National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory P.O. Box 18070 Pittsburgh, PA 15236		
Procedure No. CET-APRS-CBRN-STP-0350	Revision: 0.1	Date: 29 September 2005

DETERMINATION OF FULL FACEPIECE, TIGHT FITTING, NEGATIVE PRESSURE, AIR-PURIFYING RESPIRATOR (APR) PERFORMANCE DURING DYNAMIC TESTING AGAINST THE CHEMICAL AGENT SARIN (GB) VAPOR CBRN STANDARD TESTING PROCEDURE (STP)

1.0. PURPOSE

1.1. This test establishes the procedures for ensuring the level of respiratory protection provided under chemical, biological, radiological, and nuclear (CBRN) protection requirements for full facepiece, tight fitting, negative pressure, air-purifying respirators (APR) 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 procedure necessary to test and certify CBRN APR. This procedure is used to test CBRN APR against Sarin (GB) vapor while the respirator, as a system, is operated in a dynamic breathing mode by means of a mechanical breather pump connected to the mouth area of a given validated manikin headform. Instrumentation is integrated under this dynamic static chamber platform for the purpose of generating and controlling challenge concentrations and detecting precise agent penetration and permeation of a tested respirator system.

1.3. The procedure is a separate test under the NIOSH National Personal Protective Technology Laboratory (NPPTL) heading of CET-APRS-STP-CBRN-0350 for challenge agent Sarin (GB) vapor. This procedure is designed to rigorously test the evaluated respirator as a dynamic system and generate repeatable independent pass or fail results.

2. GENERAL

2.1. The STP describes a test titled "Determination of Full Facepiece, Tight Fitting, Negative Pressure, Air-Purifying Respirator (APR) Performance during Dynamic Testing against the Chemical Agent Vapor Sarin (GB)" 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.

Approvals:	1st Level	2nd Level	3rd Level

3. EQUIPMENT AND MATERIALS

3.1. SMARTMAN, Headform/Upper Torso or Equivalent (Figure 1). Manufactured by ILC Dover, Frederica, Delaware, the Simulant Agent Resistant Test Manikin, (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 that fits into a channel between the face and the permanent part of the head. (See figure 1.) 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 face surface of the SMARTMAN is connected in several places to outside sampling ports by means of stainless steel tubing that is located inside the headform and passes out the bottom of the headform. The largest tube, 1¼″ in diameter, leads from the mouth area to the breather pump. Four smaller tubes are also present. One tube connects to the center of the left eye and can be used to monitor the upper, or eye area, of the interior of the mask. A second tube connects to the lower middle forehead above the bridge of the nose and can be used to monitor pressure or

Figure 1. Headform/upper torso manikin, SMARTMAN.

Differential pressure when connected by means of a manometer to the nose area. And finally, 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, while the second one is used to monitor presence of agent. The four tubes are ¼″ 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 or other components as they are intended per manufacturer instructions.

3.2. Leak Detector Model TDA-99M or Equivalent (Figure 2). Manufactured by Air Techniques International in Owings Mills, Maryland, the TDA-99M is one of the primary tools for accessing aerosol particulate leaks in the mechanical seals of the respirator and proper fit of a respirator to a clean SMARTMAN headform under non-toxic oil aerosol conditions. The TDA-99M generates a polyalphaolefin aerosol that is used to detect leakage in the respirator (Emery 3004 oil manufactured by the Henkel Corporation-Emery Group or equivalent).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 mg/m^3. This aerosol is introduced by the TDA-99M's pump. The respirator interior is quantitatively monitored for the presence of aerosol. The leak detector compares the concentration inside with the concentration outside, and calculates a digital read out percent penetration value. Dataport capabilities do exist for downloading data as software is published.

3.3. Miniature Continuous Air Monitoring System, MINICAMS® or Equivalent (Figure 3). Manufactured by OI Analytical, 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

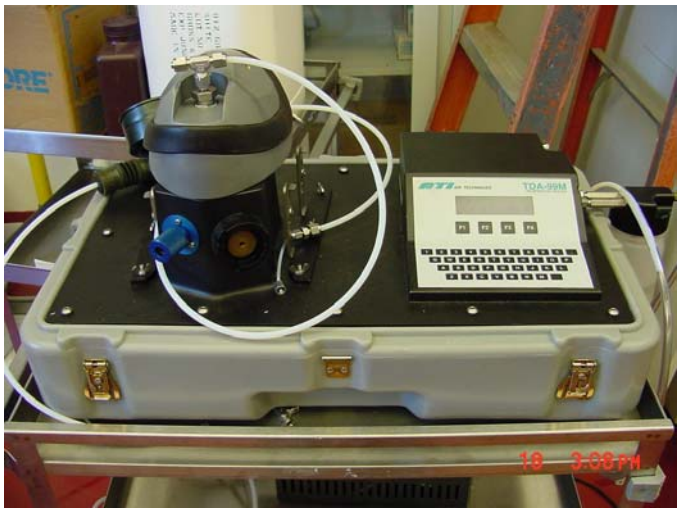

Figure 2. Leak detector model TDA-99M.

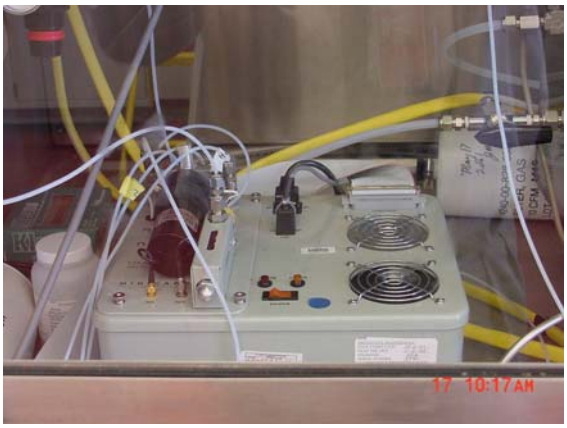

Figure 3. Miniature Continuous Air Monitoring System, (MINICAMS®).

