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2202 Aberdeen Boulevard Aberdeen Proving Ground, MD 21005-5001						11. SPONSOR/MONITOR'S REPORT NUMBER(S) Same as item 8
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	nical Information		AD NO.: ADA5972 December 2005	48		
14. ABSTRACT This TOP provides the standard for designing and conducting tests estimating penetration of chemical agent vapor and aerosol simulant through chemical/biological (CB) protective suit systems while the suits are worn. Methyl salicylate (MeS) is used to simulate a chemical agent vapor challenge. Nontoxic, fluorescent-tagged silica aerosol particles are used to simulate an aerosol chemical agent challenge. For the vapor tests, personal sampling devices (PSDs), such as passive absorbent devices, are used to monitor chemical concentration inside the suits. For the aerosol tests, a discussion is offered of the sampling methods used to determine aerosolized chemical concentration inside the suits. Test data are analyzed using a body region hazard analysis (BRHA) to provide an indication of the protection levels of the suit systems when exposed to vesicant or nerve chemical agents. 15. SUBJECT TERMS						
Aerosol; Man-In-Simulant Test; MIST; methyl salicylate; MeS; passive absorbent device; PAD; Body Region Analysis Process; BRHA; whole suit system testing; Chemical/Biological; CB; Defense Testing						
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U.S. ARMY TEST AND EVALUATION COMMAND TEST OPERATIONS PROCEDURE

*Test Operations Procedure 10-2-022A DTIC AD No. ADA597248 16 December 2013

CHEMICAL VAPOR AND AEROSOL SYSTEM-LEVEL TESTING OF CHEMICAL/BIOLOGICAL PROTECTIVE SUITS

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*This TOP supersedes TOP 10-2-022, dated 14 December 2005.

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1. <u>SCOPE</u>.

1.1 Purpose.

a. This test operations procedure (TOP) provides the standard process for designing and conducting tests estimating penetration of chemical agent vapor and aerosol simulant through chemical/biological (CB) protective suit systems while the suits are worn. Further discussion of the purpose of CB protective suits is in Appendix A.

b. This document describes standard procedures for testing complete suit systems of protective clothing worn by test participants (TPs) when exposed to vaporized and/or aerosolized chemical warfare agent (CWA) simulants. These procedures test the entire ensemble, including seams, closures, and interfaces at the ankle, wrist, waist, and neck.

c. This document describes the testing methods currently in use for CWA simulant vapor and aerosol testing of CB protective suits and the specific or range of test parameters required for each method. Usually, several tests and particular test parameters must be chosen from among those listed herein. The test parameters chosen for a particular test program may change depending upon objectives.

d. This TOP provides information necessary to plan, conduct, and report CWA simulant vapor and aerosol testing of CB protective suits and discusses required facilities, equipment, procedures, test and experimental parameters, and data obtained from such testing. It also provides the procedures for characterizing protective suit performance as a baseline for quality assurance (QA).

e. This TOP will be used as a guide in preparing program-specific test plans or detailed test plan (DTPs). Procedures described in this document may require tailoring to address the particular purpose and requirements of a specific protective suit.

f. The test procedures described in this document must be referenced and/or incorporated into a DTP or similar document. The DTP will describe the specific test methods and parameters to be used. These methods and parameters will be based on factors such as the concept of

operation requirements and/or threats to the protective suit being tested. The procedures may be modified in the DTP to accommodate unique items or materials, or to satisfy testing requirements specified in the system evaluation plan (SEP) or other acquisition document. Alteration, however, will be made only after full consideration of how the changes may affect the reliability and validity of the data. These alterations, a description of the effect desired by the change, and the changes in the assessment process must be fully described in the DTP.

g. A consideration of modifications to this TOP will include a risk assessment coordinated in advance with the organizations concerned. The assessment will address the impact of the modifications to the following test areas:

- (1) Safety.
- (2) Test conditions.
- (3) Environmental.
- (4) Human use.
- (5) Data quality.
- (6) Test validity.

1.2 TOP Limitations.

a. Data obtained by these procedures cannot be correlated to specific field conditions.

b. The DTP may require modification for unique test items or materials to satisfy specific testing requirements as may be specified in a SEP. However, alteration of the procedures contained herein will be made only after full consideration of the possible effects the changes may have upon reliability and validity of the data. Alterations to this TOP will be coordinated in advance among all concerned organizations as part of test planning.

c. This TOP provides guidance regarding test design issues and data requirements that should be augmented by information found in the SEP and test and evaluation master plan (TEMP) and described in the DTP. For those testing programs in which a SEP is not available or not applicable, the test point of contact (POC) should consult with the customer and should use previous test documentation as a guide in addition to this TOP.

d. This TOP is limited to approved standards and procedures. Developments in practices, equipment, and analysis may necessitate establishing new testing baselines. Additionally, standards of performance must be adjusted with the development of new technologies. Test procedures and parameters listed in this TOP require updating to accommodate new technologies in test items or in test instrumentation. Any updates should be described in the DTP.

2. FACILITIES AND INSTRUMENTATION.

2.1 Facilities.

2.1.1 Vapor Man-in-Simulant Testing (MIST).

Item	Requirement
Medical Treatment Facility.	A medical facility with individuals trained and equipped to treat exposure to CWA simulant or adverse reactions to physiological stress must be available.
	A method for measuring heat stress must be available.
	Trained individuals will include emergency medical technicians (EMTs) qualified in advanced life support.
	EMTs will be present during all CWA simulant trials.
	The EMTs will watch for possible adverse physiological responses in TPs and provide appropriate medical aid whenever necessary.
Test Chamber.	The test chamber must be able to prevent simulant vapor contact with the environment or areas of the facility not intended as exposure areas.
	The test chamber must be large enough to hold at least two TPs and one on-floor supervisor (TP monitor) simultaneously.
	The chamber must have sufficient room for any exercise equipment and prescribed physical activity.
	The chamber must contain fans capable of providing a stable, uniform airflow directed toward the TPs at a variety of wind speeds from 3.2 to 16.1 km/hr (2 to 10 mph).
	Chamber temperature must be controlled at 21.1 to 32.2°C (70 to 90°F) and relative humidity (RH) of 50 to 90 percent.
Operator's Area.	The operator's area will be occupied by test conduct personnel who will adjust wind speed, temperature, and RH and operate the simulant vapor generator and the chemical vapor concentration- measuring instruments.
	This room will also have some means of visually observing the TPs and communicating with the on-floor supervisor.
Chemical Laboratory.	The chemical laboratory will provide the general analytical laboratory support needed for work with CWA simulants, including sampler analysis, instrument standardization, and hazardous waste disposal.

Item	Requirement
Test Safety and Control System.	The core body temperature and heart rate of TPs will be monitored during the trials. The personal vital signs monitoring system (PVSMS) is a system suitable for this task, but other methods are acceptable if approved by appropriate medical and human use authorities.
2.1.2 Aerosol MIST.	
Item	Requirement
Medical Treatment Facility.	A medical facility with individuals trained and equipped to treat exposure to CWA simulant or adverse reactions to physiological stress must be available within 25 miles of the test facility. EMTs will be available on site and reachable by phone for immediate response to the test facility during all CWA simulant trials.
Test Chamber.	The test chamber must be able to prevent CWA simulant aerosol contact with the environment or areas of the facility not intended as exposure areas. While aerosol is generated in the exposure chamber, the air pressure must be maintained below the air pressure in surrounding rooms to avoid contamination in the adjacent rooms.
	The exposure chamber must be large enough to hold the number of TPs per test challenge required by the SEP and the DTP (typically one TP per test).
	The chamber must contain a fan capable of providing a stable, uniform airflow directed toward the TPs at a variety of wind speeds from 0 to 18 m/s (0 to 40 mph).
	Chamber temperature must be controlled to a specific temperature $\pm 2^{\circ}C (\pm 3^{\circ}F)$ between 21.1° and 32°C (70° and 90°F) and RH between 5 and 90 percent within ± 5 percent RH of target value. Historical conditions have been 23.9°C (75°F) and 50 percent RH.
Operator's Area.	The operator's area will be occupied by test conduct personnel who will adjust wind speed, temperatures, and RH and operate the CWA simulant aerosol generator and the chemical aerosol concentration- measuring instruments.
	This room will also have a means of visually observing and communicating with the TPs (communication may be nonverbal, such as via computer monitor and hand signals).
Test Safety and Control System.	The core body temperature and heart rate of TPs will be monitored during the trials. The PVSMS is a system suitable to for this task, but other methods are acceptable if approved by appropriate medical and human use authorities.

2.2 <u>Equipment</u>.

2.2.1 Vapor MIST.

Item	<u>Requirement</u>			
Vapor Generator.	The generator must dispense methyl salicylate (MeS), as a vapor, at the controlled rate required to maintain vapor concentration at the target specified in the DTP. Historic testing has been performed between 10 and 1000 mg/m ³ . The vast majority of testing has been at 100 mg/m^3 .			
	An automated data collection system (Paragon ^{®*} Automatic Data Collection System, Cleveland, Ohio, software or equivalent) must be used to collect all real-time data. The automated control system software included in the Paragon [®] system, or equivalent, must be used to control the test chamber system.			
2.2.2 <u>Aerosol MIST</u> .				
Item	Requirement			
Aerosol Generator.	The target aerosol concentration is 167 mg/m ³ averaged over the 30 minute duration of the exposure. Deviations of greater than $\pm 25\%$ will be noted in test comments. The generator must be capable of generating a particle size distribution between 0.1 and 10 µm within the test chamber for up to 1 hour of continuous operation. The aerodynamic mass median diameter must be 2.7 ± 0.5 µm and the geometric standard deviation must be 2.5 ± 0.5 . The system must provide near real-time control to allow timely adjustments of control devices within their operational limits.			
2.3 <u>Instrumentation</u> .				
2.3.1 Vapor MIST.				
Devices for Measuri	ng Measurement Accuracy			
Test chamber atmospheric temperature.	$\pm 0.5^{\circ}$ C (0.9°F) at 38.5°C (101.3°F). The device must be able to sample at least once every 2 minutes.			
Test chamber RH.	± 2.5 percent.			
Test chamber wind speed.	± 2.5 percent.			

*The use of brand names does not constitute endorsement by the Army or any other agency of the Federal Government, nor does it imply that it is best suited for its intended application.

Devices for Measuring		Measurement Accuracy
Real-time monitors (RTMs), or near RTMs, for monitoring atmosphere challenge concentration of CWA simulant vapor. A Miniature Infrared Analyzer [®] (MIRAN [®]) has been used for this function and meets the requirements.	±2.5 percent instrument.	t over the range of 10 to 1000 mg/m ³ for each
Uniformity of vapor chamber chemical concentration.	± 10 percent chamber.	averaged over all instruments across the
MeS vapor concentration. MeS vapor concentration in TP's dress and undress areas. A PVSMS or equivalent system used to monitor the TP's core temperature and heart rate.		e to monitor MeS levels down to at least
2.3.2 <u>Aerosol MIST</u> .		
Devices for Measuring		Measurement Accuracy
Test chamber atmospheric temperature.		$\pm 0.5^{\circ}$ C accuracy in the test range of temperatures. The device must be able to sample at least once every 5 minutes.
Test chamber RH.		±10 percent.
Test chamber wind speed.		±0.45 m/s (±1.0 mph).
Challenge aerosol mass concentration.		At least 98 percent efficient, by mass, at collecting the challenge aerosol.
Aerodynamic particle size distribution. A multistage cascade impactor has been used in previous aerosol challenge tests ^{1**} .		The desired measurement range of 0.5 to 10 μ m.

**Superscript numbers correspond to Appendix I, References.

3. <u>REQUIRED TEST CONDITIONS</u>.

3.1 <u>Test Planning</u>.

3.1.1 Experimental Design.

a. The test will be designed to allow data to be analyzed using standard techniques.

b. Pass/fail criteria will be based on side-by-side testing with a standard, as opposed to a fixed value.

c. The configurations will be balanced to the greatest extent possible among the trials to minimize the effect of any trial-to-trial variation in the overall analysis. Configurations will be balanced among TPs to minimize the effects of different TPs. Individual trial matrices will be provided under separate cover.

d. Historical testing has used eight replicates per configuration for vapor MIST and four replicates per configuration for aerosol MIST. The number of replicates was selected to balance data quality and cost.

e. The chamber position and rotation order of each TP must be specified. Rotation into and from the test chamber will be conducted in a manner that prevents introducing bias for any particular suit based on chamber position or rotation order.

f. The exercise stations and activities are in Appendix B.

g. The POC will have all pertinent documentation available. Documentation may include:

(1) Safety release and approval from the authorizing agency to begin testing.

(2) Human Use Committee (HUC), or equivalent authority, approval or exemption and notification.

(3) Government and manufacturer's publications, including the current material safety data sheets (MSDSs) for applicable chemicals.

(4) Requirements document.

- (5) SEP (if applicable).
- (6) Safety assessment report (SAR).
- (7) Test planning or execution directive.
- (8) System support package (SSP) and SSP list (SSPL).
- (9) Environmental impact assessment for life cycle (EIALC), if applicable.

(10) National Environmental Policy Act (NEPA) documentation for the test, if applicable. This may be a record of environmental consideration (REC), environmental assessment (EA), environmental impact statement (EIS), or other NEPA documentation as required.

(11) Other documentation as necessary [e.g., TOPs, standing operating procedures (SOPs), calibration data, QA/quality control (QC) plans].

