuous TDA-99M operations below 0.0010% penetration. If penetration exceeds 0.0010%, stop the 30 minute test and reanalyze the system then restart a new 30 minute test. The APER must pass a continuous 30 minute test at ≤ 0.0009 % penetration parameters in the exposure chamber. If after repeated attempts a successful leakage test cannot be achieved, the laboratory manager may use alternative means to seal the hood to the headform. Other methods such as allowing the respirator to purge itself of internal off gassing particulates are acceptable provided the purge time is not excessively long. If 0.0010% cannot be obtained and there are TDA-99 reading fluctuations due to residual particles from the APER manufacturing process, the laboratory manager shall make a determination whether a true leak exists or residual particles are being detected. If the respirator continues to fail the TDA 99M by exceeding 0.0010%, the APER manufacturer shall provide NIOSH upon request the Material Data Safety Sheet (MSDS) of the identified particles being detected by the TDA 99M. If leakage or contamination is detected. It is at the laboratory manager's discretion whether or not to continue with the test.
- 5.6. Ensure MINICAMS are calibrated. Check shot is complete and acceptable and ready for the operating mode. Obtain the check shot by taking an aliquot of one of the mid-range standard solutions of agent with a microliter syringe and inject it into each sampling port. The MINICAMS response should be that indicated on the standard curve for the amount of agent contained in the aliquot. The response must be within 10% of the correct value for the final check shot test to be valid. Annotate the check shot times and concentrations.
- 5.7. MINICAMS Background Characterization. A background characterization must be run before every agent test. The MINICAMS should be monitored for a period of 60 minutes prior to the initiation of the chemical warfare agent test. Confirm that background level (steady state) is less than 3% of the Maximum Peak Excursion (0.522ng or 0.00261

mg/m³ {MPE=0.087 mg/m³ }). If the background level is not less than required, trouble shoot the SMARTMAN system, do not start the test, advise laboratory manager and if necessary remove the APER hood and discard, rinse the headform with IPA. If the APER is removed from the head form, restart the test procedure from paragraph 5.2.

- 5.8. Set up standard operational mode of test equipment. Ensure all test equipment is within calibration.
- 5.9. Ensure that the challenge concentration instrument is calibrated and is ready for analysis. Monitor agent exposure chamber during the 60 minutes background characterization period. Characterization reading should reflect a steady state condition. Exposure chamber ambient atmosphere detector should be on during baseline determination.
- 5.10. GB Vapor Application:
 - 5.10.1. Start of the agent test is when the first confirmed vapor state of GB is detected in the test chamber. Vapor is pumped in for X minutes, turned off and agent decay cycle is monitored for X minutes. Annotate the start time.
 - 5.10.2. Introduce GB vapor agent challenge to the test chamber by turning the inline valve from bypass to test chamber. The total flow to the test chamber is approximately 50 L/min from Miller Nelson, which includes enough excess to make up for the clean air exhausted from the mask into the chamber and maintain the constant challenge as required. The challenge concentration in the exposure chamber shall be monitored with the MIRAN® and be recorded in relation to time with a data acquisition system. The syringe flow rate is set to introduce the quantity of agent necessary to generate the challenge concentration required. Record when the MINICAMSs begin monitoring the interior of the mask.
 - 5.10.3. The vapor syringe pump should run for the prescribed challenge period of X minutes, but no more than X+1 minutes. At the end of the challenge period, turn off the syringe pump. Record the total volume used by the syringe pump, the elapsed time and the airflow rate delivered from the Miller-Nelson. These values will be recorded in the laboratory notebook. Ensure syringe flow is off and the mixing chamber airflow line is bypassed so Miller-Nelson uncontaminated air is flowing to the agent exposure chamber.
- 5.11. Test Surveillance: The laboratory personnel shall monitor the entire test to make sure all components of the system function, collect data as required and monitor the breakthrough concentration to protect the MINICAMS against saturation. If the system is failing, the MINICAMS must capture three maximum peak excursions (0.087 mg/m³) to document the APER's failure before MINICAMS can be taken off line from monitoring.
- 5.12. Procedures for Termination of Test:
 - 5.12.1. The test should be terminated when the full time (2X) for the test has elapsed or three confirmed quantifiable consecutive maximum peak excursions (0.087 mg/m³) are verifiable. The pass/fail criteria on Ct are determined after test

