


<p>National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory Respirator Branch 626 Cochrans Mill Road Pittsburgh, Pennsylvania 15236</p> 	
Date: DRAFT 11 July 2005	NOTE: The Respirator Branch maintains an updated index of current procedures.

DETERMINATION OF CBRN TIGHT FITTING AND NON-TIGHT FITTING, POWERED AIR-PURIFYING RESPIRATOR (PAPR) PERFORMANCE DURING DYNAMIC TESTING AGAINST THE CHEMICAL AGENT VAPOR SARIN (GB) CBRN STANDARD TESTING PROCEDURE (STP)

1. PURPOSE

- 1.1 This document establishes the procedures for ensuring the level of respiratory protection provided by Chemical, Biological, Radiological, and Nuclear (CBRN) Protection requirements for Powered Air-Purifying Respirator (PAPR) 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); Federal Register Volume 60, Number 110, June 8, 1995.
- 1.2 The purpose of this Standard Test Procedure (STP) is to describe the test conditions and procedures necessary to test and certify manufacturer submitted CBRN PAPR applications. A CBRN PAPR being a complete tight fitting or non-tight fitting facepiece properly outfitted with manufacturer unique components and a properly designed manufacturer specified PAPR blower and canisters which are installed per the manufacturer's installation requirements outlined in current user's instructions. This procedure is used to test CBRN PAPR systems 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 under this static chamber platform for the purpose of generating and controlling challenge concentrations and detecting agent permeation and penetration of a tested respirator. This procedure is a separate test under the NIOSH NPPTL Respirator Branch, Certification, Evaluation and Testing Section (CET) heading of CET-APRS-STP-CBRN-0550 for challenge of Sarin Vapor. This procedure is designed to rigorously test the evaluated respirator as a dynamic breathing system and generate repeatable independent pass or fail results under laboratory conditions.

Approvals:	1 st Level	2 nd Level	3 rd Level	4 th Level
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2. GENERAL:

- 2.1 The STP describes test procedures 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 product passes the test.
- 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.

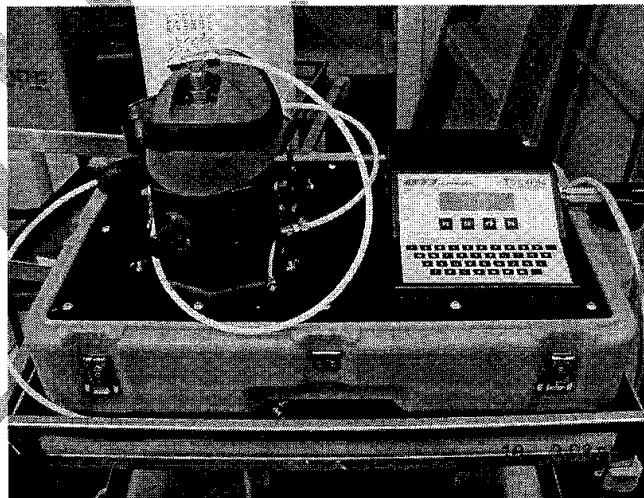
3. EQUIPMENT. List of necessary test equipment follows:

- 3.1 SMARTMAN, Head/upper torso form or equivalent (see picture 1). Manufactured by ILC Dover, Frederica, DE. The SiMulant Agent Resistant Test MANikin, a.k.a. SMARTMAN, is a cast zinc, hollow shell headform representing a static uniform surface that outlines a medium sized human male head, neck, shoulders and upper chest stature. The head features an anatomically correct semi-static surface consisting of dimensional 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, 1 1/4 inch in diameter, leads from the mouth area to the breather pump. Four smaller tubes are present. One tube connects to the center of the left eye; it is blocked off. A tube connects to the lower middle forehead above the bridge of the nose; it is blocked off. There are two metal tubes protruding outward from the oral/nasal region, they are in use. One is used to measure differential pressure by means of a magnehelic gauge, while the second one is used to monitor presence of agent. The four tubes are 1/4" diameter. 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. Average weight of hollow zinc headform is 85 pounds.



Picture 1: Head/Upper Torso Manikin, SMARTMAN

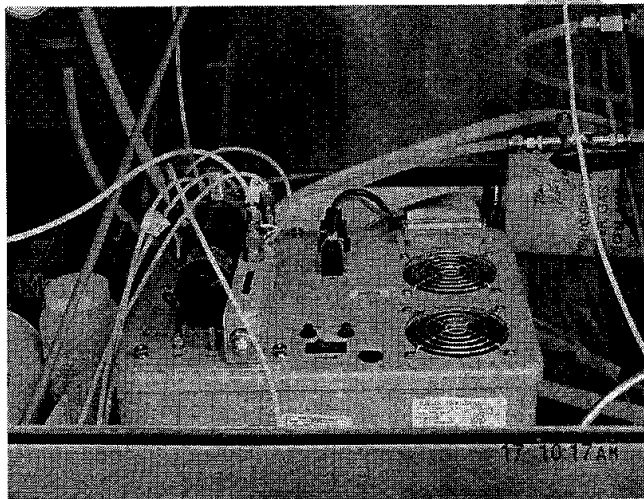
- 3.2. Leak detector Model TDA-99M or equivalent (see picture 2). Manufactured by Air Techniques, Inc., the TDA-99M is one of the primary tools for accessing aerosol leaks in the mechanical seals of the respirator and proper fit of a respirator to clean SMARTMAN headform under non-toxic oil aerosol conditions. The device generates an Emery 3004 mineral oil aerosol that is used to detect leakage in respirator. With the respirator properly installed on the SMARTMAN and the breather pump operating at manufacturer specifications, 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.