3.1.2 Familiarization.

a. Potential problem areas will be identified by reviewing previous records and results of similar tests.

b. Relevant SOPs and other procedures will be reviewed for applicability, completeness, and adequacy. These documents will be updated as required.

c. Development of DTPs will require:

(1) Review of the applicable SEP and other test guidance literature.

(2) Familiarization with preceding development and test phases.

(3) Consideration of data from previously conducted tests in order to avoid duplication and to reduce the scope of further testing.

(4) Prior validation test reports, if available.

(5) Safety and health issues, which must be given prime consideration in test planning. All applicable/available safety documents such as the SAR and health hazard assessments (HHAs) will be reviewed to determine if any safety or health issues require special test protocols.

3.1.3 NEPA Compliance.

a. In compliance with NEPA, the Department of the Army (DA) requires that an EIALC be prepared and that potential environmental impacts be assessed at the earliest possible stage in the planning process.

b. Testing at U.S. Army Test and Evaluation Commend (ATEC) facilities must also be assessed for environmental impact.

c. A detailed EIS will be prepared by the test center and evaluated in accordance with (IAW) NEPA processes when the proposed action may significantly affect the environment, is environmentally controversial, or when litigation is expected based on environmental issues.

d. A REC will be completed for the test if review indicates that there is existing NEPA documentation in place for the action or there is an applicable categorical exclusion. The REC will indicate the process for consideration of the test and rationale for the conclusion.

e. The POC will ensure that a life cycle EA, an EIS, or other appropriate documentation has been received and understood before the test begins.

3.2 <u>Test Preparations</u>.

The following will be verified before the start of testing to ensure reduction of test bias on the part of facilities or instrumentation:

- (1) The test chamber.
- (2) The instruments and instrument locations.
- (3) The sampler inlet locations in the test chamber.
- (4) Sampling and analysis process.

(5) Background testing of the TPs and ensemble items for residual MeS (for vapor MIST) or fluorescent background (for aerosol MIST).

4. <u>TEST PROCEDURES</u>.

4.1 <u>Test Method Outline</u>.

a. Receipt inspection will be conducted to document the operational status and calibrate test instrumentation. Paragraph 4.2 describes the details for this step of the test method. Receipt inspection will also be conducted on the complete CB protective ensembles to document astested material conditions.

b. Vapor MIST.

(1) Vapor MIST measures the penetration of vaporized CWA stimulants through complete CB protective ensembles worn by TPs. Detailed vapor MIST procedures are described in Paragraph 4.3.

(2) The test chamber will be assessed for background interferents as described in Paragraph 4.3.3.3. A pretest check will be performed to ensure instrument and participant readiness. The accuracy of the passive absorbent device (PAD) will be analyzed, as described in Paragraph 4.3.3.5.c.

c. Aerosol MIST.

(1) Aerosol MIST measures the penetration of aerosolized CWA simulants through complete CB protective ensembles worn by TPs. Detailed aerosol MIST procedures are described in Paragraph 4.4.

(2) The test will be set up and completed as described in Paragraphs 4.4.3 and 4.4.4.

4.1.1 Significance and Use.

a. The data collected from the receipt inspection trial will allow the tester to determine whether the received test material and instrumentation are fully functional and ready for testing.

b. The data collected from the vapor MIST and aerosol MIST will allow testers to determine the level of penetration for complete CB protective suit systems worn by TPs when exposed to vapor or aerosol CWA simulants in controlled environments.

c. The fundamental assumptions are:

(1) Repeatability is lost with outdoor testing because of the variable environmental conditions.

(2) No sample placement design or instrumentation suite can meet every operational scenario.

(3) Testing will be conducted using the specified simulants for vapor and aerosol CB agents.

(4) The time and the amount of simulant dissemination are limited by environmental, safety, and occupational health regulations.

4.1.2 Interferences.

Certain hygienic materials (such as soaps, shampoos, etc.) may interfere with the detection of the chemicals used during testing. Therefore, the TP will be instructed on the avoidance of these hygienic materials before testing. The test item and the TP will be monitored and tested before participation in the test is permitted (Paragraph 4.3.3.5).

4.1.3 Apparatus.

a. The term apparatus will be used to cover the equipment used in conducting testing, sampling, and analytical instrumentation.

b. The instrumentation that may be used while conducting these tests is listed in Paragraphs 2.2 and 2.3.

4.1.4 <u>Hazards</u>.

a. Identified safety hazards are those associated with using chemicals that may be hazardous during testing. Chemical safety guidelines are found in DA Pamphlet (PAM) 385-61².

b. Safety and health issues must be given prime consideration. TPs are monitored before, during, and after each trial using PVSMS, and EMTs with life support equipment will be available during every test.

c. A test plan will be developed with a safety section identifying and addressing all safety concerns IAW Army Regulation (AR) $385-10^3$. The safety section of the test plan will be coordinated with the test site's safety office.

d. Additional discussion on possible hazards and safety procedures are in Paragraph 4.3.1.

e. The DTP will be coordinated with the assigned health hazard analysis (HHA) project manager for the system under test to ensure health-related issues are included in the DTP.

4.1.5 Calibration and Standards.

The instrumentation that will be used during testing is discussed in Appendix C of this TOP. The calibration standard and requirements are outlined in Paragraph 4.3.3.6.a.

4.2 <u>Receipt Inspection of the Test Instrumentation and the Protective Ensemble</u>.

a. Receipt Inspection of Test Instrumentation.

(1) A visual inspection for any physical damage will be performed upon receipt of the instruments, and any damage will be reported.

(2) The instruments will be initialized, and an inspection for operational status will be performed IAW their respective operational manuals.

(3) An instrument logbook will be used to track the record of installation, calibration, maintenance, and any instrumental failures.

(4) Before beginning each test, the test officer must verify that all calibrations are current and record the calibration date.

b. Receipt Inspection of Protective Ensemble.

(1) The protective ensemble will be inspected upon receipt and compared with the purchasing inventory. The size and fits of the ensemble will be compared with the purchase order. Any discrepancies will be recorded.

(2) The interior and exterior of each item of clothing must be inspected for rips, tears, and other damage.

(3) Each suit component will be assigned and marked with an individual test item identification number (TIIN). Care must be used to ensure that the TIIN is readily visible, does not compromise the integrity of the test item, and that it does not interfere with sampling methods.

(4) Each ensemble will be given a test item control number (TICN) IAW the overall TICN numbering system. The TICN assigned to each item will uniquely identify it by test program and will be used to track the item throughout the test process.

(5) Photographic records (with metric scale and in focus) of items showing damage will be made with a written record of the damage. This record will show all areas of damage and will be cross-referenced to the recorded TIIN and TICN. Receipt inspection will be carried out as closely as possible to the time of the test.

(6) If worn suits are to be tested, the wear history of each must be provided and recorded in the chemical test database.

(7) Required maintenance operations described in applicable technical manuals will be performed and all mechanical components tested for operability.

4.3 Vapor MIST Procedures.

4.3.1 Safety.

a. The primary emphasis in testing must be on safety. CWA simulants must be handled with care.

b. Tests using simulants will only be conducted IAW the approved SOPs of the testing installation and the procedures specified in the DTP.

c. All procedures must be documented, reviewed, and approved by the responsible organizations before testing begins.

d. The test POC will ensure that all TPs are thoroughly familiar with the ensembles to be tested, test procedures, test exercise protocol, and the safety release constraints (if any).

e. The required MSDS, testing protocols, and safety procedures will be on hand at the test site.

f. The HUC has determined that the procedures in this TOP have had sufficient review and has granted an exemption so that no further review is necessary. However, notification and confirmation of the HUC exemption is still required. Review is required only if deviation from this procedure is considered⁴.

g. Each TP will be informed of potential safety and health hazards involved in test conduct and the precautions required to prevent accidents. A safety release will be provided by ATEC, or responsible organization, for each test requiring military personnel as TPs.

h. Each TP must submit to a physical examination, must be certified by a medical authority for eligibility to perform the TP assignment, and must voluntarily sign a TP informed-consent affidavit (Appendix D) before participating in the test.

4.3.2 <u>QA/QC</u>.

a. A scheme for clearly labeling all test components will be developed.

b. Suit components, samplers, sampling locations, sampler sequences (time on and time off), and raw analytical data must be labeled in a manner precluding misidentification.

c. A second person will independently verify all labeling and markings before the test begins.

d. All test support data will be entered into the proper database before the test begins.

e. Samples.

(1) Several of the same kind of samplers will be stored with the test samples as storage controls (Table 1). Some samplers will be blank, and others will be spiked at the concentration range expected to be measured beneath the suit.

(2) Storage control samples will be analyzed with test samples to determine if any sample degradation or interfering chemicals were introduced during storage.

	Builling of Condot Build	ics for Mail-III-Simulant Test (MIST).
Type of Control Sample ^a	Number of Control Samples ^b	Purpose of Control Sample ^c
Blank PADs or MINICAMS [®]	Two PADs for each TP or real-time monitoring	To check for contamination or interferents in dressing and undressing rooms.
Blank PADs on exterior of Tyvek [®] suit	One full set	To check the RTM measurement of the MeS concentration in the chamber. <u>NOTE</u> : This procedure will only be used during validation and verification of a test chamber.
Blank PADs and spiked PADs	Two of each type of PAD per set of suits	Used as interferent controls.
Spiked PAD storage controls	Several	To check sample degradation or interferent pickup during storage.
Spiked laboratory controls	10 percent of the total number of samples	A check to determine if the chemical analysis is in control.
Vapor calibration check (QC)	two/day/chamber monitor	3-point calibration check before daily use.
Spiked PADs and blank PADs	Two each per trial or TP	To check for contamination/loss during transport and testing.
Blank PADs and MIRAN [®] s	Determined by test director	To check the chamber for contamination or interferents before testing begins.

Table 1.Summary of Control Samples for Man-in-Simulant Test (MIST).

^aPADs – passive absorbent devices; MINICAMS[®] – miniature, automatic, continuous airmonitoring system; QC – quality control; MIRAN[®] – Minature Infrared Analyzer[®]. ^bTP – test participant.

^cRTM – real-time monitor; MeS – methyl salicylate.

(3) Samples will be stored in a freezer ($\leq 4^{\circ}$ C) if they cannot be analyzed within 4 hours of collecting the samples. In any case, samples must not be stored longer than 30 days before being analyzed.

f. Chemical Analysis.

(1) The chemical analysis procedure will be conducted with an appropriate number of standards, blanks, and analytical controls (10 percent of the samples as a minimum; see Table 1).

(2) These actions will ensure that the analytical procedure is reliable and will document the precision obtained from analysis of each batch of test samples.

(3) The standards need not be at equal concentration intervals; rather, they should be spaced closer together near the low concentration end of the calibration curve.

(4) Results from the analysis of PAD field QC controls (spiked and blank samples) will be reviewed to determine the amount, if any, of background, interferent, and cross-contamination that existed during testing (Table 1).

g. A 5-point calibration shot will be performed on the chamber concentration monitoring equipment (MIRAN[®]) before each test. During testing, a single check shot will be performed at the calibrated concentration (usually 100 mg/m³) before each trial. If the MIRAN[®] is within 10 percent of the target concentration, the trial will proceeded. If the check shot failed, the MIRAN[®] will be recalibrated using a 5-point calibration.

h. QA/QC for Each Trial.

(1) Each trial will have at least four QA/QC controls, two spiked and two blanks, per TP. The controls will be deployed in two ways:

(a) The spiked PAD controls will have known amounts of MeS added. The controls will be transported to the test site and returned to the chemical laboratory with the remainder of the samplers for analysis.

(b) The blank PAD controls will be transported to the test site and returned to the chemical laboratory with the samplers for analysis.

(c) Transportation sample vials will be impermeable to MeS.

(d) QA/QC is performed in the laboratory.

(e) Additional samplers may be placed in the dress and undress areas to monitor the level of MeS vapor. These samplers will be returned to the chemical laboratory for analysis.

4.3.3 Pretest Procedures.

4.3.3.1 <u>General</u>.

a. The DTP will be approved in advance of testing.

b. The test chamber and equipment will be set up and checked to ensure the instrument's operational readiness: An operational readiness inspection (ORI) will be conducted before the start of the actual test to ensure that all system components are performing adequately.

(1) The chamber and test instrumentation (Appendix C) will be tested by bringing the chamber to operational conditions. These conditions will be monitored for the length of time required to complete a test trial.

(2) In the case of an active sampling requirement, an independent referee system, such as GasmetTM (Gasmet Technologies Oy, Helsinki, Finland), or MIRAN[®], may be used to verify that the concentration of MeS vapor in the chamber is within acceptable limits.

(3) The operational readiness of the instrumentation in the dress and undress areas will also be checked.

(4) The preceding ORI process is adequate preparation to begin testing. The integrated team may, however, direct a pilot test be conducted in place of the pretest if a novel test program, new samplers, or a system with a high potential for interference will be tested. The pilot test will be conducted only if there are sufficient test items available.

c. EMTs with life support equipment will be available during every test. Before each test, the physiological signs of the TPs will be measured and recorded. Physiological signs will include pulse, blood pressure, and body temperature.

d. All TPs must be informed that they can terminate participation in the test at any time.

e. Each suit must be the correct size for each TP and must be checked to ensure that it is correctly worn.

f. The participants will be dressed in the suits to be tested; the TIIN of the suit worn by each TP will be recorded.