completion and raw data tabulation. To terminate the test, turn off breather pump. Perform a check shot of agent to ensure that the detection system is still operating correctly. Obtain the check shot by taking an aliquot of one of the mid-range standard solutions of agent with a microliter syringe and inject it into each sampling port. The MINICAMS response should be that indicated on the standard curve for the amount of agent contained in the aliquot. The response must be within 10% of the correct value for the final check shot test to be valid. Annotate the check shot times and concentrations. The response must be within 10% of the correct value for the final check shot test to be valid.

5.12.2. Turn off the MINICAMS per laboratory SOP. Turn off Miller-Nelson airflow through the exposure chamber. Remove the test respirator; separate it into components as necessary and double-bag the components in accordance with laboratory SOP. Remove the bagged components to the decontamination hood for temporary storage. If requested, a manufacture representative may review the items at this time to perform reverse engineering analysis. The test respirator will then be decontaminated, monitored and disposed according to laboratory SOP. Wipe down the interior of the agent exposure chamber and the SMARTMAN using approved cleaning solution. Dispose of cleaning materials according to laboratory SOP.

5.13. Example Step Sequence of activities for GB vapor CBRN APER test.

1. Conduct mask preparation and background contamination assessment.
2. Install APER in agent exposure chamber.
3. Photograph APER.
4. Start breathing pump and makeup air using Miller-Nelson.
5. Probe for leakage with TDA-99M.
6. Close agent exposure chamber front panel.
7. Challenge APER with TDA-99M for 30 minutes in the exposure chamber.
8. Monitor background inside the mask and do check shot on each of MINICAMS.
9. Conduct characterization for 60 min.
10. Divert Miller-Nelson flow into exposure chamber, while simultaneously starting ambient challenge concentration detection profile software, if not already started.
11. Start challenge agent syringe pump. Ensure challenge concentration is ramping up as expected.
12. Record start time on the MINICAMS, (vapor exposure).
13. Monitor MINICAMS for detection, noted penetration peaks and saturation prevention.
14. Stop syringe pump at X-minute mark, but no later X+1 minutes.
15. Record stop time for challenge agent vapor exposure.
16. Record decay time start.
17. Monitor APER for visible cracks, catastrophic breakage or failure criteria.
18. Monitor clock exposure times.
19. Stop at 2X minutes and record end time.
20. Conduct check shots

21. Record check shots results and time of last end of test check shot.
22. Prepare system for decon and remove APER.

5.14. Data Analysis

- 5.14.1. The primary operator is responsible for accurately maintaining a laboratory notebook and all required records. Hardcopies of data should be annotated when pertinent events occur, such as a catastrophic failure, obvious airflow boundary cracks, accessory cracks/failure, check shots and test start/end times. Lab supervisor must gain NIOSH approval prior to pre-approving any deviation from NIOSH standard test procedure and signoff in the technician's notebook as to the appropriate NIOSH approved change. Notebook pages should be signed and dated, copies of all hardcopies of data that are generated shall be kept in the assigned task folder with NIOSH Task number.
- 5.14.2. Laboratory manager and the primary test personnel must complete all required Test Data Sheets in accordance with Appendix A. Originals of all test data sheets must be completed and retained in the task file. Test data sheets for CBRN APER candidates are managed by digital exchange of pre-formatted blank file forms easily transferred in standard email. No NIOSH DEIMS electronic forms exist for CBRN APER test data collection. NIOSH DEIMS, current version, will assign TNs, maintain the CBRN APER test queue and process all initial, lab and final reviews. NIOSH DEIMS for CBRN APER should be reviewed every three working days by the lab technician supervisor/principal investigator or equivalent. While an application is active and has information for update, the transfer of applicable files should be updated bi-daily with all applicable information to allow timely feedback and prevention of miscommunication. Key fob holders of testing lab are required to insure all summary data sheets are reviewed for accuracy prior to final submission to NIOSH/NPPTL in a timely manner.
- 5.14.3. Transfer the penetration data from the MINICAMS computer into a computer for analysis by Microsoft Excel. This table will contain data from the nasal area and associated time markers. The resulting table will each have four columns: 1) elapsed time 2) volume collected 3) sample collection time and 4) nanograms per sample. Convert the nanograms into a concentration, ng/L, by multiplying nanograms by a factor obtained by dividing the actual sample volume (typically 200 mL but may be considerably less) into 1,000 mL/L (Example: $1.73 \text{ ng} \times 1/0.2 \text{ L} = 8.65 \text{ ng/L}$). Convert nanograms/liter to milligrams/cubic meter by dividing by 1,000 (Example: $8.65 \text{ ng/L} / 1000 = 0.0865 \text{ mg/m}^3$). Ct (Concentration x Time) is calculated by multiplying the collection duration time times the concentration (Example: $0.0865 \text{ mg/m}^3 \times 2 \text{ min} = 0.173 \text{ mg-min/m}^3$). The cumulative Ct is calculated by adding the Ct value for each sample time. Using Excel's Chart Wizard feature, a plot of concentration vs. time and the Ct vs. time can be generated and printed using all the data in the table.
- 5.14.4. Challenge Concentration Data: Using the computations generated from paragraph 5.17.2.. Plot the challenge concentration versus time and produce two