Picture 2: Leak detector Model TDA-99M

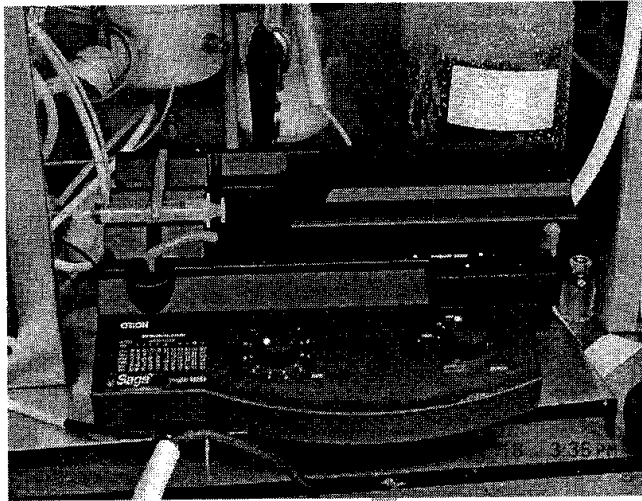
- 3.3 MINIature Continuous Air Monitoring System, MINICAMS or equivalent (see pic. 3). The MINICAMS, manufactured by OI Analytical, is a gas chromatograph equipped with a hydrogen flame emission detector and a preconcentrator tube. The preconcentrator tube is a small tube containing an adsorbent material 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 preconcentrating 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. Two MINICAMS are required in order to continuously monitor the interior of the respirator for CBRN respirator certification.



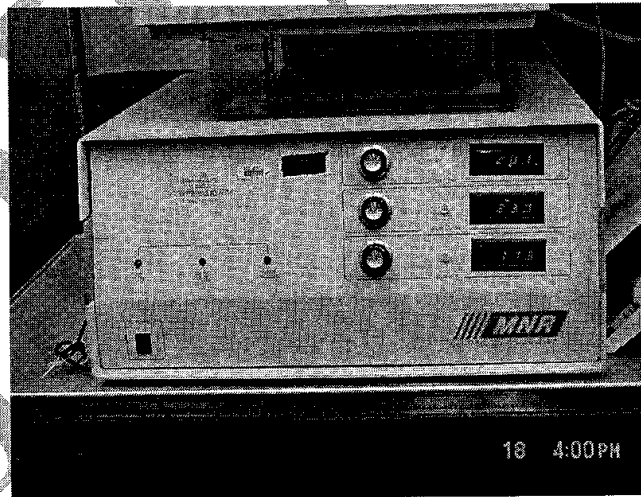
Picture 3: MINIature Continuous Air Monitoring System, (MINICAMS)

- 3.4 Syringe pump, Sage Model M365 or equivalent (see picture 4). This multirange, variable rate infusion pump is used to 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. Technicians must be proficient on the pump's user instructions.



Picture 4: Syringe pump, Sage Model M365

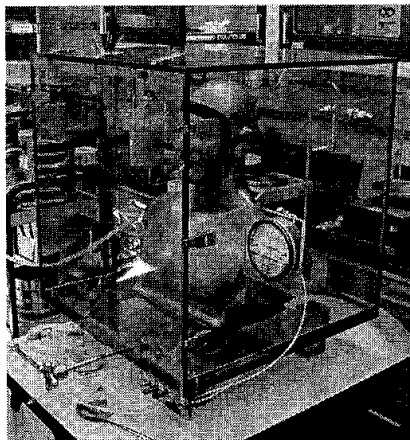
- 3.5 Flow-Temperature-Humidity Control System or equivalent (see picture 5). This system, referred to as the Miller-Nelson (MN) control system, manufactured by Miller-Nelson Research, Inc., is an automated system to control the airflow, temperature, and humidity of an air supply for an operating respirator 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 (200-50 L/min. +/- 2%), and relative humidity (20-80 +/- 3%) and temperature (20-30 °C +/- 0.3%).



Picture 5: Flow-Temperature-Humidity Control System

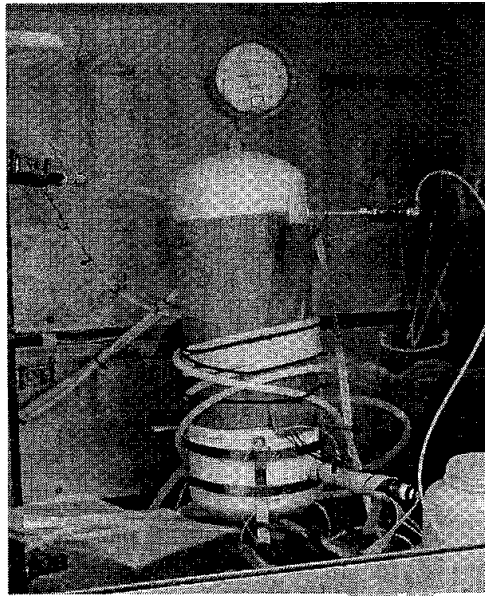
- 3.6 Exposure Chamber or equivalent (see picture 6). The respirator exposure chamber is constructed of clear, chemical resistant material (Plexiglas ® or Lexan®) or other equivalent material. The floor must be constructed efficiently to support the 85-pound SMARTMAN. The front panel is removable and 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 hold the chamber above the floor of the hood and allow room for laboratory tubing and the face adjustment handle. A M12A1 military specified air-purifying canister 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. A "Clean Exposure Chamber/Cold Box" is a unit used to perform a fit and leak check on a respirator test unit (no agents used in this chamber) before it is installed in the agent exposure chamber. An "Agent Exposure Chamber/Hot Box" is a chamber used to perform testing of the respirator unit, using live agent.