4.3.3.2 TP Background Analysis.

a. The TP background analysis will be conducted only during the validation and verification of a test chamber or if there is a contamination concern.

b. This test will be conducted after the TPs have been trained in the use of personal hygiene procedures.

c. TPs will shower and wear the test PADs for the same duration as the actual trial.

d. Two TPs will be fully instrumented with PADs.

e. Five PADs will be placed on the remaining TPs at the following locations shown in Figures 1 and 2: scalp (P12), armpit (P14), crotch (P8), glove (P18), and boot (P11).

f. TP will be dressed in a clean impermeable suit, such as Tyvek[®], Dupont[™], Wilmington, Deleware. TPs will wear PADs and the suit for the same amount of time as a full vapor MIST trial.

g. PADs will be removed, stored, and analyzed IAW procedures for a standard vapor MIST trial.

h. Results from the PAD analysis will be reviewed to demonstrate that the cleaning and hygiene protocol, as well as the analytical process, are operating correctly.

4.3.3.3 Chamber Air Sampling.

a. The air in the chamber will be sampled to determine the presence/absence of background vapor interferents. The test chamber will be operating at the environmental conditions required for the test.

b. The test can proceed even if there is measurable MeS vapor in the chamber.

c. If an interferent is present, the chamber must be purged until background sampling indicates that the interferent is less than lower detection limit (LDL) for the RTM system being used.

4.3.3.4 <u>Test Items Preparation</u>.

a. Any pretest environmental conditioning of the clothing/suit required by the SEP and the DTP will be performed.

b. After the receipt inspection, the suits will be stored in a manner preventing contamination by any chemical vapors present in the storage area. <u>NOTE</u>: Suits must be stored so as to ensure that degradation does not continue after wear. The suits may be retained for possible future evaluation IAW the DTP.

c. Suits requiring cleaning or laundering before use will be washed IAW the procedures specified in the DTP.

(1) The laundering steps and cycle⁵ are outlined in Table 2.

(2) The laundered suits should be tumble dried at low temperature setting [43°C (110°F)] and removed immediately upon completion of the cycle. Overdrying will be avoided.

d. The test POC will ensure that new equipment training (NET) is provided whenever necessary.

4.3.3.5 Interferent Controls.

a. The key factor in the success of this protocol is control of MeS and any other interferents that may contribute to testing inaccuracy.

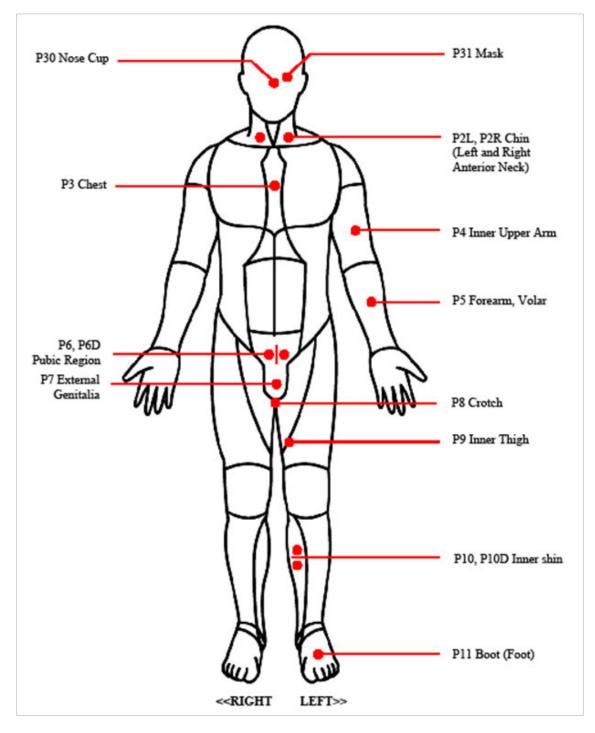


Figure 1. Vapor Man-In-Simulant Test (MIST) Passive Absorbent Devices (PADs) Sampling Locations (Front).

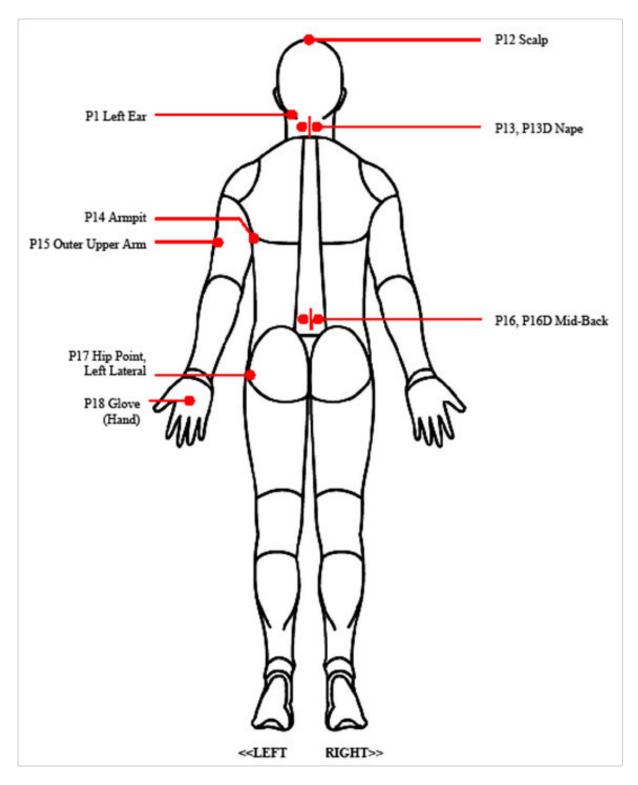


Figure 2. Vapor Man-In-Simulant Test (MIST) Passive Absorbent Devices (PADs) Sampling Locations (Back).

	Laundering		Time		_
Step	Cycles	Water Level	(Minutes)	Temperature	Supplies ^a
1	Fill	High		32.2° to 43.3°C	
1	1,111	Ingn		(90° to 110°F)	
2	Wash	High	5	32.2° to 43.3°C	6-oz PD245
		IIIgii	5	(90° to 110°F)	0-02 I D243
3	Drain				
4	Fill	High		32.2° to 43.3°C	
4	1,111	Ingn		(90° to 110°F)	
5	Wash	High	5	32.2° to 43.3°C	4-oz PD245
	vv d511	Ingn	5	(90° to 110°F)	4-02 I D243
6	Drain				
7	Fill	High		32.2° to 43.3°C	
/	1111	IIIgii		(90° to 110°F)	
8	Rinse	High	2	32.2° to 43.3°C	
		Ingn		(90° to 110°F)	
9	Drain				
10	Fill	High		32.2° to 43.3°C	
10	1111	Ingn		(90° to 110°F)	
11	Rinse	High	2	32.2° to 43.3°C	
		Ingn		(90° to 110°F)	
12	Drain				
13	Fill	High		32.2° to 43.3°C	
1.5	1 111	111511		(90° to 110°F)	
14	Rinse	High	2	32.2° to 43.3°C	2-oz Sour
				(90° to 110°F)	2 02 5001
15	Drain				
16	Extract		3 to 5		

Table 2.Laundering Step and Cycle.

^aAmount of supplies based on a 27.22-kg (60-lb) load.

<u>NOTE</u>: Grey cells indicate not applicable.

b. Before the start of each test, the test items will undergo sampling for any interferents present in the ensemble. Testing may be performed using either of two methods:

(1) The preferred method is to test each item before each trial.

(2) Alternatively, a selected number of items representative of each configuration type will be tested. If all of the test items in a population have identical histories (have been taken from the same source, have been stored together, have been treated identically, etc.) and those

selected are found free of interferents, the remaining suits of that type will be assumed free from an interferent or background levels of MeS.

(3) The alternate method may be conducted as a separate pretest before the start of all trials or as individual tests just before each trial and can be discontinued after a sufficient number of suits have been sampled.

(4) If items will be reused for testing, they must be screened again before their next use.

c. Background sampling will be performed in the following manner:

(1) One complete ensemble (or more) of each type will be placed in a impermeable bag or other suitable container, and the ensemble will be held for at least 2 hours at 32° C (90°F).

(2) The air in the bag/container will be sampled using one PAD for a length of time equal to the duration of each trial. <u>CAUTION</u>: Sample the empty bag/container for volatile interfering chemicals before sampling the suits.

(3) The PAD will be analyzed for MeS to determine whether the suit or the bag /container emits a chemical(s) that could give a false positive reading. If positive results are obtained, each component (suit, hood and mask, boots, and gloves) will be tested separately to determine the source of the interferent or background contamination. A determination can then be made to replace the item or subtract the interferent/background results from the sample results.

(4) Another analytical method may be chosen, such as RTM sampling, when time constraints are an issue, which discriminates between MeS and off-gassing chemical(s).

(5) Air supplied to the bag during sampling must be passed through a carbon filter to remove outside MeS before entering the bag.

d. Contamination and interferent control begins with the TPs; therefore, TPs will be advised of the following:

(1) TPs will be provided with instructions about foods and products containing MeS that must not be consumed or used within 24 hours before testing begins or during testing.

(2) TPs will be required to shower with MeS-free soap and dress in MeS-free clothing.

(3) Background sampling of TPs will be conducted to screen for residual MeS and to train TPs in likely areas of contamination (Paragraph 4.3.3.2).

e. Dress and Undress Areas.

(1) The dress and undress areas will be free of potential interferents.

(2) The background levels of MeS or interferents in the dress and undress areas will be monitored using PADs or RTMs.

(a) If PADs are used to monitor the background level, then mass on the PADs should be less than the minimum detection limit for the PADs.

(b) If RTMs are used to monitor the background level, the MeS level should not be greater than 0.5 mg/m^3 . If the MeS level is greater than 0.5 mg/m^3 , then the work will be stopped until the MeS level drops below 0.05 mg/m^3 .

4.3.3.6 <u>Test Setup</u>.

a. Test Instrument and Chamber Setup and Calibration.

(1) The chemical vapor generator; temperature, RH, and wind speed instruments; and RTMs will be placed at the locations specified in the DTP. <u>NOTE</u>: If a pilot test or ORI has been conducted, the instrument location should be the same as the pilot test/ORI (or mapping phase; Paragraph 7.1.b).

(2) The control and signal cables will be neatly arranged to lead from the test chamber to the operator's area. The cables will be clearly marked to identify the specific instruments to which each is connected.

(3) The RTMs will be standardized with MeS by a validated procedure IAW the RTM's user manual or applicable SOP. The RTMs will then be installed and checked at the test chamber for correct response before testing begins.

(4) The instruments for measuring the temperature, RH, and wind speed in the test chamber will be calibrated IAW their user manual or applicable SOP and installed.

(5) Chamber functions will be continuously controlled.

(6) The data collection system software will continuously record the output of the RTMs, air temperature, air pressure, and RH measuring instruments.

(7) The control system and data-collection system software will be connected to all equipment and test instruments and checked for readiness.

(8) The software used for data collection of nonreal-time data will be checked for readiness by performing the entire data-collection process using a test (dummy) data set.

b. TP Preparation.

(1) All TPs will be sized and fitted with the garments to be tested.

(2) PADs will be placed on the bodies of the TPs at the locations shown in Figures 1 and 2 described in Table 3.

<u>NOTE</u>: 1. The adhesive on the PADs may cause irritation; therefore, PAD placement may be slightly varied for TPs that perform multiple trials.

2. The detailed instructions for PAD placement in Appendix E will be used during the verification and validation of a test facility. The test facility being validated must have personnel trained IAW Appendix E.

Table 3.	Passive Absorptive Device (PAD) Placement Location Descriptions.	
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Position Number ^a	Description
P1	Left ear
P2L, P2R ^b	Chin (left and right anterior neck)
P3	Chest
P4	Inner upper arm
P5	Forearm, volar
$P6, P6D^{b}$	Pubic region
P7	External genitalia
P8	Crotch
P9	Inner thigh
P10, P10D ^b	Inner shin
P11	Boot (foot)
P12	Scalp
P13, P13D ^b	Nape
P14	Armpit
P15	Outer upper arm
P16, P16D ^b	Mid-back
P17	Hip point, left lateral
P18	Glove (hand)
P30	Nose cup
P31	Mask

^aSee Figures 1 and 2.

^bIndicates duplicate personal sampling devices (PSDs) at these locations.

4.3.4 Test Procedure.

a. This TOP is written so that MeS is the CWA simulant and PADs are used as samplers. Although the safety procedures necessary when using a CWA simulant are not as stringent as those required when working with toxic CWAs, the procedures must address all requirements for exposing TPs to MeS.

b. The TPs body core temperature will be monitored in real time. <u>NOTE</u>: If a body core temperature pill is used, it must be taken 1 to 2 hours before the trial begins in order for the pill to become active and stabilize.

c. In the dress area, test operators will attach a PVSMS. Operators will then place PADs on each test participant IAW the procedures specified in the DTP.

d. TPs will be dressed IAW the procedures specified in the DTP. TPs will also wear specified footwear, gloves, protective mask, and hood.

e. Test operators will assist the TPs in obtaining correct closure of the suit at all locations. Each suit will be inspected to ensure proper wear.

f. Generally, each test program will include test and comparison suits.

g. The number of trials specified in the DTP must be adequate to address all experimental conditions with sufficient statistical validity.

h. Temperature, RH, and wind speed instruments, as well as the RTMs, will be placed in the chamber at the locations defined in the mapping phase (Paragraph 7.1).

i. All instruments will be started and the test chamber brought to the required test conditions. The output of all instruments will be recorded by the data collection software. The chamber atmosphere will be monitored for 0.5 hour for the presence of any interferent(s).

j. The test chamber will be closed and sealed and a negative pressure established. The MeS vapor generator will produce a vapor challenge cloud at the required challenge level.

k. Simulant.

(1) The amount of MeS required to generate the vapor concentration specified in the DTP will be dispensed.