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, 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-hour TWA 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. This is quantified at the beginning of each test, the detection instrumentation must remain stable for 60 minutes prior to the initiation of any test or evaluation. A minimum of two MINICAMS® are required in order to continuously monitor the interior of the respirator. NOTE: Next generation MINICAMS® and support equipment require successful NIOSH validation testing (V-test) documentation before implementation.

3.4. Syringe Pump, Sage® Model M365 or Equivalent (Figure 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 body cavity or into a duct or vessel) to the dilution airline. The plunger of the syringe is driven at a controlled rate by the pump to deliver a constant flow of agent. The concentration of agent is adjusted by changing the speed setting of the pump. The rate flow range can be from 20.0 mL/min to 0.3 L/hr, and flow accuracy of ± 5% nominal.

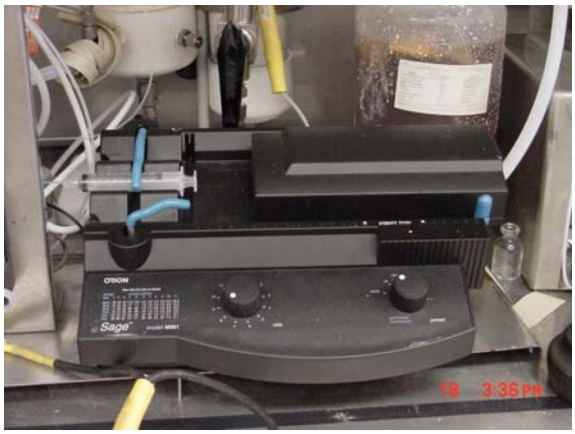

Figure 4. Syringe pump, Sage® Model M365

NOTE: Next generation syringe pumps or equivalent equipment and support equipment for data logging or automation, require successful NIOSH validation testing (V-test) documentation before implementation.

3.5. Miller-Nelson® Flow-Temperature-Humidity Control System or Equivalent (Figure 5). Manufactured by Miller-Nelson Research, Inc., this system, referred to as the Miller-Nelson® 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 and flow (50–200 L/min ± 2%), and relative humidity (20%–80% ± 3%) and temperature (20°C–30°C ± 0.3%)

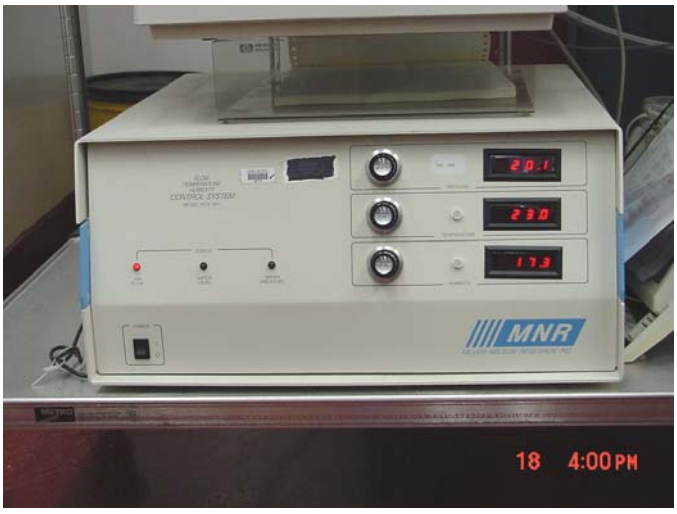

Figure 5. Miller-Nelson® flow-temperature-humidity control system.

3.6. Exposure Chamber or Equivalent (Figure 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^3. Four legs made out of the same chemically resistant material 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 is a second chamber used to perform a fit and leak check on a respirator before it is installed in the agent exposure chamber (no agents are used in this chamber). An agent exposure chamber is a chamber used to perform testing of the respirator unit, using live agent. Figure 6 shows a typical clean exposure chamber.

3.7. Agent Mixing Chamber or Equivalent (Figure 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 airflow from the Miller-Nelson® Control System 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 filtration scrubber canister, a M18 military specification canister or equivalent.

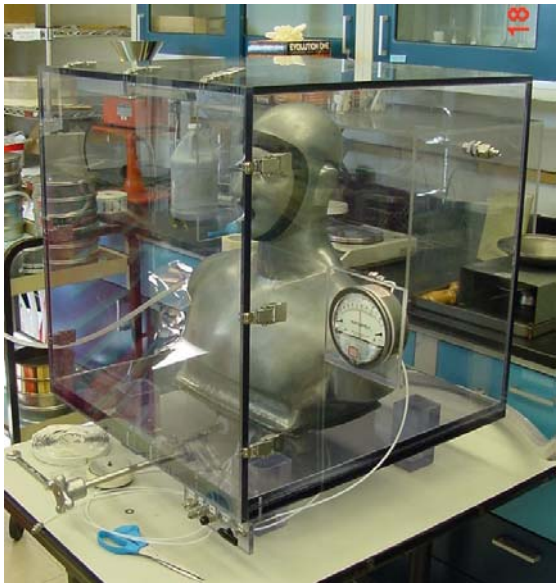

Figure 6. Exposure chamber.

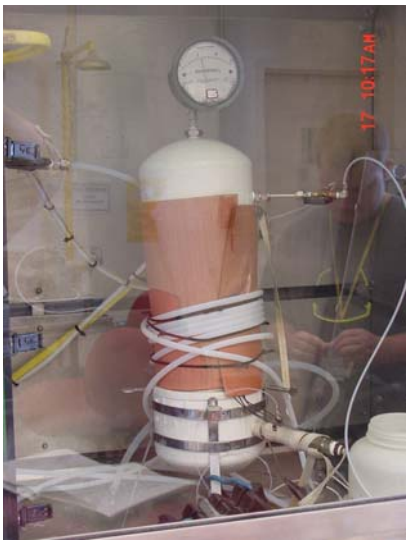

Figure 7. Mixing chamber.