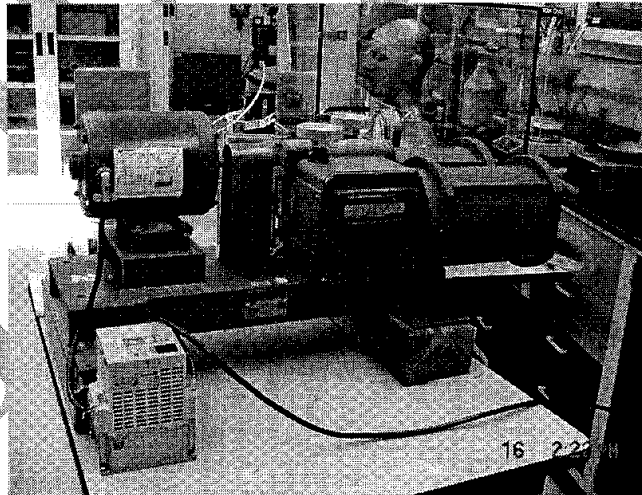
Picture 6: Exposure Chamber

- 3.7 Agent Mixing Chamber or equivalent (see picture 7). This chamber is fabricated of PVC pipe, with caps on both ends and three baffles fixed inside to ensure mixing of chemical warfare agent vapor and air. A pressure gauge, mounted on the mixing chamber, indicates internal mixture pressure and serves as a safety pressure indicator. Maximum pressure is indicated per laboratory standard operating procedures. A heating blanket is wrapped around the chamber to facilitate chemical vaporization. This is the primary mixing area that allows the chemical agent syringe pump flow and the regulated air flow from the Miller Nelson controller to mix and generate a specified concentration of chemical warfare agent. When the mixture is not being passed into the exposure chamber for a test, it is passed through a scrubber filter (an M18 mil spec canister or equivalent).



Picture 7: Mixing chamber

- 3.8 Breather Pump, Model E1R1 or equivalent (see picture 8). Manufactured by Jaeco Fluid Systems, Inc., it is a breather pump used to replicate breathing. It is 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 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 L/m 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.

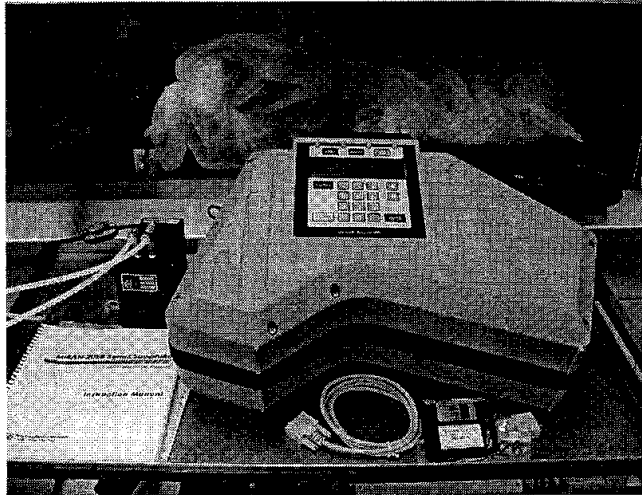


Picture 8: Breather Pump

- 3.9 Mass Flow Controllers or equivalent. Manufactured by Tylan Electronic or Brooks Instruments. 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 +/- 2% of set point. Photo not provided.

- 3.10 Ambient Air Analyzer, MIRAN model 1A or 205B, or equivalent (see picture 9 and 10). Manufactured by Thermo Environmental Instruments Inc. It 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 the challenge concentration of the vapor phase of the chemical warfare agents. Model 1A is used for the Sarin (GB) concentration and model 205B or an equivalent is generally used for the HD concentration.



Picture 9: Miran Analyzer, Model 205B

No Photo Currently Available on Model 1A. Replace PHOTO Of Model 205B with 1A

Picture 10: Miran Analyzer, Model 1A

3.11 Respirator Systems Required for Testing.

- 3.11.1 REQUIRED PAPR QUANTITIES: Number of PAPRs required for GB Live Agent Testing (LAT) is three (3) complete respirator systems. Initially, one (1) complete PAPR system which has not been subjected to Durability Conditioning is required for the GB “Qualifier Application”. Upon confirmation that the PAPR successfully passed the Qualifier Application GB Test, two (2) additional PAPRs shall be tested for GB “Remainder” LAT after they have been subjected to Durability Conditioning in accordance with CBRN PAPR Statement of Standard.
- 3.11.2 Battery Requirements: In order for the PAPR to be tested for the entire test duration of eight (8) hours, the applicant must supply a battery (for this test only) that is sufficient to operate the PAPR at the rated airflow for nine (9) hours; otherwise, the laboratory manager shall integrate a subsequent power source or an additional battery so that the PAPR operates at the rated flow rate for the entire test duration.
- 3.11.3 QUALIFIER LAT: GB Live Agent Test canisters, hoods, facepieces, blower units and accessories should be received from the appropriate NIOSH/NPPTL sanctioned source. No alterations to canisters are authorized prior to or during live agent systems testing. No

use of duct tape or 100mph tape over inlet and outlet areas is authorized in lieu of no caps or missing caps. At NIOSH/Tenant Laboratory initial certification qualifier application inventory, canisters received in the Minimum Packaging Configuration are required to be plastic bagged, regardless of type of original packaging, and delivered to LAT lab upon completion of satisfactory certification inventory.