(2) Vapor concentration inside the test chamber will be monitored by calculating the average of the readings of the RTMs.

(3) A feedback control system is recommended for maintaining a constant vapor concentration. The vapor concentration must remain within ± 10 percent of the target value during the entire test period for an acceptable trial.

1. TP Monitoring.

(1) During every trial, each TP will be continuously monitored for adverse physiological symptoms such as disorientation, hyperventilation, or breathing difficulties.

(2) If such reactions occur, the TP will be removed from the test and given appropriate medical aid. All adverse reactions will be documented.

(3) Core body temperature and pulse rate at which TPs will be removed from the test will be established by the medical staff/EMT before testing begins.

m. The on-floor supervisor dressed in protective clothing will enter the test chamber (if required) after the specified MeS vapor challenge concentration has been established.

n. TPs will enter the test chamber at a specified time interval. TPs will rotate through each station three times, for a total trial time of 2 hours. Generally, the rotation interval is 5 minutes at each station.

o. TPs will follow the protocol of exercises specified in Appendix B (or the DTP).

p. The activities of the TPs will be visually monitored by the on-floor supervisor, EMTs, test operators, and/or video cameras (recommended).

q. A 5-point calibration check of the RTMs will be performed as described in Paragraph 4.3.2.g.

r. Chamber Control Sampling.

(1) Generally, RTMs will be used for chamber control sampling and to obtain an estimate of total challenge. The RTMs are real-time samplers and continuously monitor the challenge concentration in the chamber throughout the duration of the trial. They must provide near real-time data collection and control to allow timely adjustments of control devices within their operational limits.

(2) PADs may be used as a supplemental method to validate chamber control sampling.

(a) This chamber control sampling will be accomplished by placing a TP in an impermeable suit (Tyvek[®]) and affixing one full set of PADs to the outside of the suit (Table 1).

(b) When all TPs are in the chamber, at the discretion of the test officer (TO), the TP wearing the Tyvek[®] suit with PADs mounted on the exterior will enter the chamber and will move about for 15 minutes (or other designated time), stopping by each station (Appendix B) and then exiting the chamber.

(c) These PADs will be removed and returned to the chemical laboratory for analysis and the data will be used to validate the RTM data on the MeS vapor concentration in the chamber for that trial. <u>NOTE</u>: A study must be performed if MeS is to be extracted from the PAD before analysis. This extraction study must demonstrate that MeS recoveries of \geq 95% are routinely achievable. MeS must be stable in the extraction solvent over time. Solvents that have a high volatility, such as hexane, should be avoided because of the tendency of the solvent to concentrate over time, thus biasing the concentration of MeS in solution. It has been demonstrated that acetonitrile is an acceptable solvent for this extraction process.

s. Posttest Activities.

(1) At the conclusion of the specified exercise cycle, TPs will then enter the first-stage undress area that will be monitored for MeS vapor by a low-level RTM and/or a PAD.

(2) Test operators will remove the protective ensemble and inspect the PADs for any sign of shifting orientation or position on the TP. These discrepancies will be noted.

(3) The TPs will then enter the second-stage undress area. The chamber will be monitored for MeS vapor.

(4) The test operators will remove the PADs, check them for correct identification, and place them in carrying containers for transfer to the laboratory for chemical analysis. Any discrepancies must be noted.

(5) QC personnel will randomly add control PADs spiked with known amounts of MeS to the test PADs before transfer to the laboratory.

(6) The TPs may be interviewed at the conclusion of the test and asked to complete a human factors engineering (HFE) questionnaire concerning comfort and fit, ability to communicate, visibility, and ability to perform the exercise protocol.

(7) TPs will be given an opportunity to comment on safety and health hazard issues and to suggest possible improvements to the suit. An HFE questionnaire can be prepared by using TOP $1-2-610^{6}$ and ⁷.

4.4 <u>Aerosol MIST</u>.

4.4.1 Safety.

The procedures in Paragraph 4.3.1 of this TOP will be repeated, with the following exception: Water and drinking opportunities must be provided throughout the test. <u>NOTE</u>: During a short duration test, such as a 30-minute test time, water will be available to the TP immediately after doffing.

4.4.2 <u>QA/QC</u>.

The procedures in Paragraph 4.3.2 of this TOP will be repeated with the following exceptions:

a. The ensembles and test samples will be handled as described in the DTP. The necessary precautions will be taken to ensure that contamination or destruction of the test samples does not occur.

b. The donning and doffing procedures to be used must be detailed in the DTP and/or SOP. This includes ensuring that all closures are properly secured and the ensemble is properly worn. Details such as buttoning the top shirt button, wearing the collar up or down, and tucking the shirt sleeves inside or outside of the gloves, etc., are all important. Photographs of each fully dressed TP must be taken before entering the test chamber. The photograph will identify the configuration code and TICN.

c. When doffing the ensemble, the main concern is to avoid contamination of the skin with aerosol from other sources (aerosol from the outer garments, contamination from the sampling tube, or contamination from the test operator). Therefore, an assistant will help the TP undress using the prescribed doffing method specified in the DTP. The DTP should indicate whether a light misting of the garment with water immediately before doffing is prescribed; such misting may reduce the resuspension of dusty aerosol deposits. Proper handling of the garments and

equipment will be necessary to minimize the potential for contamination. <u>NOTE</u>: Misting garment materials that look to be highly air permeable should be avoid because misting may force contaminants through the fabric.

d. Ensembles (new and used) must be sealed from contaminants during storage.

e. If it is necessary to reuse garments, the garments must be laundered IAW Formula II, Field Manual (FM) 42-414⁸, or equivalent. Laundering times, temperatures, and cycles are listed in Table 2. Before reuse, the contamination levels in the garments must be verified as similar to those of the unused garments. <u>NOTE</u>: Because there is not a valid way to verify that the garment is truly clean, reuse of garments that come in contact with the skin is not recommended.

f. The appropriate number of blanks and standards must be used to verify the accurate operation of the various measurement instruments and/or to provide a calibration curve. The calibration methods to be used must be detailed in the DTP or the test facility SOPs.

g. The collection efficiency of the concentration measurement device selected for use must be known.

4.4.3 Pretest Procedures.

The procedures in Paragraph 4.3.3 of this TOP will be repeated with the following exceptions:

a. PADs will not be used during aerosol MIST testing.

b. Samples will be obtained by direct rinsing of prescribed skin areas.

c. Candidate ensembles will be tested in random order whenever possible. Some grouping of tests may be needed, depending upon availability of test garments and size-match to available TPs. Also, if testing garments which vary widely in their level of aerosol protection, some order in the test sequence may be necessary to prevent carry-over contamination from TPs wearing suits with high levels of aerosol penetration to subsequent tests with suits having low aerosol penetration.

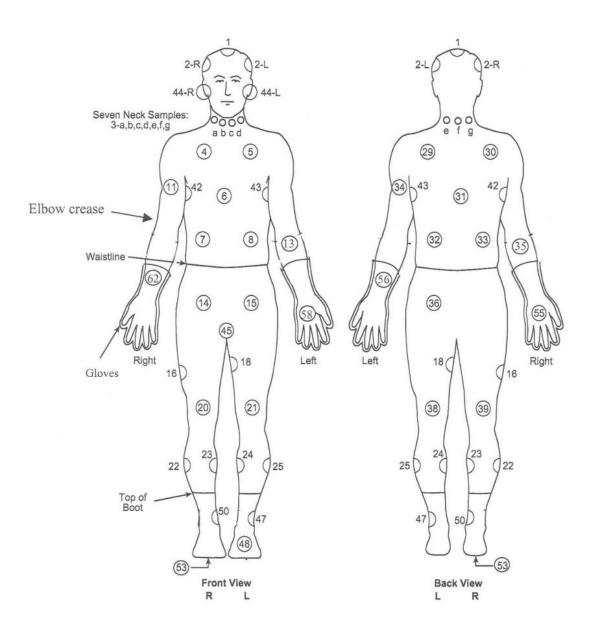
d. The DTP and the conditions of human participation will be approved in advance.

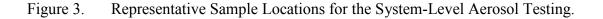
e. The chamber operator will perform one or more trial runs (without a TP) to ensure that the desired aerosol concentration over time and chamber temperature, humidity, and wind speed can be reliably achieved.

f. An ORI (a test run with no aerosol exposure) is recommended for a new test chamber or an existing chamber with 6 months between aerosol MIST tests. The ORI will be performed to evaluate the readiness of all systems and will include: background sampling a TP; donning a mock garment; facemask fit testing; operating the exposure chamber with aerosol; temperature, humidity, and wind speed, all at target levels; operating the mass-loader filter samplers; doffing the mock garment; skin sampling; and fluorometric analysis of all samples. An SOP must be prepared, written, and approved before an ORI is performed.

g. The performance of additional ORI runs may be conducted as deemed necessary by the principal test operator.

h. The sampling locations on the bodies of the TPs are shown in Figure 3 and described in Table 4. <u>NOTE</u>: The detailed instruction on the sampling locations found in Appendix F will be used during the verification and validation of a test facility. The test facility being validated must have personnel trained using the procedures in Appendix F.





Position Number ^a	Description
1	Head, top
2-R	Head, right side
2-L	Head, left side
3-а	Neck
3-b	Neck
3-с	Neck
3-d	Neck
3-е	Neck
3-f	Neck
3-g	Neck
4	Upper chest, right
5	Upper chest, left
6	Mid chest
7	Lower chest, right
8	Lower chest, left
11	Upper arm, front right
13	Lower arm, front left
14	Pelvic area, right
15	Pelvic area, left
16	Outside upper leg, right
18	Inside upper leg, left
20	Mid leg, front right
21	Mid leg, front left
22	Outside lower leg, right
23	Inside lower leg, right
24	Inside lower leg, left
25	Outside lower leg, left
29	Upper back, left
30	Upper back, right
31	Mid back

Table 4. Sampling Location Descriptions for System-Level Aerosol Testing.

Position Number ^a	Description
32	Lower back, left
33	Low back, right
34	Upper arm, left
35	Lower arm, right
36	Rump
38	Mid leg, back left
39	Mid leg, back right
42	Side of Torso, Right
43	Side of Torso, Left
44-R	Ear lobe, right
44-L	Ear lobe, left
45	Scrotum
47	Outside of lower leg, just above ankle, left
48	Top of foot, left
50	Inside of lower leg, just above ankle, right
53 ^b	Bottom of foot
55	Back of hand, right
56	Back of lower arm, near wrist, left
58	Palm of hand, left
62	Front of lower arm, near wrist, right

 Table 4.
 Sampling Location Descriptions for System-Level Aerosol Testing (Cont'd).

^aSee Figure 3.

^bThe bottom of the foot is an especially difficult area to keep uncontaminated during pretest activities, donning and doffing. Therefore, sampling this area is optional.

i. The dress and undress areas will be free of potential interferents.

j. The aerosol generator will be placed at the locations specified by the DTP, SOP, or at the same location as when the pilot test/ORI was conducted.

k. TP Background Analysis.

(1) The TP's skin will be sampled to measure the background fluorescence before each aerosol exposure trial. Samples will be collected from the body regions that will be sampled

following aerosol exposure (Figure 3). The sites for background samples will be determined in the DTP.

(2) If the background fluorescence levels are too high, based on experience and the levels of aerosol expected to be deposited on the skin during testing, the TP must shower to reduce the background. Samples will be collected in the identical manner as those collected after an aerosol exposure test, except the sample locations will be offset so as not to overlap the previous sample location.

1. Interferent Controls.

(1) Past testing¹ has shown that test garments have not had a significant interferent present that impacted the quantitative fluorometric analysis of the skin-rinse samples that is tuned to the emission and excitation wavelengths of the test aerosol. Thus, no interferent control is performed on the test garments. However, if interferents are suspected to be present, the following methods can be used to investigate the presence of the interferents:

(a) A blank test will be performed with the TP wearing the full ensemble in an area known to be free of the test aerosol.

(b) After doffing, the TP's skin will be sampled by direct rinsing of prescribed skin areas to quantify the level of interference present.

(2) Some test materials may contaminate the skin such that brightness is seen on the skin when viewed under black light. While not an interferent for the quantitative analysis (which uses different wavelengths), such contamination can impact the interpretation of black light photographs taken after doffing.

(a) If such contamination is suspected to be present, a blank test will be performed with the TP wearing the full ensemble in an area known to be free of the test aerosol.

(b) After doffing, the TP's skin will be examined under black light to determine if such interference is present.

(3) Soaps and shampoos can present an interferent to the fluorometric analysis (typically products that contain green and gold color dyes). Therefore, the TPs will be required to use soaps and shampoos before testing that are known to be free of significant levels of these contaminants.