3.8. Breather Pump, Model E1R1® or Equivalent (Figure 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 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 L/min and drops back to zero. The exhalation stroke of the pump is the same sinusoidal pattern. The volume per breath or tidal volume is adjustable up to 1.5 liters.

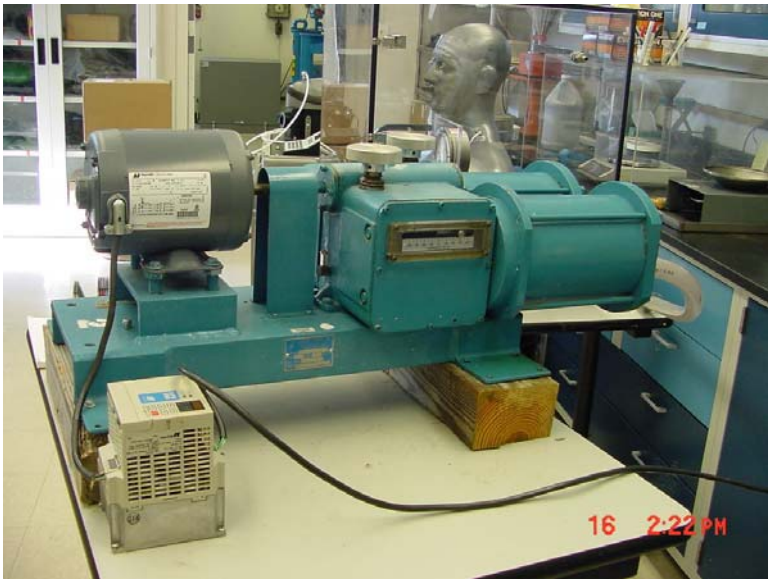

Figure 8. Breather pump.

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.

3.10. Ambient Air Analyzer, MIRAN® Model 205B and Model 1A, or Equivalents (Figures 9 and 10). Manufactured by Thermo Environmental Instruments, Inc. in Franklin, Massachusetts, these are 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.

3.11. Test Material and Respirator System Quantities and Relevant Policy.

3.11.1. Required Quantities: Quantity of respirators for GB Live Agent Testing (LAT) is per NIOSH/NPPTL *CBRN APR Statement of Standard*, Table 7, Test Sequence and Quantity Matrix. Overall GB LAT quantity is three complete respirator systems. One respirator system is tested as a qualifier in this STP and is commonly known as the Qualifier Live Agent Test (QLAT). Remaining two respirator systems are tested in sequence and are commonly known as the Remainder Live Agent Tests (RLAT).

3.11.2. In the case of canisters, 125 canisters only go through hot, cold, humidity, vibration, and 117 of the 125 are manually dropped as a final conditioning process, before being tested in one of five types of follow on CBRN service life tests. RLAT penetration and permeation testing is one of those five types of service life tests for CBRN APR protocol. Initially, one respirator is required in a GB QLAT "as is/received". Then, two environmentally conditioned canisters come out of environmental processing go to GB RLAT utilizing environmentally conditioned like respirators. Upon confirmation that the initial new application testing the QLAT samples are a success and completion of environmental conditioning, remainder LAT is completed by randomly selecting Task Number (TN) respirator systems for follow on remainder LAT, GB and HD, in accordance with *CBRN APR Statement Of Standard*, Paragraphs 4.7. and 4.9. Respirators designated as "spare queue" conditioned respirators are stored and available for use by the testing laboratory in situations where ongoing test processes are delayed or stopped by installation power failures, inaccurate test processing or other mid-test termination events identified by the test laboratory manager. In most cases, spare queue respirators are not to be used for additional certification testing because the applicant or manufacturer requests it. NIOSH should be informed of spare queue inventory testing conducted by the testing laboratory.

3.11.3. Qualifier LAT (QLAT): New GB LAT canisters and face blanks should be received from NIOSH/NPPTL in a "as is/received" condition. No modifications to the tested canisters, components or APR are authorized prior or during live agent systems testing. At the NIOSH tenant laboratory initial certification qualifier application inventory conducted first, canisters received "as is" in the ready-to-use packaging are required to be inspected in accordance with the

manufacturers user instructions (UI), kept in original packaging, and provided to testing laboratory upon completion of certification inventory.

3.11.4. Remainder LAT (RLAT): Commencement of GB RLAT is contingent upon testable canisters completing all required NIOSH/NPPTL CBRN APR environmental durability processing prior to any live agent testing. Environmentally conditioned canisters can be attached per manufacturer instructions to available faceblanks prior to live agent testing by qualified and designated laboratory live agent testing technicians only. Environmentally conditioned canisters should be received in manufacturer specified minimum packaging and administratively labeled with a conditioning administrative number matching the task number. Only the manufacturer's inlet and outlet plugs that come with the canister are to be used to seal up the canister after environmental testing. 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 environmentally pre-conditioned canisters and facepieces. Any canister damage during environmental processing is required to be preserved, not altered and noted on administrative reports to the NIOSH.

3.11.4. If practical, GB live agent systems test canisters and respirators can be labeled prior to actual live agent testing with the following administrative information:

— NIOSH task number (TN number)

— Model of APR

— 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 investigations.

4. TESTING REQUIREMENTS AND CONDITIONS

4.1. Any laboratory using this procedure to supply certification test data to NIOSH will be subject to the provisions of the NIOSH Supplier Qualifications Program (SQP). This program is based on the tenets of *ISO/IEC 17025*, the *NIOSH Manual of Analytical Methods* and other NIOSH guidelines. An initial complete quality system audit and follow on audits are requirements of the program. Additional details of the program and its requirements can be obtained directly from the NIOSH.