3.11.4 REMAINDER LAT: Start of GB Remainder LAT is contingent upon testable PAPR systems completing all required NIOSH/NPPTL CBRN PAPR Durability Conditioning testing. Durability Conditioned canisters will be attached per manufacturer instructions to available compatible application PAPR assemblies prior to live agent testing by qualified and designated laboratory live agent testing technicians only. Durability Conditioned canisters should be received in an air tight durable Ziploc bag and administratively labeled with the date the Durability Conditioning started, completed, type of damage if any observed, manufacturer and laboratory responsible individual for the Durability Conditioning, phone number and laboratory name. Only the manufacturer's inlet and outlet plugs that come with the canister are to be used to seal up the canister after Durability Conditioning. If no plugs are provided, no other form of sealant is authorized. Start of live agent testing must commence within 12 hours of receiving the Durability Conditioned canisters and PAPR assemblies. Any canister damage during Durability Conditioning is required to be preserved, not altered and noted on administrative markings for shipment to LAT lab.

3.11.5 Annotation: GB Live agent systems test canisters and blower assemblies should be labeled prior to actual Live agent testing with the following administrative information:

- NIOSH Task Number (TN Number) from NIOSH DEIMS.
- Model of PAPR 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 and instruments to be used must have been calibrated using a method traceable to the National Institute of Standards and Technology (NIST) in accordance with the manufacturer's calibration procedure and schedule.

4.2. System Test Conditions:

4.2.1 Breathing Machine:

4.2.1.1 Breathing Machine Requirement (Both Constant Flow and Demand Response Flow)

Airflow = 40 liters per minute
Respirations = 36 +/- 2 strokes per minute
Tidal Volume = 1.1 liters

4.2.1.2. Breathing Machine Requirement (Demand Response Flow)

Airflow = 60 liters per minute
Respirations = 55 +/- 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 exhausted from the PAPR.

Relative Humidity: 25 ±5% RH
Temperature: 25 ± 3°C

4.2.3 SMARTMAN Sampling Point:

Breathing zone sampling point is a single SMARTMAN nasal port that allows sequential dual MINICAMS detections.

4.2.4 Sarin (GB) Vapor Test.

4.2.4.1 Vapor Challenge Concentration = 210 mg/m³ ± 10 %

Vapor Challenge Time (disseminator on) = 30 minutes, but no longer than 31 minutes

Monitor & Exposure Hold Time = 7.5 hours

Total Test Time = 8.0 hours

Syringe Injection Rate = as required based upon syringe pump used and PAPR airflow rate.

Syringe Injected Volume = as required based upon syringe pump used and PAPR airflow rate.

4.2.4.2 Sarin (GB) must be Chemical Agent Standard Analytical Reference Material (CASARM). Analysis must be NIST traceable. Proper CASARM storage requirements must be followed.

4.2.5 Test Termination Parameters: The test will be terminated to protect the detectors from over-saturation provided a candidate PAPR shows failing criteria prior to the eight (8) hour mark. 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, butyl apron 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 glass laboratory equipment, lab technicians and 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 responsible technician must be knowledgeable about the specific CBRN PAPR being tested and should be able to readily identify all CBRN PAPR hardware components, subassemblies and accessories and be able to support accurate trouble shooting of the CBRN PAPR and subassemblies to ensure it is properly operating properly in accordance with the manufacturer's operating instructions. The responsible technician must be able to properly align and fit the respirator facepiece on the SMARTMAN headform without malformation or destruction of any CBRN PAPR material.
- 4.3.6. All LAT equipment passing or failing these NIOSH test protocols will be treated as hazardous materials in accordance with local laboratory procedures and methods. Disposal of such contaminated CBRN PAPR materials is the responsibility of the testing laboratory. In accordance with this STP, respirator manufacturers are released of equipment accountability IAW local testing lab test equipment procedures per Department of Defense HAZMAT protocol.
- 4.3.7. Surety lab procedures outlined in applicable SOPs are required to be on hand. Annual training classes focus on the familiarization of required occupational safety and health subjects in accordance with specified surety lab procedures.
- 4.3.8. 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: A Laboratory MINICAMS, as opposed to a Field MINICAMS, is used as the detector for agent penetration/permeation into the CBRN PAPR. It consists of a monitor, PC computer, Linear Mass Flowmeter and optional printer or recorder. Before the PAPR is placed on the exposure SMARTMAN, the MINICAMS are required to show steady state background readings lower than the lowest point on the current MINICAMS calibration curves. This is accomplished per local laboratory procedures but may involve the use of a clean M40 mil spec respirator mounted on the SMARTMAN

head form. The SMARTMAN is then allowed to breathe for the required time (8, 12, 48, 72 hours etc.) until a steady state background is achieved that is lower than the lowest current calibration curve point indicated on the respective MINICAMS performance results. 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 preconcentrator tube containing an adsorbent material: GB sample volume is approximately 200 mL. 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 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 application. GB analysis can require up to a 4-minute cycle. The two MINICAMS will be synchronized so that one minicam sampling begins when the other minicam sampling ends.
- 4.4.4. GB Detection Principle. The MINICAMS is installed in accordance with the operating manual. 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 chemical species (phosphorus) 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 uL) of a known standard solution of the agent onto the pre-concentrator tube during the INJECT segment of the test cycle IAW 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/m³. 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 filtered and exhaled air of the PAPR.

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 PAPR 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.

The example conditions below can be used as guidelines. Conditions for each individual system will have to be determined for each laboratory setup to achieve the required ramp up time for ARP exposure concentration.

GB Setup (Mass Balance Analysis or Equivalent)

Chamber size = 8 ft³

Target Challenge Concentration = 210 mg/m³ + 21 mg/m³

Ramp Up Time = 4 - 5 minutes (Time from initial start of syringe pump to 189 mg/m³ lowest acceptable Challenge Concentration start point.)

Dilution Air from Breather Pump = 40 l/m or 60 l/m (Demand Response Only)

Miller-Nelson Challenge Mixing Air = PAPR airflow rate Dependent

Syringe Rate for Challenge Injection = PAPR airflow rate Dependent

Total GB Projected for Use in 30 minutes = PAPR airflow rate Dependent

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 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 technician's lab logbook 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 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 the 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. The syringe rate will depend on the airflow rate of the PAPR and must be set to maintain the requirement challenge concentration.