4.4.4 Aerosol MIST Procedure.

a. The trials will consist of a human subject wearing a correctly-donned, complete chemical-protective clothing ensemble in a test chamber while exposed to a fluorescent-tagged, nontoxic, aerosol simulant. The TP will perform a motion routine (Appendix B) for the entire duration (30 minutes) of the trial. After the trial, the TP's skin will be analyzed for the amount of fluorescent tracer present at various locations. The rate of aerosol deposition to the various sampled areas can then be computed from the amount of fluorescent tracer present. These measurements can then be used to determine a relative protection rating for the ensemble. The

use of a fluorescent tracer allows the measurement of minute quantities of aerosol, while minimizing the interference from background aerosol and dust.

b. Clean filters will be inserted into the filter holders, and then slides will be inserted into the stages of the impactors that will be used to measure the concentration and size distribution of the aerosol. Care must be taken to ensure that the slides are properly labeled, carefully handled, and properly positioned. All flow-measurement devices and monitors must be observed to ensure that they are functioning properly. The wind speed, RH, and temperature controllers for the wind room will be set to the required settings and the blower turned on.

c. While the conditions in the wind room equilibrate, the test garment is removed from storage and donned by the TP. Clothing items worn beneath the test garment will be specified in the DTP. (Typically, the TP wears only briefs and socks before donning the ensemble.) The principal test operator will note on the test run data sheet that the complete ensemble is properly donned and will note any taping or anything that does not represent doctrine wear. The test operator will also ensure that the ensemble is properly fit on the TP and that the TP has been informed of the proper execution of the motion routine.

d. When the TP is prepared and the test chamber has reached the conditions outlined in the DTP, the TP will enter the exposure chamber and be properly positioned in the wind. The airflows of the filter samplers and the impactor will be initiated simultaneously and the time recorded (t = 0 minutes).

e. The TP will begin the motion routine. The test duration will be 30 minutes. The principal test operator will observe the TP during the entire test. Any significant unusual activity during the test that may impact the results (such as a sudden change in a test condition, the TP slipped and fell, etc.) will be noted in the logbook or test form.

f. After the 30-minute exposure, the airflows of the filter samplers will be terminated simultaneously and the time recorded. (Other wind room controls may also be terminated at this time.)

g. The TP and an assistant will proceed to the doffing area, where the ensemble will be carefully removed. The doffing procedure detailed in the DTP must be followed carefully. When the ensemble is removed, it must be transported away from the TP to avoid any contamination. After the ensemble has been removed, the undergarments (T-shirt, briefs, and socks) must be removed in the same manner (described in the DTP).

h. When all of the TP's clothing has been removed, the TP's skin will be sampled to recover aerosol that has deposited. This skin-rinse sampling will be performed by pressing a tube against the skin in the area to be sampled and then adding 20 mL of 0.01 N sodium hydroxide (NaOH). The solution will be washed over the skin for approximately 10 seconds and then pipetted into a clean container.

i. The number and location of the areas to be sampled must be indicated in the DTP. Recommended sampling locations are shown in Figure 3 and described in Table 4 and Appendix F. For some areas of the skin (such as the earlobe), a series of three cotton swab samples will be taken rather than using the tube method. Each cotton swab sample will be placed in a container with 20 mL solution of 0.01 N NaOH. All samples will be labeled appropriately before they are analyzed.

j. After the skin-rinse samples are collected, the TP will be viewed and photographed under black light. These photographs provide a qualitative assessment of the pattern and intensity of aerosol deposition on the skin.

k. After each trial, upon completion of the skin-rinse sampling and black light photography, the TP will return to a locker room and shower.

l. For each of the skin-rinse samples, approximately 5 mL of each of the samples will be analyzed in a fluorometer in order to determine the mass of aerosol that is present in the sample. The results will be recorded and verified to identify and eliminate any errors in reading or recording the data.

m. Aerosol collection substrates will be recovered from the filter holders and impactors, properly labeled, and stored or transported to the chemical laboratory for subsequent analyses. The mass of aerosol collected on the impactor slides and on the filters will be determined by fluorometric analysis.

n. Temperature, RH, and wind-velocity data will be recorded in the logbook or data sheet and/or stored electronically for subsequent data reduction and review.

o. Any anomalies with filters, holders, impactors, etc., must be recorded.

p. All of the resulting data (including the names of any computer files) will be recorded in the logbook or test data sheets for subsequent calculations.

q. All samples (and filters) will be clearly labeled and stored in an appropriate storage cabinet or facility until the sample analysis for the trial has been completed; any anomalies may be retested, if needed. When data analysis has been completed, the samples may be discarded. Procedures for disposition of overgarments will be described in the DTP.

5. DATA REQUIRED

5.1 <u>Vapor MIST</u>.

The following test data will be provided:

a. The average challenge dosage generated during each trial over time (target $12,000 \text{ mg} \times \text{min/m}^3$).

b. Description of activities during test period, which consists of the time spent in the test chamber.

c. Cumulative MeS mass that permeated the suit, measured at each location after 2 hours of exposure.

d. The core body temperature and heart rate for each TP in each trial for the duration of that trial.

e. Anthropometric measurements from TPs.

f. Description of adequacy of fit of candidate ensembles to include slack measurements taken at the chest, upper arm, lower arm, wrist, waist, hips, thigh, calf, and ankle.

g. Condition of each suit.

h. Chemical analysis results of all samples, including controls, reported as mass of MeS found in each sample.

i. Concentration values, calculated and reported with flow rates for each sampling system used.

j. Results identified by trial number, TICN, and sampler location on each TP.

k. Photographic records documenting the ensemble TICN.

l. The individual results and precision obtained from the analytical controls added in the laboratory.

m. Required controls (Table 1).

n. Computer files, graphs, and printouts of the following recorded real-time test chamber data:

(1) Environmental data (temperature, RH, wind speed).

(2) MeS vapor concentration data from the RTMs marked with the following:

- (a) Date of the test.
- (b) Trial duration.
- (c) Serial numbers of the instruments.
- (d) Locations sampled.
- (e) Operator's name.

o. Any notable observations by the test operators (especially system openings, mask breaches, and poor fit).

p. Pretest and posttest physiological data on the TPs.

q. Logbooks from test chamber and laboratory operators and laboratory QA chemist.

- r. Completed HFE questionnaires, if required.
- s. Results of the body region hazard analysis (BRHA).

5.2 Aerosol MIST.

The following test data will be provided:

- a. Chemical analysis results of all samples, including aerosol control samples.
- b. Aerosol deposition values.
- c. Results identified by trial number, TICN, and sampling location on each TP.
- d. Photographic records documenting the test garment ensemble and results consisting of:

(1) Photographs of the test participant in the full test ensemble immediately before entering the aerosol chamber. The photographs will consist of overall front, back, and side views with closeup photographs of the ankles, wrists, and neck closure areas.

(2) Black light photographs of the TP after doffing. These photographs will cover all body locations with the TP wearing gym shorts and, for female TPs, a sports bra.

- e. The individual results for each sample.
- f. Any required control results.
- g. The test conditions including:
 - (1) The challenge aerosol mass concentration averaged for the duration of the test.
 - (2) The average wind speed, temperature, and RH for the test.
 - (3) Date of test and the test operator.
 - (4) The duration of the test and the computed cytotoxicity (CT).

h. Any notable observations by the test operators (especially system openings, mask breaches, or poor fit).

i. Logbooks from test chamber and laboratory operators.

- j. Completed HFE questionnaires, if required.
- k. Results of the BRHA (Appendix G).

6. PRESENTATION OF DATA

6.1 <u>Vapor MIST</u>.

6.1.1 Data Review.

The data obtained will be reviewed for consistency and acceptability. Specifically, the following will be reviewed:

a. The mass (ng) of simulant detected by the samplers at each sampling position for each TP.

b. Control-Data Analysis. The chemist must examine the control data (Table 1) to determine if the chemical analysis process was in control. The chemist will approve the data if the process is in control. The chemist will flag the data with a warning that the data are suspect if outside control.

c. The precision obtained on the analytical controls.

d. Printouts and graphs of the following data. These data will be provided to demonstrate that the target values were achieved and maintained within the required tolerance limits during the test.

(1) Recorded results from the MeS challenge concentrations.

- (2) Wind speeds.
- (3) Air temperatures.
- (4) RHs.

e. The interferent control results. These results will reflect any false positive values obtained, as well as how the analytical procedure was altered to discriminate between simulant and interferent.

f. Any variation in TP performance of the exercise protocol as observed by test operators or as shown on the videotape of the actual exercises performed. TPs will be identified by the TIIN of the suit worn.

- g. Pretest and posttest physiological data on the TPs.
- h. Completed HFE questionnaires, if required.
- i. Any notable observations made by the test operators or the TPs.

6.1.2 <u>BRHA</u>.

a. The BRHA (Appendix G) will be used to analyze penetration data recorded by the PADs. The results from the BRHA will be used to compare ensemble performance. The absolute assessment of ensemble performance relative to hazards or casualties is not currently possible.

b. Missing data points from the PSDs will be estimated as the geometric mean of the same body point from all ensembles of the same configuration.

c. Penetration data will be entered into the BRHA model and will be normalized to correspond to a challenge concentration of 12,000 mg \cdot min/m³.

d. The BRHA model then divides the penetration values by the average dose received [the average of the cumulated RTM readings for the three (or more) instruments]. This process produces a protection factor (PF) for each region. These PF data will then undergo two separate analysis regimes:

(1) Localized Effects.

(a) To evaluate for localized effects, the PF values will be multiplied by the weighing factor specified in the BRHA for localized effects, corresponding to the effect of distilled mustard (HD).

(b) The resulting local exposure dosage (LED) values will be compared with each other, and the lowest value will be selected as the suit performance value. The local minimum effective dosage (MED_{HD}) for the configuration is then calculated as the geometric mean of the individual local effects and represents the highest agent exposure dosage to which the ensemble could theoretically be externally exposed to HD before the wearer experienced the onset of initial symptoms.

(2) Systemic Effects.

(a) To evaluate for systemic effects, the PF value for each region will be multiplied by a systemic weighing factor for each endpoint provided by the BRHA (Appendix G).

(b) The resulting values will be summed over all regions and divided into a constant provided by the BRHA in order to establish an overall PF. The systemic agent minimum effective dosage (MED_{SYS}) is calculated by multiplying this overall PF by another constant provided by the BRHA. The MED_{SYS} for the configuration is then calculated as the geometric mean of the individual systemic effects and represents the highest vapor agent [sarin (GB)] exposure dosage to which the ensemble could be externally exposed before the onset of initial symptoms.

e. After the BRHA is complete, an initial analysis of variance (ANOVA) will be performed to check for outliers.

(1) If necessary, a natural log transformation will be performed on the LEDs.

(2) An outlier will be defined as a point having a studentized residual with an absolute value greater than 3.

(3) If any outliers are identified, those values will be reviewed to determine if there is a discernible cause for each outlier.

(a) If there is a discernible cause, the values will be adjusted, if possible, to reflect the true value; otherwise, the value will be replaced with the geometric mean of the same body point from all ensembles of the same configuration.

(b) If there is no discernible cause for the outlier, the original value will be used.

(4) The outlier analysis will be repeated only once.

f. After outlier analysis is complete, a second ANOVA will be performed.

(1) Penetration data will be analyzed in the second ANOVA to characterize the protective ensembles and to perform comparisons with other ensembles.

(2) The design of the ANOVA will vary by program IAW the objectives of the program; however, there will be similarities among the ANOVAs.

(a) The dependent variable will be the minimum effective dosage (MED) or LED of interest calculated by the BRHA.

(b) The main factor(s) will be the variable(s) under question, such as amount of wear or material type.

(c) Factors such as "trial" must be included as blocking factors in order to remove known unwanted sources of variation.

g. Detailed description of the BRHA is found in Appendix G.

6.1.3 Data Presentation.

a. Because of the natural logarithmic transformation performed on the dosage data before analysis, the endpoint values for a particular suit type, mask, hood, etc., will be summarized in terms of geometric means (exponentiation of the least-squares means from the ANOVA) rather than arithmetic means.

b. The number of observations, standard deviations, and 95 percent confidence intervals based on the geometric mean will also be reported.

6.2 <u>Aerosol MIST</u>.

6.2.1 Data Review.

The data obtained will be reviewed for consistency and acceptability. Specifically, the following will be reviewed:

a. The concentration and particle size distribution of the challenge aerosol to ensure that they were within specifications.

b. The wind velocity, temperature, and RH measurements to ensure that they were within specifications.

c. The variables relevant to aerosol recovery from the skin, including area sampled, volume of extract, and location identification to ensure that proper quantification of mass recovered.

d. Results from the fluorometric analysis and the standards and blanks analyzed with the collected samples to ensure accurate and valid data. If the standards are not within specification to ensure a valid fluorometer calibration, samples will be reanalyzed.

e. Comments made by the principal test operator during the donning and doffing of the ensemble and during the execution of the test to determine whether anomalous data could be attributed to improper fitting, improper movement, or other test variables.

6.2.2 Data Analysis/Procedure.

6.2.2.1 <u>BRHA</u>.

a. The BRHA (Appendix G) will be used to analyze penetration data from the fluorometric analysis. The results from the BRHA will be used to compare ensemble performance. The absolute assessment of ensemble performance relative to hazards or casualties is not currently possible.

b. Missing data points from the fluorometric analysis will be estimated as the geometric mean of the same body point from all ensembles of the same configuration.

c. Aerosol deposition velocity (Vd) values are calculated and used by the BRHA in the local and systemic effects evaluation (Paragraph 6.2.2.2).

(1) The rate of aerosol deposition to the TP's skin is expressed as the Vd. The general equation for computing Vd is in equation 1:

$$V_d = \frac{M_d - M_b}{A_s \times C_m \times T}$$
 Equation 1

Where:

 V_d = Aerosol deposition velocity. M_d = Mass of deposited aerosol. M_b = Background mass. A_s = Sample area. C_m = Aerosol mass concentration (typically in mg/m³). T = Sample duration (typically in minutes).

(2) Because the fluorescence of the samples is directly related to the mass of the aerosol in the samples, the fluorescence of the samples will be used instead of determining the mass of aerosol in the samples. Therefore, V_d will be computed as described in Equation 2:

$$V_d = \frac{F_d - F_b}{A_s \times C_f \times T}$$
 Equation 2

Where:

 V_d = Aerosol deposition velocity.

 F_d = Fluorescence of deposited aerosol.