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

4.3. Prior to beginning any testing, all measuring equipment to be used must have been calibrated in accordance with its' calibration procedure and schedule. At the minimum, all measuring equipment utilized for this testing must have been calibrated within the preceding 12 months or as required by manufacturer, using a quantifiable method traceable to the National Institute of Standards and Technology (NIST).

4.4. System Test Conditions

4.4.1. Breathing Machine

— Airflow = 40 liters per minute (Lpm)

— Respirations = 36 ± 2 strokes per minute

— Tidal Volume = 1.1 liters

4.4.2. Miller-Nelson® Control System airflow settings into exposure chamber:

Airflow Rate: The actual value here is to be determined based on laboratory test conditions and dependent method. The actual air flow value arrived at must be documented with a working equation showing supporting repeatable computations. Technicians determine an appropriate airflow rate based upon obtaining a stable concentration in the given volume of the exposure chamber and considering the agent challenge concentration desired, volume of chamber, breather pump airflow and dilution air exhaled from the APR.

Relative Humidity: 50% ± 5% RH.

Temperature: 25°C ± 3°C

4.4.3. SMARTMAN Sampling Point:

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

4.4.4. Sarin (GB) Vapor Test.

4.4.4.1. GB vapor: General.

— Vapor Challenge Concentration = 210 mg/m^3 ± 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

— Syringe Injected Volume = as required based upon syringe pump used

NOTE: LAT vapor challenge concentrations for GB and HD are different. The GB vapor challenge concentration is 210 mg/m^3 ± 10%, while that for HD is 50 mg/m^3 ± 10%.

4.4.4.2. Liquid Sarin (GB) must be Chemical Agent Standard Analytical Reference Material (CASARM) grade. Agent purity analysis must be NIST traceable, documented and meet CASARM grade agent purity requirements. Proper CASARM storage requirements per local regulation are required to be adhered to.

4.4.5. Test Termination Parameters: The test will be terminated to protect the MINICAMS® detectors from over-saturation when a candidate APR shows failing criteria prior to the 8-hour mark. The decision termination point should be set at or above the highest calibration point for each one of the MINICAMS® in use.

4.5. 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 include all safety precautions described in the current *Centers for Disease Control and Prevention (CDC) General Laboratory Health and Safety Manual*, the applicable US Army Regulations, the *U.S. Army Soldiers and Biological Chemical Command Laboratory Safety Procedures*, and any other equivalent manuals and periodicals.

4.5.1. Safety glasses, lab coats, assigned respirator, butyl apron and butyl gloves are required be available, worn and replaced as laboratory standard operating procedures apply.

4.5.2. Work and walking surfaces must be maintained free of clutter and non-essential test equipment.

4.5.3. 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.

4.5.4. 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. Training records are accountable during laboratory audits.

4.5.5. The responsible technician must be knowledgeable about the specific CBRN APR being tested and should be able to readily identify all CBRN APR hardware components, subassemblies and accessories. Technicians are required to be able to support accurate trouble shooting of the CBRN APR and subassemblies to ensure it is operating in a correct negative pressure mode. The technician must be able to properly align and fit the respirator facepiece on the SMARTMAN

headform, without malformation or destruction of any CBRN APR component or material. Correct nose-cup positioning is an example of one area that requires proper inspection per the UI.

4.5.6. 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 APR materials is the responsibility of the testing laboratory. In accordance with this STP, respirator manufacturers are released of equipment accountability once equipment is formally tested in the appropriate NIOSH recognized test laboratory. Manufacturer warning and caution statements for the respirators are subject to legal interpretation and most likely will not apply once the respirator has been contaminated by toxic chemical warfare agents and processed thru the decontamination procedure.

4.5.7. 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.

4.5.8. 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.

4.6. Equipment Pre-Test Conditions: MINICAMS®

4.6.1. Background Reading: A laboratory MINICAMS®, as opposed to a field MINICAMS®, is used as the detector for agent permeation and penetration of the CBRN APR. It consists of a monitor, personal computer, linear mass flow meter and optional printer or recorder. Before the APR 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. A clean M40 military specified respirator, mounted on the SMARTMAN head form, may be used. The SMARTMAN is then allowed to breathe for the required time (8, 12, 48, 72 hours etc, however long it takes coupled with intermittent decontamination wipedowns as necessary.) 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 LAT for certification is not authorized to start without the background readings of the assigned SMARTMAN system (tested respirator and headform) are within the limits specified.

4.6.2. Unit of Measure. A small volume of air is drawn through a pre-concentrator 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.

4.6.3. 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 minutes), depending on the application. GB analysis can require up to a 4-minute cycle. The two MINICAMS® will be synchronized so that one MINICAMS® sampling begins when the other MINICAMS® sampling ends. Raw data results confirm this requirement.

NOTE: LAT analysis cycles for GB and HD are different. GB analysis can require up to a 4-minute cycle whereas HD requires a 6-minute cycle. These times can be sub-divided into 2-minute cycles for each MINICAMS® during the LAT with GB and 3-minute cycles for each MINICAMS® during testing with HD. Raw data tables are required to demonstrate this repeatable process and the actual tables are required to be provide to the NIOSH in support of finalizing the NIOSH test report.

4.6.4. GB Detection Principle. The MINICAMS® are 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, 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.

4.6.5. 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 µL) of a standard solution of the agent onto the pre-concentrator tube during the INJECT segment of the test cycle. The standard solutions of agent are made in spectrophotometric grade isopropanol. At least three injections of each quantity of agent should be injected.

4.6.6. Pretest activities for the MINICAMS® are as follows:

— Start the MINICAMS®

— Set or verify operational parameters for appropriate agent

— Perform standardization

— Record ASCII file name on internal lab work sheet/notebook

— Standby for start of testing

4.7. Equipment Pre-Test Conditions: SMARTMAN GB Vapor Generation.

4.7.1. 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® Control System air controller and a syringe pump for injecting the agent through a heated "tee" into the air stream. Technicians 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 APR.