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 oil particulate aerosol leaks into the CBRN PAPR after it has been installed on the SMARTMAN headform cold box. Ensure the canister and all components are correctly mounted and tightened per the current manufacturer instructions and specifications. The PAPR shall be activated in the operational mode (blower operating). Ensure that procedures for the PAPR follow the manufacturer's installation procedures for gasket seal and facepiece donning and interface. 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. However, if the canister or canister interface thread is deformed from Durability Conditioning (If applicable), continue with the test by attaching the canister per manufacturer instructions. Do not make any corrections for canister deformities at this time. Ensure the lab book is annotated and digital photos are taken / available 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. 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 wand to various portions of the facepiece 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 to form through the metal casting. 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 rated helium concentration and purity. 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 head-forms 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. This 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 and use instruments traceable to NIST. Flow meters to be checked against calibrated meters are the Miller-Nelson Air Flow Controller, electronic flow meters used for the MINICAMS pre-concentrator tube, flow meters from the breather pump and the syringe pump agent injector.
- 4.9.4. Aerosol Leak Testing: PAPR leak testing using the TDA-99M Aerosol Tester is performed on the facepiece after installation on the SMARTMAN and while the breather pump and PAPA are 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.
- 4.9.5. 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 oral-nasal 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.

5. PROCEDURE (GB Vapor Challenge (0550):

5.2 GB LAT (0550)

- 5.2.1 Assemble PAPR per manufacturer's instructions. Non-Durability Conditioned PAPRs will be tested in the Qualifier Application. For the Remainder Application, Durability Conditioned units per CBRN PAPR Statement of Standard shall be tested. After Durability Conditioning the items, conditioned canisters that were not stored in the PAPR's Minimum Packaging Configuration (Inside PAPR carrier or case) shall be placed on the PAPR and tested. If the PAPR uses disposable batteries, install new batteries on the PAPR before testing. If the PAPR uses rechargeable batteries, fully recharge the batteries and install them on the PAPR.

NOTE: The applicant must provide a battery(ies) (for this test only) that is sufficient to operate the PAPR at the rated airflow for nine (9) hours; otherwise, the laboratory manager shall integrate a subsequent power source or an additional battery so that the PAPR operates at the rated airflow rate for the entire test duration.

- 5.2.2 Take digital photographs of the assembled unit prior to start of LAT. These photographs are required to be available for NIOSH/NPPTL review.
- 5.2.3 Mount the respirator on the SMARTMAN in the clean exposure chamber. The facepiece should be mounted to the SMARTMAN per the manufacturers' operating/user instructions with special emphasis on head harness fitting and canister tightness. Ensure all parts of the facepiece are mounted / seated correctly on the headform. If a shroud or other accessory is being tested as part of the respirator system, ensure that they are mounted properly and serviceable. If a battery is required for a communication device, ensure it is fully charged and properly installed; then, activate the communication device. Monitor the communication device for malfunctions during the course of the test and visually check it and other accessories at the termination of the test for visible cracks and/or breaches of the airflow boundary, a.k.a. compromises of form, fit or function.
- 5.2.4 Turn on the breathing pump (See Requirements in Paragraph 4.2.1. for the prescribed breathing rates). Use the integrated SMARTMAN magnehelic pressure gauge as required as a qualitative indicator of PAPR performance and can serve as a tool for observation purposes.
- 5.2.5 Using the TDA 99M, leak test the PAPR in the operational mode (blower operating). Connect the detector inlet to a sample line from the SMARTMAN, allow the PAPR to breath, and create a stable value on the TDA-99M. When the aerosol is being generated, direct the wand to various portions of the facepiece and all mechanical seals and joints to

detect any leaks. The aerosol will be detected inside the facepiece if it finds a leak path. If any leaks are found, they must be corrected by only authorized laboratory personnel or the manager. If a leak is found through the canister, connect a clean airline from outside the exposure chamber. 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 thirty (30) minutes of continuous TDA-99M operations below 0.0010% penetration. If penetration exceeds 0.0010%, the TDA-99M alarm sounds, and/or the digital readout shows higher values, stop the 30 minute test, reanalyze the system and restart a new 30 minute test period. The PAPR must pass a continuous 30 minute test at $\leq 0.0009\%$ penetration parameters in separate clean exposure chamber and an agent exposure chamber to be considered "qualified" to progress on in the agent testing. If after repeated attempts a successful leakage test cannot be achieved, the laboratory manager may use alternative means to seal the facepiece to the headform such as sealing the facepiece and nose cup to the headform using non-toxic adhesive with the concurrence of the NIOSH/NPPTL. Other methods such as allowing the respirator to purge itself of internal offgassing particulates are acceptable provided the purge time is not excessively long. All adhesive designated for CBRN certification use is required to undergo verification testing (V-Test) prior to use as a CBRN LAT capable substance (Successful performance to the given STP using three consecutive V-Test trial samples). If the respirator continues to fail the TDA 99M, the manufacturer must supply confirmed MSDS on the type of particulate being picked up by the TDA 99M and a confirmation analysis by a third party laboratory must confirm the manufacturer's MSDS and the particulates must be determined to be non-toxic in the acute and chronic human toxicology perspective before a NIOSH letter of approval is issued for a passing LAT respirator. If the applicant requests to continue despite the high TDA 99M readings, the 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.