 F_b = Background fluorescence.

 A_s = Sample area.

 C_f = Aerosol fluorescence concentration (F/m³, for example).

 \vec{T} = Sample duration (typically in minutes).

(3) For samples where the measured fluorescence is less than or equal to twice the background fluorescence, the Vd will be computed using the background level (Equation 3):

$$V_d = \frac{F_b}{A_s \times C_f \times T}$$
 Equation 3

$$V_d = \frac{F_b}{(A_s) \times C_f \times T}$$

Where:

 V_d = Aerosol deposition velocity

 F_b = Background fluorescence

 A_s = Sample area

 C_f = Aerosol fluorescence concentration (F/m³, for example)

T = Sample duration (typically in minutes)

(4) This will establish the minimum measurable V_d and preclude reporting zero and negative values (which may occur when the measurements are at the noise level).

6.2.2.2 Local and Systemic Effects Evaluation.

The V_d will undergo two separate analysis regimes:

a. Localized Effects.

(1) To evaluate for localized effects, the V_d at each end point will be divided into the weighing factor specified in the BRHA (Appendix G) for localized effects corresponding to the effects of HD.

(2) The resulting LED values will be compared with each other, and the lowest value will be selected as the suit performance value. This minimum value is the MED_{HD} . The MED_{HD} for the configuration is calculated as the geometric mean of the individual MED_{HD} values and represents the highest theoretical aerosolized agent exposure dosage to which the ensemble could be externally exposed to HD before the onset of initial symptoms.

b. Systemic Effects.

(1) To evaluate for systemic effects, the V_d at each end point will be multiplied by the systemic weighing factor provided by the BRHA (Appendix G) corresponding to the effects of GB.

(2) The resulting values will be summed over all regions and divided into a constant provided by the BRHA in order to establish an overall PF. The MED_{SYS} is calculated by multiplying this overall PF by another constant provided by the BRHA. The MED_{SYS} for the configuration is then calculated as the geometric mean of the individual systemic effects and represents the highest aerosolized agent exposure dosage to which the ensemble could be externally exposed to GB before the onset of initial symptoms.

6.2.2.3 Suit Evaluation.

a. An initial ANOVA will be performed to check for outliers.

(1) If necessary, a natural log transformation will be performed on the LEDs.

(2) An outlier will be defined as a point having a studentized residual with an absolute value greater than 3.

(3) If any outliers are identified, those values will be reviewed to determine if there is a discernible cause for each outlier.

(a) If there is a discernible cause, the values will be adjusted, if possible, to reflect the true value; otherwise, the value will be replaced with the geometric mean of the same body point from all ensembles of the same configuration.

(b) If there is not a discernible cause for the outlier, the original value will be used.

(4) The outlier analysis will be repeated only once.

b. After outlier analysis is complete, a second ANOVA will be performed.

(1) Penetration data will be analyzed in the second ANOVA to characterize the protective ensembles and to perform comparisons with other ensembles.

(2) The model used in the ANOVA will vary by program, IAW the objectives of the program; however, there will be similarities among the ANOVAs.

(a) The dependent variable will be the MED or LED of interest calculated by the BRHA.

(b) The main factor(s) will be the variable(s) under question, such as amount of wear or material type.

(c) Factors such as "trial day" must be included as blocking factors in order to remove known unwanted sources of variation.

6.2.3 Data Presentation.

a. Because of the natural logarithmic transformation performed on the dosage data before analysis, the endpoint values for a particular suit type, mask, hood, etc., will be summarized in terms of geometric means (exponentiation of the least-squares means from the ANOVA) rather than arithmetic means.

b. The number of observations, standard deviations, and 95 percent confidence intervals based on the geometric mean will also be reported.

7. CHAMBER VERIFICATION AND VALIDATION

All verification and validation testing must show that a chamber will perform to the specifications outlined in this TOP. Any verification will need to be reviewed and accepted by the IP Commodity Area Process Action Team (CAPAT).

APPENDIX A. BACKGROUND FOR CHEMICAL VAPOR AND AEROSOL SYSTEM-LEVEL TESTING OF CHEMICAL/BIOLOGICAL PROTECTIVE SUITS.

a. To estimate penetration of chemical-protective ensembles by chemical vapor or aerosol, it is necessary to test the entire suit system, including seams, closures, and the areas of transition to other protective equipment (i.e., areas at the ankles, wrists, and neck).

b. The fit or size of the clothing has an effect on penetration. When worn by a person, clothing is subjected to pressure differentials across the garment from wind, the bellows effect created by movement, breathing, or a combination of the three, all of which may force chemical warfare agent (CWA) vapor or aerosol through the clothing fabric and closures. Bending and moving stresses clothing, particularly over the joints⁹.

c. The inner sorptive layer/reactive layer may partially remove CWA or simulant vapor that penetrates clothing. Perspiration decomposes the CWA or simulant. For aerosol protection, the fabric, if air permeable, must remove aerosols from the air. For permeable and impermeable fabrics, aerosol infiltration at closures must be minimized. The inner sorptive layer/reactive layer is not an effective sink for aerosol particles that have penetrated to the interior of the garment.

d. Human Subjects Versus Mannequins

(1) Static mannequins dressed in protective suits can be tested in CWA-contaminated air but cannot show the effects of physical motion and perspiration. Correlation tests have been conducted using mannequins capable of limited movement with agent. This testing indicates a general agreement in results, but the actual man/system interface can best be tested using actual servicemen and servicewomen wearing the systems. This testing can only be conducted using simulants because the use of agents presents significant safety hazards.

(2) Test participants (TPs) exercising in approved simulant vapor and aerosol environments provide data on the effects arising from physical motion, breathing, and perspiration.

e. Man-in-simulant test (MIST) procedures are described in this test operations procedure (TOP). The MISTs are conducted with vapor or aerosol challenges. They are referred to as vapor or aerosol MISTs.

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APPENDIX B. LIST OF EXERCISE STATIONS, EXERCISES, AND INSTRUCTIONS FOR VAPOR AND AEROSOL MAN-IN-SIMULANT TESTING (MIST).

a. For MIST, exercise equipment will be placed in the test chamber at the numbered positions shown in Table B.1. The test participants (TPs) will move from station-to-station, in numerical order, at the time interval specified in the detailed test plan (DTP) and will perform the exercise required at each station.

b. For aerosol tests, exercises will be performed in the order shown in Table B.2. Each exercise will last for the time interval specified in the DTP.

Station	Exercise	Instructions
1	Jumping jacks	Test participants (TPs) will perform simulated jumping jacks by repetitively extending arms laterally moving them together above their heads, and placing feet approximately 1.5 times their shoulder width apart, then returning the feet heel-to-heel and arms to their sides. Repeat this routine every 6 to 8 seconds.
2	Sitting rest	TPs will be seated with right side facing into the wind.
3	Walking simulation	TPs will walk, facing into the wind, on a treadmill operated at 4.8 km/hr (3 mph) with a 3 percent incline.
4	Sitting rest	TPs will be seated with left side facing into the wind.
5	Lifting weights	TPs will move two 10-kg (22.05-lb) weights from the top shelf to the middle shelf, to the bottom shelf, and finally back to the top shelf by (1) grasping the weight on the top shelf and bending at the waist to place it on middle shelf;(2) squatting in front of the middle shelf, grasping the weight, and then moving it to the bottom shelf; (3) kneeling on one knee (alternate knees for this portion of the routine), grasping the weight on the bottom shelf and moving it to the middle shelf; and (4) bending at the waist, grasping the weight on the middle shelf, and moving it to the top shelf.
6	Taking cover	TPs will assume a prone position, sight the mock weapon into the wind, and stay in that position.
7	Step simulation	TPs will repetitively step up, with back to the wind, onto a 30.5-cm (12- in)-high step with both feet, and then return to the floor. Repeat this routine every 6 to 8 seconds while alternating the leading leg.
8	Reaching simulation	TPs will repetitively extend their arms above their heads as far as possible in order to touch, grab or replace a designated item. Repeat this routine every 10 to 12 seconds while alternating arms.

Table B.1. List of Exercise Stations, Exercises, and Instructions for Man-in-Simulant Test.

APPENDIX B. LIST OF EXERCISE STATIONS, EXERCISES, AND INSTRUCTIONS FOR VAPOR AND AEROSOL MAN-IN-SIMULANT TESTING (MIST).

Station	Exercise	Instructions
Station	LACICISC	L
1	Standing rest	The first time through the cycle, test participants (TPs) will stand facing the fan. Each time through the cycle, the subject will rotate 90 degrees from the previous position.
2	Walking	TPs will walk back and forth on a 4.88-m (16-ft) long platform, standing tall with arms swinging slightly at their sides.
3	Bending and reaching	Starting with hands on hips and standing, TPs will slowly bend at the waist, touch their toes, and return to a standing position with hands on hips. Then TPs will extend arms upward above their heads and move heads once up, down, left, and right, and then return hands to hips.
4	Squatting and reaching	Starting from a standing position, TPs will bend down on one knee, reach down toward the left and then down toward the right, rotating hands at wrists as if working with tools; then TPs will return hands to hips. The TPs will extend arms upward above head and reach up to the left and then up to the right and look up as if fixing something overhead. TPs will continue this motion for the remainder of the 30 seconds.
5	Trunk twisting	Starting with hands on hips and standing, TPs will turn their upper bodies to the left 90 degrees while simultaneously extending their arms outward, return to starting position, and repeat procedure while turning 90 degrees to the right.
6	Walking	Repeat Station 2.
7	Running	TPs will run in place. Each time through the cycle, TPs will rotate 90 degrees to the right.
8	Standing rest	Repeat station 1.
9	Bending and reaching	Repeat station 3.
10	Squatting and reaching	Repeat station 4.
11	Trunk twisting	Repeat station 5.
12	Walking	Repeat station 2.
13	Prone sighting	TPs will lie down on the platform with their heads towards the fan and take a sighting position.
14	Lying on back	TPs will roll over from the sighting position onto their backs with arms positioned to hold a rifle across the upper chest.

APPENDIX C. TEST EQUIPMENT DESCRIPTION.

1. Vapor MIST

a. Instruments, samplers, and equipment used for this test will be required to undergo a validation process.

b. Passive absorbent devices (PADs) are small sampling devices designed to evaluate the total dose of simulant received at a specific location. The device is a small packet filled with Tenax[®] absorbent material backed with adhesive to enable the device to be placed directly on the skin. Ten percent of the total number of PADs used in the test must be available for use as controls.

(1) The PAD sampler, developed by U.S. Army Natick Soldier Research, Development, and Engineering Center (NRDEC), Natick, Massachusetts, was selected as the best passive absorbent sampler for the MIST. The selection criteria included the following:

- (a) Sensitivity.
- (b) An agent uptake rate similar to skin.

(c) Size and shape that did not interfere with normal movements and suit configuration.

(d) Easy adherence to human skin.

(2) PADs are small samplers that use diffusion to collect chemical vapor from the air. These samplers do not pump air, which is an advantage because no tubing or wiring breaches the suit system and no air circulation is induced by the sampling process.

(3) PAD Packet

(a) The PAD sampler is a small packet [approximately $3.8 \times 3.2 \times 0.3$ cm ($1.5 \times 1.25 \times 0.125$ in)].

(b) The exposed face of the packet is a 0.025-mm (0.001-in) thick high-density polyethylene film that acts as the diffusion barrier.

(c) The back of the packet is an aluminum foil/polyethylene/nylon membrane impermeable laminate.

(d) Identical quantities of Tenax[®] TA absorbent (Buchem B.V., Apeldoorn, The Netherlands) are sealed inside each packet.

(e) The samplers are sealed inside foil/plastic laminate (impermeable) packages by the manufacturer to prevent exposing the sampler before use.

(f) A coating of medical adhesive on the back of the packet allows attachment directly to the skin of the test personnel (TP).

APPENDIX C. TEST EQUIPMENT DESCRIPTION.

(4) The mass of chemical absorbed is proportional to:

(a) The vapor concentration.

(b) The rate of chemical diffusion through the diffusion barrier, also known as the uptake rate.

(c) The area of the sampling surface.

(d) The exposure time.

(5) PADs usually require a significant concentration of chemical vapor in order to register a detection; therefore, they are suited for use in cases where large concentrations of the chemical are expected.

(6) PADs estimate the total amount of chemical absorbed over the entire sampling period. This estimate can be converted into the average concentration of agent present in the vapor during the sampling period.

(7) Upon receipt, if all samplers in the population have identical histories (have been taken from the same source, have been stored together, have been treated identically, etc.), these samplers must be subjected to a lot acceptance test designed to determine if the samplers are suitable for use.

(8) The sampler must collect chemical vapor at a specified rate, stick to TPs, and be free from contamination in order for the sampler to operate properly.

(9) The following tolerances are proposed for lot acceptance:

(a) Sampler area: 2 percent relative standard deviation (RSD).

(b) Weight of absorbent: $10 \text{ g to } \pm 25 \text{ percent.}$

(c) Sampler uptake rate (at one concentration): 5 percent RSD.

(d) Spike recovery (at one concentration): 95 percent.

(e) Chemical cleanliness: 3-ng interferents.

(10) Samplers must be handled in such a way as to avoid contamination. Handlers must wear new latex gloves when handling the samplers, avoid touching the sampling surface, work in a clean environment (preferably a clean box), and use tweezers whenever possible.

(11) Upon removal from the TP, the samplers must be attached to individual pieces of aluminum foil with dimensions greater than that of the sampler.

APPENDIX C. TEST EQUIPMENT DESCRIPTION.