4.7.2. Ramp-up Tome: 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. The ability to accurately detect and quantify this agent ramp up time is a requirement for the testing laboratory and agent duration exposure time graphs should be available to confirm agent exposure duration in accordance with the procedures of this STP.

4.7.3. Concentration Verification Summary:

GB Setup Variables: (Mass balance analysis method or another demonstrated equivalent method is used to confirm repeatable GB quantity sampling and amount of agent used per test.)

- Chamber size = 8 ft^3
- Target Challenge Concentration = 210 mg/m^3 ± 21 mg/m^3
- Ramp Up Time = 4–5 minutes (Time from initial start of syringe pump to 189 mg/m^3 lowest acceptable challenge concentration start point.)
- Dilution Air from Breather Pump = 40 L/min
- Miller-Nelson® Challenge Mixing Air = 50 L/min ± 2%
- Syringe Rate for Challenge Injection = 0.34 mL/min
- Total GB projected for use in 30 minutes = 10.2 mL

4.7.4. 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. Changes to this process require updating to NIOSH as necessary.

4.8. Equipment Pre-Test Conditions: Miller-Nelson® Control System.

4.8.1. The Miller-Nelson® receives compressed air from the laboratory air supply system. Operate the Miller-Nelson according to the manufacturer's instructions. Insure it is calibrated correctly prior to starting the test. The sensors for relative humidity and temperature must be calibrated, as must be 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 is logged in the technician's logbook prior to commencing actual testing. Changes to this

4.8.2. Set the readout panels on the Miller-Nelson® according to Paragraph 4.4.2. 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.

4.9. Equipment Pre-Test Conditions: Syringe pump.

4.9.1. 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.

4.9.2. 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.

4.9.3. 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 a predetermined time.

4.10. Equipment Pre-Test Conditions: TDA-99M Aerosol Leak Detector.

4.10.1. The TDA-99M leak detector is used to detect oil particulate aerosol leaks in the CBRN APR after it has been installed on the SMARTMAN headform cold box/clean chamber. Ensure the canister and all components are correctly mounted and tightened per the current manufacturer instructions and specifications. The APR is operated under negative pressure using air supplied to the APR from the Miller-Nelson® filtered house air of the laboratory. Ensure that procedures for the APR follow the manufacturer's installation procedures for gasket seal, facepiece donning and interface. The canister and gasket, if provided, should be the same product that has undergone recent NIOSH/NPPTL environmental durability processing or in the "as is/received" condition. Ensure the seal, threaded interface inlet and outlet areas and canister housing are not

changed in any manner prior to or after the LAT. However, if the canister or canister interface thread is deformed from environmental processing, 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 and available for follow up incident review if necessary. Advise NIOSH.

4.10.2. Turn on the power and let the leak detector equilibrate, according to the manufacturer's instructions. The APR should be operating. Turn on the breather pump to activate the test mask. 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. Any leaks found must be corrected. If no localized leaks are found, replace the front panel of the exposure chamber and start the actual TDA-99M test.

4.10.3. Connect the TDA-99M to a port into the exposure chamber and fill the chamber with aerosols. 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. If there is evidence of leakage, attempt to find and eliminate the leak. When the detector indicates a maximum penetration of less than 0.0010% for 30 minutes, the screening is complete. Continue with the next the test procedure. If a leak is detected by isolating the filter or canister, use a dedicated clean Teflon tube to draw clean air from the outside of the chamber to test the canister. Ensure Teflon tube data and configuration drawing is annotated in lab book.

4.11. Equipment Pre-Test Conditions: Quality Control Measures.

4.11.1. SMARTMAN Leak Test: Because the SMARTMAN is made of cast zinc, it is unlikely, but possible, for leak paths to result. These may occur after extensive LAT or heavy dosage exposure due to incorrect APR assembly or mounting. They may form through the metal casting, allowing chemical warfare agent vapor to penetrate through the headform into the breathing zone 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 maximum pressure of 3 psi. 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 headforms when they are in continuous daily use.

4.11.2. Standardization of Instrumentation: Standardize the MINICAMS® by using liquid standard solutions of the agents at various concentrations. These solutions are made in accordance with US Army, *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 value of $r^2 = 0.999$ for GB. Agent solutions must be stored at 4^oF or lower and periodically monitored with a calibrated thermometer.

4.11.3 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® airflow controller, all electronic flow meters used for the MINICAMS® pr-concentrator tube and the flow meters from the breather pump and the syringe pump agent injector.

4.11.4. Aerosol Leak Testing: APR 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.

4.11.5. MINICAMS® Detector Response: Check the response of the MINICAMS® detector, before and after each test. 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 checkshot does not reproduce a verifiable result, repeat the checkshot. If the second checkshot is not within the 10% parameter, the test is invalid and preparations for a retest should start. A quantifiable check shot should be made within 3 hours of the start of the actual test and at the end of 8-hour mark.

5. PROCEDURE

5.1. Vapor Challenge GB (0350)

5.1.1. Assemble APR per manufacturer's instructions. Ensure the packaged canister is received as specified in Paragraph 3.11 and *CBRN APR Statement of Standard*, Paragraph 4.10, Table 7, Note 2. The note here identifies the canisters only being in the "minimum manufacturer's recommended packaging", which is interpreted

as the manufacturers specified packaging for storage of the canister. Facepieces will be tested "as is/received" when submitted in the qualifier application, conditioned in the remainder application and matched with appropriate conditioned canisters in accordance with *CBRN APR Statement of Standard.*

5.1.2. Take digital photographs of the assembled unit prior to start of LAT. These photographs are required to be available for NIOSH/NPPTL review and they should accurately and clearly indicate how the APR was configured with all components and tested.