- 5.2.6 Before the PAPR facepiece or hood can be placed on the SMARTMAN in the agent exposure chamber, the MINICAMS must have shown a steady state background lower than the lowest point on the calibration curves. This is accomplished by installing a M40 military protective mask on the SMARTMAN. Ensure a new or sanitized/deconned M40 mask is used. The SMARTMAN should be allowed to breathe until the steady state background is lower than the lowest calibration curve point indicated on the respective MINICAMS. The use of the M40 may or may not be equivalent to the actual use of a tested respirator on the headform, therefore in test situations where background is not stable use all means necessary to gain a steady state background lower than the lowest calibration curve point for both MINICAMS before starting LAT.
- 5.2.7 Remove PAPR from clean exposure chamber and install on SMARTMAN in the GB agent exposure chamber.
- 5.2.8 Mount the PAPR on the SMARTMAN in the agent exposure chamber. Conduct a TDA-99M 30 minute test by repeating steps of paragraph 5.2.5, with the exception that once the agent exposure chamber is sealed and no leaks are confirmed with the TDA-99M, the TDA-99M aerosol challenge is discontinued. Ensure the agent exposure chamber is purged of Emery Oil particulates for at least 15 minutes. Ensure that the removal of the TDA-99M test hardware does not disturb the established seal of the PAPR facepiece to the SMARTMAN system. Remove the clean airline from the canister system, if it was used to isolate leaks.

- 5.2.9 Turn on the Miller Nelson Flow temperature and humidity controller.
- 5.2.10 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 is less than the lowest point on the MINICAM calibration curve. 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 PAPR facepiece or hood, rinse the headform with IPA, redon the facepiece or hood and restart the procedure for characterization as necessary. If the PAPR is removed from the head form, restart the test procedure from paragraph 5.2.3.
- 5.2.11 Set up standard operational mode of test equipment. Ensure all test equipment is within calibration.
- 5.2.12 Set Miller-Nelson for airflow into exposure chamber set to deliver required rates. See paragraph 4.2.2.
- 5.2.13 Ensure the MINICAMS are calibrated, check shot is complete and acceptable and ready for the operating mode. Annotate the check shot times and concentrations.
- 5.2.14 Ensure that the challenge concentration instrument is calibrated and is ready for analysis. Monitor the 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.
- 5.2.15 Load liquid agent in syringe and set syringe pump to correct flow rate to achieve the required agent challenge concentration. See paragraph 4.7.
- 5.2.16 GB Vapor Application:

There are two different breathing rate requirements that only apply to the first 30 minute vapor challenge phase. The breathing rate shall depend on whether the PAPR being tested is a Constant Flow or a Demand Response type. If the PAPR is a Constant Flow Type, the Breathing machine rate will remain at 40 lpm (36 +/- 2 strokes per minute) during the first 30 minute vapor challenge phase and through out the remainder of the 8 hours test. If the PAPR is a Demand Response, the breathing rate shall be set at 40 lpm (36 +/- 2 strokes per minute) for the first 15 minutes of the vapor challenge then be increased to 60 lpm (55 +/- 2 strokes per minute) between the 15 minute to 30 minute mark of the vapor challenge. After the 30 minute vapor challenge, the breathing rate for the Demand Response type shall be decreased to 40 lpm for the remainder of the test.

5.2.16.1. Vapor Challenge (Constant Flow)

5.2.16.1.1. Time zero (0) + One second or start of the agent test is when the first confirmed vapor state of GB is applied to the interior of the exposure chamber while the MINICAMS are actively sampling. Vapor is pumped in for 30 minutes, turned off and agent decay cycle is monitored for 7.5 hrs.

5.2.16.1.2. Ensure the breathing pump is set at 40 lpm for the entire duration of the test. Start of the 30-minute vapor exposure is when GB vapor is injected into the GB exposure chamber and initially detected. Annotate this starting time. Ensure time management is accomplished that allows the efficient tracking of two simultaneous events: one clock for total test time from start of GB exposure for 8 hours and another clock for GB Vapor at 30 minutes.

5.2.16.1.3. Introduce GB vapor agent challenge to the agent exposure chamber by first starting the syringe pumping and turning the valve inline from bypass of the mixing chamber to direct flow from the mixing chamber to the internal ambient space of the agent exposure chamber. Using the appropriate Miran detector, monitor the concentration build up in the exposure chamber generated by the mixing chamber. The total flow to the mixing chamber from Miller Nelson is dependent on the airflow rate of the PAPR, which includes enough excess to make up for the clean air exhausted from the PAPR into the exposure chamber and maintain the constant challenge as required. The syringe flow rate is set to introduce the quantity of agent necessary to generate the challenge concentration required. Record when the MINICAMS begin monitoring the interior of the facepiece.

5.2.16.1.4. The vapor syringe pump should run for the prescribed challenge period of 30 minutes, but no more than 31 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, simulating weathering.

5.2.16.2. Vapor Challenge (Demand Response Flow)

5.2.16.2.1. Time zero (0)+ One second or start of the agent test is when the first confirmed vapor state of GB is applied to the interior of the exposure chamber while the MINICAMS are actively sampling. Vapor is pumped in for 30 minutes, turned off and agent decay cycle is monitored for 7.5 hrs.

5.2.16.2.2. Ensure the breathing pump is set at 40 lpm (36 +/- 2 strokes per minute) between time zero (0) to the 15 minute mark. Start of the 30-minute vapor exposure is when HD vapor is injected into the HD exposure chamber. Annotate this starting time. Ensure time management is accomplished that allows the efficient tracking of two simultaneous events: one clock for total test time from start of HD exposure for 8 hours and another clock for HD Vapor at 30 minutes.