(12) Foil-backed samplers must be placed in individual airtight vials. The vials must be placed in a refrigerator at 4° to 6°C (40° to 42.8°F) within 1 hour.

(13) The samplers must be analyzed within 24 hours of collection or stored in a freezer for no longer than 30 days.

c. Chamber Concentration Monitors

(1) Real-time monitors (RTMs), such as Miniature Infrared Analyzer[®]s (MIRAN[®]s), are required for monitoring methyl salicylate (MeS) concentration in the test chamber atmosphere.

(a) The MIRAN[®] is an RTM that measures absorption of infrared energy using an infrared spectrometer. The instrument includes a gas cell with a volume of 5.6 L and a variable path length ranging from 0.75 m (2.5 ft) to 20.25 m (66.4 ft). The spectrometer provides a chemical vapor concentration estimate as air is drawn through the gas cell.

(b) When vapor concentration changes, the response time of the MIRAN[®] lags behind until the vapor concentration in the sampling cell reaches the new concentration. Lag time can be controlled by adjusting the vapor flow through the instrument.

(c) The instrument has a relatively high lower detection limit (LDL) and is suitable primarily for monitoring the challenge concentration. The LDLs of the RTM 1A for four selected simulants are given in Table C.1.

(2) The number and location of RTMs required must be determined by test chamber mapping performed during the pretest mapping phase (Paragraph 7.1.b).

(3) If air from the chamber will be drawn into the RTMs by a pump, the tubing must have a low absorption factor for the simulant. Fluorinated polymers are resistant to chemical absorption. Examples of acceptable flexible tubing are: Teflon[®] fluorinated ethylene propylene (FEP); Teflon[®] perfluoroalkoxy (PFA); Teflon[®] polytetrafluoroethylene (PTFE) (all from Cole-Parmer, Vernon Hills, Illinois); and Pureline II[®] (Dixon Industries, Charlotte, North Carolina).

(4) The pressure inside each RTM while drawing air must not differ from the ambient air pressure by more than 2 percent.

APPENDIX C. TEST EQUIPMENT DESCRIPTION.

Table C.1. Typical Lower Detection Level (LDL) for Miniature Infrared Analyzer[®] (MIRAN[®]) 1A for Selected Chemical Simulants for a 20.25-m Path Length, Defining the LDL at 0.005 Absorbance Units.

Chamisel	Analytical Wavelength	LDL
Chemical	[m (ft)]	(mg/m^3)
Diethyl malonate (DEM)	8.8 (28.9)	1.9
Methyl salicylate (MeS)	8.3 (27.2)	1.7
Dimethyl methylphosphonate (DMMP)	9.5 (31.2)	0.9
Sulfur hexafluoride (SF ₆)	10.7 (35.1)	0.2

(5) The RTMs will be calibrated for MeS concentrations over a range such that the desired challenge concentration is mid-range (i.e., a range of 0 to 200 mg/m^3 for a 100-mg/m^3 challenge).

d. The clear areas must be monitored. A RTM, such as a MINICAMS[®] (a miniature, automatic, continuous air-monitoring system), will be required for monitoring the dress and undress areas for MeS concentration. The number and location of monitors required must be specified for each test.

(1) The MINICAMS[®] is a near RTM containing a solid sorbent trap; a gas chromatograph (GC); and the connections, ovens, and other equipment necessary to sample an airstream for a selected interval of time.

(2) Analyte is collected and concentrated using a solid sorbent tube. Once collected, the analyte is then thermally desorbed from the tube into the GC for chemical analysis.

(3) According to the manufacturer's operation manual, the MINICAMS[®] can measure CWA vapors in air to a level meeting the Surgeon General's 8-hour time-weighted average concentration when operating on the 3-minute cycle (1 minute of air sampling at 1 L/min). Longer cycle times provide longer air sampling periods and lower detection levels.

(4) The MINICAMS[®] is capable of giving near real-time estimates of chemical concentration present in the air sampled. One MINICAMS[®] can be dedicated to sampling a single area.

(5) In addition, an automated valving system using a single MINICAMS[®] can also be used to sequentially sample a series of test areas. Such sequential sampling increases the time between data points obtained from any single test area but provides near real-time information across several test areas.

(6) Suitable care must be given to the choice of sampling lines, airflow rates, and sequencing valve construction materials in order to minimize chemical loss through sorption onto surfaces and time delays caused by stagnant air in the sampling lines leading to the sequencing valve.

APPENDIX C. TEST EQUIPMENT DESCRIPTION.

(7) The instrument can be rendered unresponsive to changes in chemical concentration due to saturation by exposure to high concentrations. In such a case, time must be allowed for the instrument to purge and recover.

e. A core temperature and heart-rate monitoring device, such as a personal vital signs monitoring system (PVSMS), will be required for monitoring the safety of each TP.

(1) The PVSMS is a small transistor-based system that relays physiological data about each TP to a computer-based data collection and readout station used in the man-in-simulant test (MIST). This system will allow emergency medical technicians (EMTs) and test control personnel to monitor each TP (in the MeS environment) for heat stress and other physiological signs of distress.

(2) The system measures:

(a) Core body temperature by use of a small, pill-sized monitor (which is swallowed).

(b) Heart rate by use of a heart monitor strapped around the TP's chest.

(c) Skin temperature taken by a probe attached to the skin next to the heart monitor.

(d) Skin temperature taken by a probe attached to the skin on the TP's side next to the suit and the heart monitor harness.

(e) Skin temperature taken by a probe attached to the skin underneath each of the TP's arms.

(3) These readings are transmitted to the personal data collection instrument package that is attached to the TP's left side, outside the suit. The instrument package will be maintained on the outside of the TP's clothing in a manner that minimizes interference with the test, such as in a garment pocket on the TP's left arm or taped to the upper left arm.

(4) A radio-frequency antenna that is mounted inside of the test chamber will transmit the data from the pill receivers to a data-collection system and an auxiliary station inside the control room.

f. Physical Environment Monitors

(1) The temperature, RH, and wind speed inside the chamber must be monitored.

(2) The number and location of the temperature, RH, and wind speed sensors required to adequately monitor the chamber must be determined by test chamber mapping (Paragraph 7.1.b).

APPENDIX C. TEST EQUIPMENT DESCRIPTION.

g. Communication

(1) If the protective suit does not include a communication system, or if the communication system within the suit is incompatible with available communication systems, a means must be provided for the test point of contact (POC) and the TPs to communicate with each other.

(2) The on-floor supervisor must be in direct communication with the test control center at all times.

2. Aerosol MIST.

a. Instruments, samplers, and equipment used for this test must meet strict criteria. All instrumentation must undergo a validation process.

b. Appropriate types and numbers of instruments will be selected for the size of the test chamber.

c. The following equipment, materials, and supplies are required and must be available at the test site.

(1) A fluorometer is required for the analysis of filters, impactor slides, and samples of aerosol rinsed from the TP's skin and garment. The fluorometer must be capable of measuring the fluorescence of a sample within ± 10 percent. The fluorometer will be operated with excitation and emission filters appropriate for fluorometric analysis of uranine.

(2) Test Aerosol

(a) The test aerosol is a synthetic amorphous silica powder (Syloid[®] 244, W.R. Grace & Co., Augusta, Georgia) tagged with tetra ethylene glycol, uranine, and Tinopal[®] (BASF Corporation, Florham Park, New Jersey). A tetra ethylene glycol/Tinopal[®]/uranine liquid solution is made by mixing 167 g of Tinopal[®] with 500 g of uranine and 3.33 L of tetra ethylene glycol. To tag the solid aerosol, 300 g of the mixture is slowly added to 300 g of Syloid[®] 244 amorphous silica while constantly mixing in a Waring-style blender. The product will be a dry powder. The aerodynamic mass median diameter of the solid aerosol must be 2 to 3 μ m with a geometric standard deviation of 2 to 3 (a lognormal particle-size distribution) when dispersed in the exposure chamber. The aerosol must be homogeneously dispersed in the wind stream.

(b) To disperse the fluorescent-tagged powder into the exposure chamber, it is first loaded into a hopper of a screw-feeder-type powder feeder. The output of the dust feed is entrained into the intake airflow of a high-volume blower positioned in the wall of the exposure chamber directly behind the chamber's fan intake. The high turbulence and sheer forces within the high-volume blower disperse the powder into an aerosol. Passage through the fan (plus recirculation through the fan) provides a uniform dispersion of the aerosol throughout the exposure chamber.

APPENDIX C. TEST EQUIPMENT DESCRIPTION.

(3) Chamber Concentration Monitors

(a) Challenge aerosol mass concentration will be measured using two filter samplers located in the upstream vicinity of the TP. Sample filters will be at least 98 percent efficient, on a mass basis, for collecting the challenge aerosol.

(b) The filters must be placed in in-line filter holders that are equipped with a sampling probe. The sampling probe diameter must be designed such that the air velocity in the sampling probe is the same (within 20 percent) as the test velocity (isokinetic sampling). The probes must be aligned parallel to the flow field and approximately 0.9 m (3 ft) above the floor, within 0.9 m (3 ft) upstream of the TP's activity zone, and approximately 0.3 m (1 ft) left or right of center. Starting and stopping sample collection must be performed remotely.

(c) The mass of aerosol collected on the filters will be determined by fluorometric analysis. Aerosol deposition within the sampler inlet will be included in the mass determination.

(d) The duration of the sample collection (typically 30 minutes) will be measured with a laboratory timer.

(e) The complete measurement technique must be capable of measuring the aerosol mass concentration with an accuracy of ± 10 percent, and the samples must be collected for the complete duration of the test.

(4) Temperature, RH, and wind speed inside the chamber must be monitored.

(5) If the protective suit does not include a communication system, or if the communication system within the suit is incompatible with available communication systems, a means must be provided for the test POC and the TP to communicate with each other. This may be via hand signals and computer monitor.

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APPENDIX D. SAMPLE INFORMED CONSENT AFFIDAVITS.

A. Vapor Man-In-Simulant Test (MIST)

INFORM CONSENT AFFIDAVIT FOR MAN-IN-SIMULANT TEST (MIST) PROGRAMS

<u>PROTOCOL OBJECTIVE</u>: MIST programs are designed to test various chemical/biological personal protective ensembles and equipment for possible adoption to provide military personnel with state-of-the-art protection against known chemical and/or biological threats.

INSTITUTION: U.S. Army Dugway Proving Ground

TEST LOCATION: Dugway Proving Ground, Utah.

TEST EXECUTION RESPONSIBILITY:

Director, West Desert Test Center US Army Dugway Proving Ground, UT 84022-5000 DSN/AV: 789-5614 COMMERCIAL: (435) 831-5614

<u>TEST OFFICER</u>: A test officer will be assigned for each MIST program. This individual is responsible for on-site execution of the MIST program. All activities at the MIST site are under direction of the assigned test officer. This individual will be your day-to-day contact for receiving instructions regarding your personal participation. Questions or concerns regarding your participation in the MIST program should be directed to this individual for resolution. This individual will be made known to test participants during orientation briefings.

1. <u>PROGRAM OBJECTIVES</u>: To obtain sufficient data to characterize the vapor-protective performance of candidate chemical-protective ensembles and equipment. The data from this comparative analysis will support the evaluation of the chemical protection capability provided by the candidate ensembles and equipment in order to further determine acceptance for future military use.

2. <u>GENERAL NOTICE</u>:

a. This research does not expose you, or any test participant, to any chemical or biological agent.

APPENDIX D. SAMPLE INFORMED CONSENT AFFIDAVITS

<u>INFORM/CONSENT AFFIDAVIT FOR</u> MAN-IN-SIMULANT TEST (MIST) PROGRAMS (CONT'D)

b. All records of this study, including the names and social security numbers of each test participant, will be stored, upon completion of this study, in accordance with Army Regulation (AR) 340-21.

c. There are no hidden experimental procedures within this study.

d. This research has been reviewed for scientific validity, military significance, and ethical concerns. As a volunteer, you will be authorized, under the provisions of AR 70-25, all necessary medical care for injury or disease which is the proximate result of your participation of this study.

e. The complete plan for this study is contained in the detailed test plan for this MIST program. A copy of the detailed test plan will be made available to you upon request.

f. You have been asked to participate in a research study conducted by [Name of the Test Facility]. It is important that you read and understand the following principles that apply to all participants in our studies:

(1) Your participation is entirely voluntary.

(2) You may withdraw from participating in this study at any time. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

(3) After you read the explanation, please feel free to ask any questions that will allow you to clearly understand the nature of the study.

(4) <u>Inclusion Criteria</u>. Subjects in this test must be active military, government civilian, or government contractor.

(5) <u>Exclusion Criteria</u>. Subjects with the following conditions will be excluded from test participation:

(a) Anyone with a known heart problem.

(b) Anyone with high blood pressure (systolic above 160 or a diastolic above 100).

3. <u>DESCRIPTION OF STUDY</u>: Detailed information concerning the specific nature of the study in which you have been asked to participate is provided below:

a. <u>Title of Test</u>: [Name of Test].