5.1.3. 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 and 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 batteries are required for communications devices, ensure they are available and easily fit into the device but do not expose them to live agent. Rather during TDA-99M aerosol testing, ensure the batteries are in the communications device and the device is turned on during aerosol screening but then take the batteries out for live agent testing. Contaminated batteries place an undue burden on the test laboratory and do not substantiate the use of extensive disposal methods to dispose of them. Properly close the communications 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 or breaches of the airflow boundary or material detioration.

5.1.4. Turn on the breathing pump. Insure that the APR is in the negative pressure mode by conducting negative pressure seal check(s) with protected hand over required surfaces of the tested respirator per on hand current manufacturer operating instructions or use instructions. Use the integrated SMARTMAN magnehelic pressure gauge as required to support confirmation of negative pressure cycles. Magnehelic pressure gauge is used only as a qualitative indicator of APR performance and it can serve as a tool for cyclic air flow observation to confirm the APR is "breathing". Do not allow the tested CBRN APR to go into or maintain positive pressure for any reason, such as misdirected house air from air flow tubing cracks, kinks or line failure.

5.1.5. Using the TDA-99M, leak test the APR in the negative pressure mode, connect the detector inlet to a sample line from the SMARTMAN, allow the APR to breathe, and create a stable value on the TDA-99M. If a communications device is present ensure batteries are installed and it is operational. 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 the authorized laboratory technicians or manager only. 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 30 minutes of continuous TDA-99M operations below 0.0010% penetration. If penetration exceeds 0.0010%, the TDA-99M alarm sounds or the digital readout shows higher values, stop the 30-minute test, re-analyze the system and begin a new 30-minute test period. The APR must pass a continuous 30-minute test at ≤ 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 nosecup to the headform using non-toxic adhesive with the concurrence of the NIOSH/NPPTL. 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 to NIOSH, on the type of particulate being picked up by the TDA-99M. In addition, the manufacturer must obtain an analysis by a third party laboratory confirming the manufacturer's MSDS and the toxicity of the particulates.

5.1.6. Before the APR respirator facepiece can be placed on the SMARTMAN in the agent exposure chamber, the MINICAMS® must show a steady state background lower than the lowest point on the calibration curves. This is accomplished by installing a M40 respirator on the SMARTMAN. 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®.

5.1.7. Remove APR from clean exposure chamber and install on SMARTMAN in the GB agent exposure chamber.

5.1.8. Conduct a second TDA-99M 30-minute test, but this time in the agent exposure/hot box chamber by repeating paragraphs 5.1.3.–5.1.5., 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. Insure that the removal of the TDA-99M test hardware does not disturb the established seal of the APR facepiece to the SMARTMAN system. Remove the clean airline from the canister system, if it was used to isolate leaks.

5.1.9. Turn on the Miller-Nelson® Flow temperature and humidity controller.

5.1.10. MINICAMS® Background Characterization. A background characterization must be run before every chemical warfare agent test. The MINICAMS® should be monitored for a period of 60 minutes prior to the initiation of the chemical agent warfare 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 APR, decon the headform, redon the APR and restart the procedure for characterization as necessary. If the APR is removed from the headform, restart the procedure at Paragraph 5.1.8.

5.1.11. Set up standard operational mode of test equipment. Ensure all test equipment is within calibration.

5.1.12. Set the Miller-Nelson® for air flow into exposure chamber set to deliver required rates. See Paragraph 4.7.3.

5.1.13. Load liquid agent in syringe and set syringe pump to correct flow rate to achieve the required agent challenge concentration. See Paragraph 4.8 (GB).

5.1.14. Ensure MINICAMS® is standardized, perform check shot, and ready for operating mode. Annotate the check shot time and concentration percentage.

5.1.15. Ensure that the challenge concentration instrument is calibrated and is ready for analysis. Monitor agent exposure chamber during the 60-minute background characterization period. Characterization reading should reflect a steady state condition.

5.1.16. Time zero, or start of the agent test, is when the syringe pump is turned on and agent is allowed into the agent exposure chamber. Annotate this time.

5.1.17. Introduce GB vapor agent challenge to exposure chamber. Turn the valve in the line from by-pass to the mixing chamber to direct flow to the exposure chamber. The total flow to the chamber is approximately 50 L/min from the Miller-Nelson®, which includes enough excess to make up for the clean air exhausted from the respirator into the chamber and maintain the constant challenge as required. The concentration of challenge agent is monitored using the Miran detector or equivalent. The syringe flow rate is set to introduce the quantity of agent necessary to generate the challenge concentration required. Record the time when the MINICAMS® begin monitoring the interior of the APR. It is required to start the MINICAMS® before introducing agent into the chamber so that the first sampling period will coincide with the first agent challenge.

5.1.18. The 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 air flow rate delivered from the Miller-Nelson. These values will be recorded in the laboratory notebook and test sequence sheets. Ensure the syringe flow is off and the mixing chamber airflow line is bypassed so Miller-Nelson® uncontaminated air flow is going to the agent exposure chamber.

5.1.19. The MIRAN® will be 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 verses time and generating a final concentration detection graph per max peak attained and overall CT.

5.1.20. System Hold or Agent Decay Monitor Time: Continue flushing the agent exposure chamber with the Miller-Nelson® uncontaminated air to allow the simulation of the natural effects of ambient environmental conditions and the actual vapor effects of GB. Ensure the breathing machine operates at the same rate for the remaining 7.5 hours.

5.1.21. 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 breathing zone breakthrough concentration to protect the MINICAMS® against saturation. If the APR is failing, the MINICAMS® must record three consecutive maximum peak excursions to document the APR's failure before MINICAMS® can be taken off the detection line. Maximum peak values and overall Ct calculation and end point must be documented to show reliable and repeatable data collection.