5.2.16.2.3. Introduce GB vapor agent challenge to the agent exposure chamber by first starting the syringe pumping and turning the valve inline from bypass of the mixing chamber to direct flow from the mixing chamber to the internal ambient space of the agent exposure chamber. Using the appropriate Miran detector, monitor the concentration build up in the exposure chamber generated by the mixing chamber. The total flow to the mixing chamber from Miller Nelson is dependent on the airflow rate of the PAPR, which includes enough excess to make up for the clean air exhausted from the PAPR into the exposure chamber and maintain the constant challenge as required. 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 facepiece.

5.2.16.2.4. After the PAPR has been exposed to 15 minutes of vapor exposure, increase the breathing pump to 60 lpm (55 +/- 2 strokes per minute) until the 30 minute mark of the vapor challenge phase. After the 30-minute vapor challenge, the breathing rate for the Demand Response PAPR shall be set back to 40 lpm for the remainder of the test.

5.2.16.2.5. The vapor syringe pump should run for the prescribed challenge period of 30 minutes, but no more than 31 minutes. After the PAPR has been exposed to 15 minutes of vapor exposure, the syringe rate shall be increased between the 15 minute to 30 minute mark of the vapor challenge test in order to maintain the required GB concentration in the exposure chamber resulting from the increasing the breathing pump rate to 60 lpm. 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, simulating weathering.

5.2.17. A detector is used to monitor the challenge concentration in the exposure chamber. This will be recorded on a computer with compatible software capable of accurately depicting the agent concentration versus time.

5.2.18. System Hold or Agent Decay Monitor Time involves the continuance of flushing the agent exposure chamber with the Miller-Nelson uncontaminated air to allow the simulation of the natural effects of ambient environmental conditions while the persistent vapor effects of GB react.

5.2.19. Test Surveillance: The laboratory technicians should 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 of 0.044 mg/m³ to document the PAPR's failure before MINICAMS can be taken off line from detecting.

5.2.20. Procedures for Termination of Test:

5.2.20.1 The test should be terminated when the full time for the test has elapsed or three confirmed quantifiable consecutive maximum peak excursions are verifiable. The pass/fail criteria on Ct are determined after eight (8) hour 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. Take an aliquot of one of the mid-range standard solutions of agent with a microliter syringe and inject it into the nasal sampling port by injecting the line at the bottom of the exposure chamber. 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.

5.2.20.2 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 manufacturer 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. Test Service Agreements (TSA) between the manufacturer and the test laboratory on materials swatch testing or entire respirators is authorized off line from the timeline of the conduct of this standardized test procedure. However, in support of the TSA testing concept, the NIOSH/NPPTL CBRN Respirator Research and Development (R&D) Test Program, current letter, provides for prioritized use of dedicated NIOSH test equipment in support of research and development that is separate and distinct from certification.

5.2.21. Example Step Sequence of activities for GB vapor CBRN PAPR test.

1. Conduct M40 preparation and background contamination assessment.
2. Install PAPR in clean exposure chamber.
3. Close clean exposure chamber, ensure PAPR blower is operating.
4. Challenge clean PAPR with TDA-99M for 30 minutes
5. Verify that clean PAPR has passed TDA-99M, retest/refit, go to next step or if failure, substitute failed PAPR with a new untested PAPR. Ensure an environmentally pre-tested canister or a qualifier canister is used and properly labeled for LAT.
6. Install PAPR in agent exposure chamber.
7. Photograph PAPR.
8. Close agent exposure chamber, ensure PAPR blower is operating and start breathing pump.
9. Challenge PAPR with TDA-99M for 30 minutes in the hot box.
10. Start MINICAMS.
11. Monitor background inside the mask and perform chamber concentration/check shot.
12. Conduct characterization for 60 min.
13. Ensure front panel is readily available for replacement on agent exposure chamber
14. Start makeup air using Miller-Nelson Controller while simultaneously starting ambient challenge concentration detection profile software, if not already started.
15. Start syringe pump.
16. Record start time of MINICAMS.
17. Initiate challenge agent
18. Record 30-minute GB vapor start time.
19. Record challenge agent start time, GB vapor exposure.
20. Ensure chamber ambient challenge concentration is ramping up as expected.
21. Monitor MINICAMS for detection, noted penetration peaks and saturation prevention.
22. Stop syringe pump at 30-minute mark, but no later 31 minutes.
23. Record stop time for challenge GB vapor exposure.
24. Record hold time start (7.5 hours).
25. Eight (8.0) hours, end test.

26. Record end time and local time at 8.0 hours
27. Conduct check shot instrumentation
28. Record check shot results and time of last end of test check shot.
29. Prepare system for decon and removal of tested components.

5.2.23 Data Analysis

- 5.2.23.1 Lead technician 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. Laboratory Notebooks shall be signed and dated by technician, copies of all hardcopies of data that are generated shall be kept in the assigned task folder with NIOSH Task number.
- 5.2.23.2 Laboratory manager and technician 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 PAPR 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 PAPR test data collection. NIOSH DEIMS, current version, will assign TNs, maintain the CBRN PAPR test queue and process all initial, lab and final reviews. NIOSH DEIMS for CBRN PAPR 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.
- 5.2.23.3 Transfer the permeation 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 1000 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 1000 (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.
- 5.2.23.4 Challenge Concentration Data: Using the computations generated from para 5.2.23.3 above. Plot the challenge concentration versus time and produce two

data graphs that track total detection events covering any maximum peak excursions over 8.0 hours and total concentration over time known, as Cumulative Ct, covering the total 8.0 hours of potential cumulative and instantaneous dosages. If the test is terminated prior to the completion of 8.0 hours due to PAPR 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. The following criterion shall be met to Pass the Chemical Agent Permeation and Penetration Resistance Against GB Agent Requirement as indicated in final CBRN PAPR Statement of Standards dated ### :

Vapor challenge of PAPR 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 test time) (mg-min/m ³)	Number of Systems Tested
GB	210 [*]	30	40 60§§	0.044 [†]	1.05 [‡]	3

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

† The test period begins upon initial generation of vapor concentration and ends at 8 hours. Supplemental electrical power to the PAPR is permissible to allow the system to run for the purpose of this test.