data graphs that track total detection events covering any maximum peak excursions over 2X minutes and total concentration over time known, as Cumulative Ct, covering the total 2X minutes of potential cumulative and instantaneous dosages. If the test is terminated prior to the completion of 2X minutes due to APER failure, MINICAMS saturation preventive measures or other situations as outlined, laboratory technician supervisor or equivalent is responsible for accurately recording all applicable maximum peak excursions and cumulative Ct detected in the tested time.

6. PASS/FAIL CRITERIA

- 6.1. The criterion for passing is set within the authority of 42 CFR, Part 84, Subpart G, Section 84.63(a), (c) & (d); Volume 60, Number 110, June 8, 1995. A Two-fold pass/fail criterion is required for successful passing of GB testing. The criterion is as follows in the table below:

Vapor Challenge of APER with Sarin (GB)

Challenge Concentration	Vapor Concentration (mg/m ³)	Vapor Challenge Time (minutes)	Breathing Machine Airflow Rate (L/min)	Maximum Peak Excursion mg/m ³	Maximum Breakthrough (concentration integrated over minimum service life) (mg-min/m ³)	Number of Systems Tested	Minimum Service Life (minutes)
GB	210	15, 30, 45, or 60 ⁽¹⁾⁽⁵⁾	40	0.087 ⁽³⁾	0.9 for 15 and 30 minute devices 2.1 for 45 and 60 minute devices ⁽⁴⁾⁽⁷⁾	3	30/60/90/120 ⁽²⁾⁽⁶⁾

⁽¹⁾ The vapor challenge concentration generation will be initiated immediately after test chamber has been sealed.

⁽²⁾ The test period begins upon initial generation of vapor concentration and ends at 2X minutes.

⁽³⁾ Three consecutive sequential test data points at or exceeding 0.087 mg/m³ will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.

⁽⁴⁾ The cumulative Ct including all maximum peak excursion data points must not be exceeded for the duration of the test.

⁽⁵⁾ Duration of challenge is 15, 30, 45, or 60 [(X) minutes], equal to applicants identified rated duration.

⁽⁶⁾ Minimum test life is 30, 60, 90 or 120, [(2X) minutes] equal to twice the applicant's rated duration.

⁽⁷⁾ Respirators will be monitored in the oronasal and ocular regions.

Challenge: 210 mg/m³ ± 10 % for X minutes (but not more than X+1 minutes).

Test Time: 2X minutes

6.2. Neither the Oronasal region nor the Ocular region shall exceed the following:

- a) Maximum Agent Breakthrough (Ct) = 0.9 mg-min/m³ for 15 and 30 minute devices 2.1 mg-min/m³ for 45 and 60 minute devices. Concentration integrated over minimum service life is Ct. The Ct data value, including all maximum peak excursion data points, must not be exceeded for the duration of the test.
- b) Maximum Peak Excursions = 0.087 mg/m³. Three (3) consecutive data points at or exceeding the peak value constitutes a failure.