5.1.22. Procedures for Termination of Test:

5.1.22.1. 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 or fail criteria on CT are determined after 8-hour completion and raw data tabulation. To terminate the test, turn off the breather pump. Perform a check shot of agent to assure 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 disconnecting the line from the bottom of the exposure chamber. The MINICAMS® response should be that indicated on the standard curve for agent contained in the aliquot. The response must be within 10% of the correct value for the final check shot test to be valid.

5.1.22.2. 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 view the APR this time, in accordance with local surety safety standard operating procedures. The test respirator will then be decontaminated, monitored and disposed of according to laboratory SOP. Wipe down the interior of the agent exposure chamber and the SMARTMAN using approved decontaminating 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 an option to the applicant.. However, in support of the TSA testing concept, the NIOSH/NPPTL CBRN Respirator Research and Development (R&D) Test Program does provide for use of dedicated NIOSH test equipment in support of research and development, R&D that is separate and distinct from certification.

5.1.23. Abbreviated Sequence

1. Conduct M40 preparation and background contamination assessment.
2. Install APR in clean exposure chamber.
3. Close clean exposure chamber, ensure APR is breathing.
4. Challenge clean APR with TDA-99M for 30 minutes.
5. Verify that clean APR has passed TDA-99M, retest or refit, go to next step or if failure, substitute failed APR with a new untested APR. If RLAT, ensure an environmentally conditioned canister is used.
6. Install APR in agent exposure chamber.
7. Photograph APR.
8. Close agent exposure chamber, ensure APR is in negative pressure mode and start breathing.
9. Challenge APR with TDA-99M for 30 minutes in the agent exposure chamber.
10. Start MINICAMS®.
11. Monitor background inside the APR and chamber concentration/check shot.
12. Conduct characterization for 60 minutes.
13. Start makeup air using Miller-Nelson® while simultaneously starting ambient challenge concentration detection profile software.
14. Start syringe pump.
15. Record start time of MINICAMS®.
16. Initiate challenge agent.
17. Record challenge agent start time of vapor exposure.
18. Simultaneously start ambient challenge concentration profile software.
19. Monitor MINICAMS® for detection, noted penetration peaks and saturation prevention.
20. Stop syringe pump at 30-minute mark.
21. Record stop time for challenge agent vapor exposure.
22. Record hold time start (7.5 hours).
23. End test.
24. Record end time at 8.0 hours.
25. Conduct check shot instrumentation.
26. Record check shot results and time of last end of test check shot.
27. Prepare system for decon and removal of tested components.

5.1.24. Data Analysis

5.1.24.1. 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 or failure, check shots and test start and 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. Notebooks 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 and maintained in accordance with NIOSH policies concerning the FOIA.

5.1.24.2. Laboratory manager and technician must complete all required test data sheets. Originals of all test data sheets must be completed and retained in the task file. Test data sheets for CBRN APR candidates are managed by digital exchange of pre-formatted blank file forms easily transferred in standard email. NIOSH DEIMS, current version, will assign TNs, maintain the CBRN APR test queue and process all initial, lab and final reviews. While an application is active in testing and has information for update, no release of test information to third party agencies of any type is authorized. NIOSH is the only agency authorized to tell the applicant the status of final test results. The transfer of applicable files sent to NIOSH should be updated daily or weekly with all applicable information to allow timely feedback and prevention of miscommunication. Testing lab is required to insure all summary data sheets are reviewed for accuracy prior to final submission to NIOSH/NPPTL in a timely manner. NIOSH requires test data summary sheets, test data graphs showing max peaks and separate graphs showing CT, raw test data and one digital picture of before and after testing.

5.1.24.3. Transfer the penetration and permeation data from the MINICAMS® computer into a computer for analysis by Microsoft Excel. This analysis 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) into 1000 mL/L (Example: 1.73 ng x 1/0.2 L = 8.65 ng/L). Convert nanograms/liter to milligrams/cubic meter by dividing by 1000 (Example: 8.65 ng/L / 1000 = 0.0865 mg/m^3). CT (concentration x time) is calculated by multiplying the collection duration time by the concentration (Example: 0.0865 mg/m^3 x 2 min = 0.173 $mg \cdot min/m^3$). The cumulative CT is calculated by adding the CT value for each sample time successively. 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.

5.1.24.4 Challenge Concentration Data: Using the computations generated from Paragraph 5.1.24.3, plot the challenge concentration versus time and produce two data graphs that track total detection events covering any maximum peak excursions over 8 hours and total concentration over time known, as cumulative CT, covering the total 8 hours of potential cumulative and instantaneous dosages. If the test is terminated prior to the completion of 8 hours due to MINICAMS® preventive measures or the APR failing, the 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 OR FAIL CRITERIA

6.1. The criteria for passing this test is set within the regulatory authority of the U.S. Department of Health and Human Services, 42 CFR, Part 84, Subpart G, Section 84.63(c); Volume 60, Number 110, June 8, 1995. A dual-pass-data criteria must be simultaneously met for GB passing test results. The criteria are:

6.1.1. Sarin (GB) Test:

Challenge: 210 mg/m^3 ± 10% for 30 minutes (but not more than 31 minutes)

Test Time: 8 hours

Dual Pass or Fail Criteria:

a) Maximum Agent Breakthrough (Ct) = 1.05 mg·min/m^3. Concentration integrated over minimum service life is Ct and it is based on a detection sample time of approximately 2 minutes for 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 = 0.044 mg/m^3. Three consecutive data points at or exceeding the peak value constitutes a failure where each test value is based on detection sample time of approximately 2 minutes for 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 lab manager final determination under advice from NIOSH/NPPTL.

NOTE: Any APR test that fails as a result of laboratory test equipment failure or malfunction, laboratory electrical power loss or incorrect technician operating procedures or 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.

Table 1, Vapor Challenge of CBRN APR with Sarin (GB), Chemical Warfare/Terrorism Nerve Agent:

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/m3)	Number of Systems Tested	Minimum Service Life (hours)
GB	210(1)	30	40	0.044(3)	1.05(4)	3	8(2)

(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 8 hours.