‡ Three consecutive sequential test data points at or exceeding 0.044 mg/m³ will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.

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

§§ The breathing rate shall be increased to 60 lpm during the 15 minute to 30 minute mark of the vapor challenge phase while testing Demand Response PAPR.

6.1.1 Sarin (GB) Penetration and Permeation Test:

Challenge: 210 mg/m³ + 10 % for 30 minutes (but not more than 31 minutes).

Test Time: 8.0 hours.

Two-Fold Pass/Fail Criteria:

a) Maximum Agent Breakthrough (Ct) = 1.05mg-min/m³. Concentration integrated over minimum service life is Ct and it is based on a detection sample time of approximately three (3) minutes for eight (8) hours. 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 = 0.044mg/m³. Three (3) consecutive data points at or exceeding the peak value constitutes a failure where each test value is based on detection sample time of approximately three (3) minutes for eight (8) hours.

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 PAPR Guidelines for Identification of Test Configurations for Exposure to GB, current version.

NOTE: Any PAPR 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.

6.1.2 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.

6.2. This test establishes the procedures for ensuring the level of respiratory protection provided under special Chemical, Biological, Radiological, and Nuclear (CBRN) requirements for Powered Air-Purifying Respirator (PAPR) 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); Federal Register Volume 60, Number 110, June 8, 1995.

7. RECORDS/TEST SHEETS

7.1. All test data will be recorded in the NIOSH DIEMS and STP recognized formatted CBRN PAPR test data sheets (Appendix A). All applicable data, graphs and photographs taken/made by laboratory technicians, technician 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 Certification

Evaluation and Testing (CET) Section Chief 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.

RECORD OF CHANGE:

DRAFT

DRAFT

**APPENDIX A:
 CBRN PAPR GB LAT Certification Test Data Summary Sheet;
 NIOSH Procedure No. CET-APRS-STP-CBRN -0550**

1. TEST TITLE: Determination of CBRN Tight and Non-Tight Fitting Powered Air-Purifying Respirator (PAPR) Performance During Dynamic Testing Against Chemical Agent Sarin (GB) Vapor.

- A. Task Number (TN): _____
- B. Manufacturer: _____
- C. PAPR 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:

Each of three CBRN Tight and Non-Tight Fitting Powered Air-Purifying Respirator (PAPR) shall demonstrate no permeation or penetration of GB Vapor equal to or greater than the stated maximum peak excursions and the stated cumulative concentration over time (Ct) for the duration of the eight (8) hour test. GB vapor challenge concentration will start immediately after the test chamber has been sealed. Three consecutive sequential test data points at or exceeding 0.044 mg/m³ will collectively constitute a failure. The cumulative Ct, including all maximum peak excursion data points, must not exceed 1.05 mg/m³ for the duration of the test. The test period begins upon initial generation of GB vapor concentration and ends at 8 hours. One respirator system is tested in the AS IS/Ready to Use configuration and remaining two respirator systems are tested in the environmentally pre-conditioned configuration prior to LAT.

OVERALL RESULT: *PASS or FAIL*

3. SUPPORTING REQUIRED DATA:

- | | |
|--|-----------|
| A. Has Canister expired prior to LAT in accordance with User Instructions? | YES or NO |
| B. Is Canister bent, cracked or disfigured prior to any portion of LAT? | YES or NO |
| C. Does Canister to facepiece connection violate Form, Fit or Function? | YES or NO |
| D. Is Facepiece fully serviceable prior to any portion of LAT? | YES or NO |
| E. Are Sub Assemblies free of visible deformations or aberrations? | YES or NO |
| F. Are remainder components environmentally conditioned prior to LAT? | YES or NO |
| G. Does blower operate prior to LAT? | YES or NO |

GB CBRN PAPR LAT Certification Summary Continuum:

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

Test Title: Determination of CBRN Tight and Non-Tight Fitting Powered Air-Purifying Respirator (PAPR) Performance During Dynamic Testing Against Chemical Agent Sarin (GB) Vapor.

- | | |
|---|--------------|
| H. Did each PAPR pass or fail maximum peak excursions? | PASS or FAIL |
| I. Did each PAPR pass or fail Ct? | PASS or FAIL |
| J. Was all lab test equipment verified calibrated prior to LAT? | PASS or FAIL |

K. Were the SAF Configuration Part Numbers verified on the actual testable hardware?
 PASS or FAIL

<u>QUALIFIER TEST # 1</u>	<u>Total Test Time</u>	<u>Max Peak Excursions</u>	<u>Ct</u>	<u>RESULT</u>
(e.g. TN –GB 1	480 minutes or less	Quantity failing	Value	Pass/Fail)
<u>REMAINDER TEST # 2</u>	<u>Total Test Time</u>	<u>Max Peak Excursions</u>	<u>Ct</u>	<u>RESULT</u>
(TN – GB 2)	Same as above (sab).	sab	sab	sab
<u>REMAINDER TEST # 3</u>	<u>Total Test Time</u>	<u>Max Peak Excursions</u>	<u>Ct</u>	<u>RESULT</u>
(TN – GB 3.)	sab	sab	sab	sab

4. COMMENTS:

(e.g. CBRN PAPR candidate was tested in non-environmentally conditioned /Ready to Use configuration for initial Qualifier Application. CBRN PAPR passed initial Qualifier Application LAT. However, when Conditioned Configuration was tested in Remainder Application tests, candidate CBRN PAPR 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 Technician: _____ Date: _____
 B. Laboratory Supervisor: _____ Date: _____

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