Note: Any visible respirator deterioration in assigned material components such as breakage, distortion, hazing of lens, cracking or separation shall also constitute a system warning and qualify as a potential failure based upon assessment of NIOSH CBRN APER Guidelines for Identification of Test Configurations for Exposure to GB/HD, current version.

Note: Any APER test that fails as a result of laboratory test equipment failure or malfunction, laboratory electrical power loss or incorrect technician operating procedures/actions will be considered by NIOSH/NPPTL as a test termination and immediate mandatory retest upon lab supervisor confirmation. In this case, the testing laboratory, at no additional cost to NIOSH/NPPTL or the manufacturer concerned, retests the respirator.

- 6.3. Precision and accuracy must be determined for each instrument in accordance with laboratory procedures and follow on NIOSH/NPPTL guidance to be published. Sound practice under NIOSH Manual of Analytical Methods supports a plus or minus 25% tolerance of a 95% confidence interval. NIOSH/NPPTL CBRN STP P&A tolerance can be higher but not lower.
- 6.4. This test establishes the procedures for ensuring the level of respiratory protection provided under special Chemical, Biological, Radiological, and Nuclear (CBRN) requirements for Air Purifying Escape Respirator APER submitted for Approval, Extension of Approval, or examined during Certification Product Audits, meet the minimum certification standards set forth in Title 42 CFR, Part 84, Subpart G, Section 84.63(a)(c)(d).

7. RECORDS/TEST SHEETS

- 7.1. All test data will be recorded in the NIOSH DIEMS and STP recognized formatted CBRN APER test data sheets (Appendix A). All applicable data, graphs and photographs taken/made by laboratory personnel, supervisors or the equivalent will remain on file at

the actual lab where the test was conducted, is required to be retrievable within 24 hour notification, and be maintained in accordance with local administrative SOPs and NIOSH/NPPTL Respirator Branch CET historical filing requirements.

- 7.2. All videotapes and photographs of the actual test being performed by testing laboratory personnel, or of the test 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 a failure occurs on a new certification application (Qualifier or Remainder Application), testing laboratory will send a test report to the NIOSH, NPPTL Respirator Branch, Certification Evaluation and Testing (CET) Section Leader and await further instructions on prepare/action any uncontaminated hardware for return to the manufacturer.
 - 7.3.2. If the failure occurs on hardware examined under NIOSH directed Off-the-Shelf Audit, the hardware will be examined by a technician and the Laboratory Manager for cause. All equipment failing or passing any portion of this test will be contaminated with chemical warfare agent; upon request; the contaminated equipment can be viewed by designated NIOSH personnel in support of incident investigation proceedings. Upon completion of NIOSH proceedings, the equipment is disposed of in accordance with testing laboratory chemical surety practices.

APPENDIX A

CBRN APER GB LAT Certification Test Data Summary Sheet; NIOSH Procedure No. CET-APERS-STP-CBRN -0450; Current Revision.

1. TEST TITLE: DETERMINATION OF CHEMICAL AGENT PERMEATION AND PENETRATION RESISTANCE PERFORMANCE AGAINST SARIN (GB) VAPOR OF THE CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR (CBRN) AIR-PURIFYING ESCAPE RESPIRATOR (APER) STANDARD TEST PROCEDURE (STP)

- A. Task Number (TN): _____
- B. Manufacturer: _____
- C. APER Model #/Type: _____
- D. Test Start Date of Qualifier Application: _____
- E. Test Start Date of Remainder Application: _____
- F. Test End Date of Remainder Application: _____
- G. Primary P/N and Subject for LAT Configuration: _____
- H. Gaining NIOSH CBRN Approval Numbers: _____

2. REQUIREMENT:

Three CBRN Air Purifying Escape Respirator (APER) systems, including all components and accessories shall resist the permeation and penetration of Sarin (GB) chemical agent when tested on an upper-torso manikin connected to breathing machine operating at an air flow rate of 40 lpm, 36 respirations per minutes, 1.1 liters tidal volume. One of the APER shall be tested in the “as received condition” as a qualifier and remaining two will be tested after undergoing Environmental Conditioning. Test requirements are listed below: in Table A1:

Table A1. Vapor Challenge of APER with Sarin (GB)

Challenge Concentration	Vapor Concentration (mg/m ³)	Vapor Challenge Time (minutes)	Breathing Machine Airflow Rate (L/min)	Maximum Peak Excursion mg/m ³	Maximum Breakthrough (concentration integrated over minimum service life) (mg-min/m ³)	Number of Systems Tested	Minimum Service Life (minutes)
GB	210	15, 30, 45, or 60 ⁽¹⁾⁽⁵⁾	40	0.087 ⁽³⁾	0.9 for 15 and 30 minute devices 2.1 for 45 and 60 minute devices ⁽⁴⁾⁽⁷⁾	3	30/60/90/120 ⁽²⁾⁽⁶⁾

⁽¹⁾ The vapor challenge concentration generation will be initiated immediately after test chamber has been sealed.

GB CBRN APER LAT Certification Summary Continuum:

Task Number: _____ STP No. _____
 Manufacturer: _____ Reference No. _____

- (2) The test period begins upon initial generation of vapor concentration and ends at 2X minutes.
- (3) Three consecutive sequential test data points at or exceeding 0.087 mg/m³ will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.
- (4) The cumulative Ct including all maximum peak excursion data points must not be exceeded for the duration of the test.
- (5) Duration of challenge is 15, 30, 45, or 60 [(X) minutes], equal to applicants identified rated duration.
- (6) Minimum test life is 30, 60, 90 or 120, [(2X) minutes] equal to twice the applicant's rated duration.
- (7) Respirators will be monitored in the oronasal and ocular regions.

Challenge: 210 mg/m³ ± 10 % for X minutes (but not more than X+1 minutes).

Test Time: 2X minutes

Neither the Oronasal region nor the Ocular region shall exceed the following:

- a) Maximum Agent Breakthrough (Ct) = 0.9 mg-min/m³ for 15 and 30 minute devices
 2.1 mg-min/m³ for 45 and 60 minute devices. Concentration integrated over minimum service life is Ct. The Ct data value, including all maximum peak excursion data points, must not be exceeded for the duration of the test.
- b) Maximum Peak Excursions = 0.087 mg/m³. Three (3) consecutive data points at or exceeding the peak value constitutes a failure. .

OVERALL RESULT: PASS or FAIL

3. SUPPORTING REQUIRED DATA:

- A. Is APER disformed or damaged in any fashion prior to any portion of LAT? Yes or No
- B. Is APER fully serviceable (exceeded expiration date) and operable prior to any portion of LAT?
 Yes or No
- C. Are PER components and accessories free of visible deformations or aberrations? Yes or No
- D. Did APER pass or fail maximum peak excursions? Yes or No

GB CBRN APER LAT Certification Summary Continuum:

Task Number: _____ STP No. _____
 Manufacturer: _____ Reference No. _____

- E. Did each APER pass or fail Maximum Breakthrough Concentration (Ct)? YES or NO
- F. Was all lab test equipment verified calibrated prior to LAT? YES or NO
- G. Were the SAF Configuration Part Numbers verified on the actual testable hardware? Yes or NO

No.	APER Tested	Pass	Fail	Total Test Time (2X)	Oralnasal		Ocular	
					Number of Max. Peaks	Total CT	Number of Max. Peaks	Total CT Value
# 1	QUALIFIER (GB 1)							
#2	Envir. Conditioned (GB 2)							
#3	Envir. Conditioned (GB 3)							

4. COMMENTS:

(e.g. CBRN APER candidate was tested in AS IS/Ready to Use configuration for initial Qualifier Application. CBRN APER passed initial Qualifier Application LAT. However, when Conditioned Configuration was tested in Remainder Application tests, candidate CBRN APER failed max peak excursion criteria and exhibited canister thread dents and bends as a result of environmental pre – conditioning prior to Remainder LAT.)

5. SIGNATURES:

A. Laboratory Tester: _____ Date: _____

B. Laboratory Supervisor: _____ Date: _____

Legible Signatures infer concurrence with test summary findings as indicated above.

Revision History

Revision	Date	Reason for Revision
0	8 January 2004	Historic document
1.1	22 December 2005	Update header and format No changes to method