(3) 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.

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

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 full facepiece, tight fitting, negative pressure air purifying respirator submitted for approval, extension of approval, or examined during certification product audits, meet the minimum certification standards set forth in *42 CFR, Part 84, Subpart G, Section 84.63(a)(c)(d).*

7. RECORDS AND TEST SHEETS

7.1. All test data will be recorded and transmitted to NIOSH using approved NIOSH test data sheet formats.

7.2. Typical test data required by NIOSH for this STP is raw data of MINICAM readings, conversion of raw data into test trial graphs depicting agent concentration exposure curve over time and the official NIOSH test data sheet summarizing the test trials and results.

7.3. A digital photograph is required to be taken at the beginning of each independent test. If observable defects are noted at the end of test, another digital photograph is required to be taken to document the observable defects. All applicable data, graphs and photographs taken or made by laboratory technicians, technician supervisors or the equivalent will remain on file at the actual lab where the test was conducted and will be retrievable within 24 hour notification from NIOSH and maintained in accordance with local administrative SOPs.

7.4. 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.

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

7.5.1. If a failure occurs on a new certification application, or extension of approval application, RDECOM will send a test report to the NIOSH Certification Team Leader and prepare any uncontaminated hardware for return to the manufacturer.

7.5.2. If a failure occurs on hardware examined under an Off-the-Shelf Audit the hardware will be examined by the laboratory technician and the Laboratory Manager for cause. All equipment failing or passing any portion of this test will be contaminated with chemical warfare agent and will be disposed of in accordance with chemical surety practices.

7.5.3. Sample information for a data test report is in Appendix A. Actual NIOSH test report, test data sheets, graphs and raw data are maintained separately from this STP for quality assurance requirements.

APPENDIX A

CBRN APR GB LAT Certification Test Data Summary Sheet

(Test Data Sheet 1 of 3)

1. TEST TITLE: Determination of Full Facepiece, Tight Fitting, Negative Pressure, Air-Purifying Respirator (APR) Performance During Dynamic Testing Against Chemical Agent Sarin (GB) Vapor.

   A. Task Number (TN): _____

   B. Manufacturer: _____

   C. APR Model # and Components (Hydration device, communications device, shroud, etc.)
   _____

   D. Qualifier Application Test Date:_____

   E. Remainder Application Test Dates: _____

2. REQUIREMENT:

   Three of each CBRN full facepiece, tight fitting, negative pressure, CBRN Cap 1, 2, 3 or 4, consecutive air-purifying respirators (APR) shall demonstrate no permeation or penetration of Sarin (GB) vapor equal to or greater than the stated maximum peak excursions and the stated cumulative concentration over time (CT) including all maximum peak excursion data points 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/m^3 will collectively constitute a failure where each test value equals to or exceeds 0.044 mg/m3 and is based on a detector sample time of approximately 2 minutes. The cumulative CT, 1.05 $mg \cdot min/m^3$, including all maximum peak excursion data points, must not be exceeded for the duration of the test. The test period begins upon initial generation of GB vapor concentration and ends at 8 hours.

   OVERALL RESULT: PASS or FAIL

APPENDIX A (Continued)

CBRN APR GB LAT Certification Test Data Summary Sheet

(Test Data Sheet 2 of 3)

3. SUPPORTING REQUIRED DATA:

A. Has canister expired in accordance with user instructions? YES or NO.

B. Is canister bent, cracked or disfigured prior to LAT? YES or NO.

C. Is facepiece fully serviceable prior to LAT? YES or NO.

D. Are sub-assemblies free of visible deformations or aberrations? YES or NO.

E. Was all lab test equipment verified calibrated prior to LAT? YES or NO

GB CBRN APR LAT Certification Test Report Continuum:

Task Number: _____ STP No.: _____

Manufacturer: _____ Reference No.:_____

A. Did each APR pass or fail maximum peak excursions? PASS or FAIL

B. Did each APR pass or fail Ct? PASS or FAIL

QUALIFIER TEST # 1	Total Test Time	Max Peak Excursions	Ct	*RESULT*
e.g., TN –GB 1	480 minutes or less	Quantity failing Value		PASS or FAIL

REMAINDER TEST # 2	Total Test Time	Max Peak Excursions	Ct	*RESULT*
TN – GB 2	same as above(SAB).	SAB		SAB SAB

REMAINDER TEST # 3	Total Test Time	Max Peak Excursions	Ct	*RESULT*
TN – GB 3.	SAB	SAB		SAB SAB

APPENDIX A (Continued)

CBRN APR GB LAT Certification Test Data Summary Sheet

(Test Data Sheet 3 of 3)

4. COMMENTS:

   For example, "CBRN APR XXXX was tested in the "as is" configuration for initial qualifier application and passed. However, when conditioned APR were tested in RLAT CBRN APR failed max peak excursion criteria, most likely due to canister thread dents and bends as a result of environmental conditioning prior to RLAT."

5. SIGNATURES:

   A. Laboratory Technician: _____ Date: _____

   (Signature)

   _____

   (Printed Name)

   B. Laboratory Supervisor: _____ Date: _____

   (Signature)

   _____

   (Printed Name)

   Legible signatures mean concurrence with test summary data and results as indicated.

Revision History

Revision	Date	Reason for Revision
0	24 December 2003	**Interim Guidance Version:** Initial version dated March 18, 2003 was converted from an interim guidance STP to a draft final standard test procedure dated December 24, 2003. Integration of actual NIOSH DIEMS test data sheet was standardized between the STP and the NIOSH administrative project management system (DIEMS).
0	30 September 2004	**Final STP**: Incorporated next generation equipment guidance on MINICAMS® and syringe pump into STP. Inserted GB performance values table from standard. Added registered trademarks.
0.1	29 September 2005	Update header and format to reflect lab move from Morgantown, WV No changes to method