APPENDIX D. SAMPLE INFORMED CONSENT AFFIDAVITS

INFORM/CONSENT AFFIDAVIT FOR MAN-IN-SIMULANT TEST (MIST) PROGRAMS (CONT'D)

b. <u>Purpose</u>: To obtain sufficient data to characterize the vapor-protective performance of candidate chemical-protective ensembles and equipment. The data from this comparative analysis will support the evaluation of the chemical-protection capability provided by the candidate ensembles and equipment in order to further determine acceptance for future military use.

c. <u>Duration</u>: The duration of this program is dependent on the number of protective ensembles to be tested. The current schedule is to test _____ ensembles per trial day with _____ test participants in each trial. You will be informed of the number of trial days during the in-brief.

d. <u>Chemical Agent Simulant</u>: The simulant to be used in this program is methyl salicylate (MeS). This chemical is also known as oil of wintergreen which is used in many products that are used internally and externally. A copy of the material safety data sheet (MSDS) will be provided to you on request.

e. <u>Test Procedure</u>: Each test participant will be wearing prototype or standard chemicalprotective garments during a 2-hour mission scenario. Only one wearing or MIST trial per test participant will be conducted in a given day.

4. <u>REASONABLE FORESEEABLE RISKS OR DISCOMFORTS</u>: The risks or discomforts that may arise from this study include heat stress caused by moderate to heavy work performed while wearing the standard and prototype garments.

a. Heat stress may occur during periods of moderate work while wearing the standard garments in hot weather. Water will be made available throughout the test, and participants should drink ample amounts to protect against heat stress. Symptoms of heat stress include: heat cramps of the muscles of the stomach, arms, or legs and heat exhaustion which may cause you to be dizzy, faint, or weak. A test participant experiencing heat stress should notify a buddy, seek shade, drink water, remove outer clothing, lie down, and elevate feet. Although heat stress is not in itself life threatening, if ignored it could lead to a much more serious situation called heat stroke. Heat stress monitoring and egress procedures are incorporated into the MIST to ensure the maximum protection for each individual.

APPENDIX D. SAMPLE INFORMED CONSENT AFFIDAVITS

<u>INFORM/CONSENT AFFIDAVIT FOR</u> MAN-IN-SIMULANT TEST (MIST) PROGRAMS (CONT'D)

b. Heat stroke is always life threatening. In heat stroke, the person's temperature-control system that causes sweating stops functioning properly. The body temperature rises so high that brain damage and death will result if the person is not cooled quickly. The main signs of heat stroke are: red or flushed skin; hot, dry skin (although the person may have been sweating earlier); and extremely high body temperature (up to 106°F). There may be dizziness, nausea, headache, rapid pulse, and unconsciousness. If you feel these symptoms or notice a buddy who appears to have these symptoms, immediately notify the on-site floor boss, emergency medical technician (EMT), test officer, test data collector, or a buddy. The test participant will be given immediate first aid and evacuated to the Aid Station or Health Clinic.

c. EMTs will be onsite throughout the test. Test participants will have their core body temperature monitored using the Personal Vital Signs Monitoring System (PVSMS). The purpose of the PVSMS is to help mitigate the occurrence of heat stress during the trials. You will be requested to swallow a disposable monitor pill and wear a small transmitter on your upper arm. The pill has been used in hospitals and in previous field studies and is considered safe. The pill will measure your core body temperature and transmit the measurement to the transmitter using a low-power transmitter. You will also be asked to wear heart rate and activity monitors throughout the test, which will also provide safety-monitoring data. The Army Surgeon General's Office and the ATEC's Human Use Review Board approved the PVSMS for use during this test. The pill is eliminated from your body through normal waste elimination processes. The pill is processed like any other medicine or food except that the pill does not break down or get digested; it goes in and comes out whole. The pill is a little larger than the average medicine capsule and will only be used once and then be discarded. More information is available about the PVSMS upon request.

5. <u>PRECAUTIONS TO BE OBSERVED BEFORE AND AFTER THE TEST</u>: Do not drink alcohol for 12 hours before participating in this test. This may cause dehydration and lead to heat stress. Drink plenty of liquids (preferably water) before, during, and after participation. Water or Gatorade[®] will be provided throughout the test trials. Notify the on-site EMT or test officer of any change in your health status. A list of foods and products, e.g., wintergreen-flavored gum and lifesavers, Ben-Gay[®], etc., that may not be used before testing will be provided. Use of these foods/products will have a detrimental effect on the test data results.

6. <u>BENEFITS TO SUBJECTS OR TO OTHERS</u>: The subjects who participate in this test will gain a unique training experience in the operation, wear, and maintenance of the newest chemical-protective garments available and other candidate commercial garments. The results (comments and statistical data) will be used as input for upgrading the design and operation of the chemical-protective suits in the future and providing guidance and procedures for safe operation today.

APPENDIX D. SAMPLE INFORMED CONSENT AFFIDAVITS

INFORM/CONSENT AFFIDAVIT FOR MAN-IN-SIMULANT TEST (MIST) PROGRAMS (CONT'D)

7. <u>ASSURANCE OF CONFIDENTIALITY OF SUBJECT'S IDENTITY</u>: I understand that this study is affected by the Privacy Act of 1974 (top of the Inform/Consent Affidavit) and have been made aware of the safeguards available to me because of that act. I also understand that the information gained from this study may be analyzed and used as part of a scientific publication, but I will in no way be personally identified. I understand that it may be necessary for representatives of the Surgeon General's Human Subjects Research Review Board to inspect my records concerned with this study in their capacity as reviewing officials.

8. <u>CIRCUMSTANCES UNDER WHICH YOUR PARTICIPATION MAY BE TERMINATED</u>

<u>WITHOUT YOUR CONSENT</u>: At the discretion of a physician, you may be withdrawn at any time from this study for medical reasons. You will be removed if your core body temperature reaches $38.8^{\circ}C$ ($102^{\circ}F$). You may also be removed, at the discretion of the test officer, if it becomes obvious that continuation in the study is likely to result in injury to you or others in the study.

9. <u>COMMENTS FROM SUBJECTS</u>: Your safety is our primary concern. Any feedback in the form of questions, comments, and criticism is essential to the success of the test. You will be asked to fill out human factors engineering questionnaires and to comment on safety and health hazard issues.

APPENDIX D. SAMPLE INFORMED CONSENT AFFIDAVITS

<u>INFORM/CONSENT AFFIDAVIT FOR</u> MAN-IN-SIMULANT TEST (MIST) PROGRAMS (CONT'D)

IF THERE IS ANY PORTION OF THIS EXPLANATION THAT YOU DO NOT UNDERSTAND, ASK THE TEST OFFICER BEFORE SIGNING.

I concur that the use of the PVSMS has been explained to me and is considered an experimental device. I understand that my signature below is an agreement to use the PVSMS and associated pill as a safety monitor.

I have received a copy of the volunteer explanation and volunteer inform/consent affidavit that I may keep.

VOLUNTEER'S SIGNATURE DATE

VOLUNTEER'S PRINTED NAME

PERMANENT ADDRESS

I was present during the explanation referred to above, as well as during the volunteer's opportunity to ask questions. I hereby witness the volunteer's signature.

WITNESS' SIGNATURE

DATE

WITNESS' PRINTED NAME

APPENDIX D. SAMPLE INFORMED CONSENT AFFIDAVITS

B. Aerosol Testing

INFORM/CONSENT AFFIDAVIT AND EXPLANATION FOR PARTICIPATION IN AEROSOL TESTING

The affidavit and explanation are presented in two parts as follows:

1. Part 1 is the Examination of the Wind Tunnel Facility and Protective Garments Before Participation in the Aerosol Challenge Test Programs.

This inform/consent affidavit and explanation will allow you to examine the wind tunnel facility, to wear protective garments and mask, and to be in the wind tunnel with the fan running (but with no aerosol). The purpose of this is to provide you with information you may need in order to make an informed decision about participating in subsequent aerosol challenge tests (Aerosol Challenge of Chemical-Protective Garments).

2. Part 2 is the Aerosol Challenge of Chemical-Protective Garments.

This volunteer agreement affidavit and explanation will allow your participation in the aerosol challenge test program.

Part 1

Examination of the Wind Tunnel Facility and Protective Garments Before Participation in the Aerosol Challenge Test Programs General Informed Consent

The examination of the wind tunnel facility and protective garments before participation in the aerosol challenge test programs is a program to allow you to participate in a visit to the wind tunnel and protective garments in order for you to make an informed decision relative to your participation in the aerosol challenge study.

This program is being conducted by the testing organization under contract or subcontract with U.S. government agencies.

Your participation in the examination of the wind tunnel facility and protective garments before participation in the aerosol challenge test programs is completely voluntary, and you are free to withdraw at any time. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

APPENDIX D. SAMPLE INFORMED CONSENT AFFIDAVITS

You are being asked to participate in a visit to the wind tunnel. You will have the opportunity to examine the wind tunnel, wear the protective garments and respirator, and ask any questions you may have. The protective garments include an overgarment that you will wear over your clothes, full-face respirator, gloves, and boots. New and previously-worn laundered garments may be tested. No aerosols or chemicals will be used, and your time in the wind tunnel will be limited to not longer than roughly ____ minutes. Your participation in this visit will be about ____ hour(s).

This research does not directly or indirectly expose you, or any study personnel, to any chemical, biological, or nuclear warfare agent. Some people find that wearing a protective respirator gives them a claustrophobic feeling and are, therefore, uncomfortable. Also, wearing the protective garments, hearing protectors, or eye goggles may be uncomfortable for some. Except for these discomforts, there are no known health risks or discomforts associated with your visit. The adequacy of safety measures has been examined by the monitoring agency. Authority to use human volunteers has been granted by the project sponsor.

You will receive no benefit for your participation except gaining insight into what the full-scale tests will involve.

If you have any questions regarding this program, you may contact the Principal Investigator, _____(NAME), at (___)-___. If you have any questions regarding the rights of research subjects or problems resulting from the research, you may contact _____(NAME) at (___)-___.

Your signature below indicates that the purposes and procedures of the examination of the wind tunnel facility and protective garments before participation in the aerosol challenge test programs have been explained to you and that you consent to participate. It does not, however, obligate you to participate in any part of the examination of the wind tunnel facility and protective garments before participation in the aerosol challenge test programs.

Participant's Name – Printed

Participant's Signature and Date

Signature of Person Obtaining Consent

Date

APPENDIX D. SAMPLE INFORMED CONSENT AFFIDAVITS

Part 2

Aerosol Challenge of Chemical-Protective Garments General Informed Consent

The "Aerosol Challenge of Chemical-Protective Garments" is a study to determine the rate at which wind-driven aerosol particles deposit on the skin and clothing of a person wearing chemical-protective clothing. A wide range of protective-clothing configurations will be evaluated. Possible garments include Joint Services Lightweight Integrated Suit Technology (JSLIST) garments and the chemical-protective undergarment (CPU). Also, the effects of movement, such as walking, reaching, bending, etc., will be evaluated for their effect on aerosol deposition to the subject's skin. During the past years, we have conducted similar tests with protective clothing without problems. Information gained from this protocol may be used as part of a scientific publication in professional journals, but you will in no way be personally identified.

This program is being conducted by the testing organization under contract or subcontract with U.S. government agencies.

Your participation in "Aerosol Challenge of Chemical-Protective Garments" is completely voluntary, and you are free to withdraw at any time. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

Your participation in the study will involve wearing chemical-protective garments that include a face mask, hood, jacket, pants, and gloves. In some tests, you will wear the same clothing items that you wore previously in wear trials. For other tests, new clothing items will be used. You will then enter a wind tunnel that has been filled with the test aerosol. The test aerosol contains a fluorescent tracer that is used to detect its presence on your skin and in the clothing. Because of the aerosol, the wind tunnel air will be hazy. After you enter the wind tunnel, the fan will be turned on to produce a wind speed of 10 mph. This portion of each test will last 30 minutes. During the test, you will perform a series of motions, including walking, squatting, standing, reaching, twisting, and briefly running in place. At the end of the test, the fan will be turned off and you will leave the wind tunnel. An assistant will help you undress down to your undergarments. In a private room, you will remove the briefs and put on a pair of gym shorts. The assistant will then rinse approximately 50 areas of your skin with a dilute rinsing solution.

The aerosol on your skin will, in nearly all cases, not be visible to the naked eye. However, because the aerosol is fluorescent, it may be visible under ultraviolet light. Your skin will be examined with an ultraviolet light to help determine where aerosol deposition has occurred. Photographs and videotape may be taken of your body while you are wearing gym shorts in order to document patterns of aerosol deposition. Photographs and videotape may also be taken of you wearing the protective garments to document the garment configuration worn in the test.

Your participation in each test will involve approximately ____ hours of your time. Your participation will occur over an approximate ____-week period currently scheduled for ____(MONTH) ___(DAY) through ___(MONTH) ___(DAY), ____(YEAR).

APPENDIX D. SAMPLE INFORMED CONSENT AFFIDAVITS

During this period, approximately _____ tests will be performed, divided roughly equally between _____ volunteers; thus, you will perform approximately _____ of the _____ tests. You will participate as a test volunteer in no more than one test per day.

This research does not directly or indirectly expose you or any study personnel to any chemical, biological, or nuclear warfare agent. Your exposure will be limited to only those substances that have been reviewed by the project's medical monitor. These substances include Syloid[®] tagged with uranine, tetra ethylene glycol, and Tinopal[®] CBS-X, and 0.01N sodium hydroxide (NaOH). Inhalation of the test aerosol poses a minimal hazard to you; minor skin irritation and/or allergic reaction is possible for a few sensitive individuals. There are no other known health risks or discomforts associated with this study. The adequacy of safety measures has been examined by the monitoring agency.

There will be no compensation for your participation in this program. Your participation will, however, help to improve chemical-protective clothing used by the U.S. Armed Forces. Circumstances under which your participation may be terminated without your consent include: health conditions under which your participation would possibly be dangerous, other conditions that might occur to make your participation detrimental to your health, and, at the discretion of the test point of contact (POC), you may be removed if, in his/her opinion, you have demonstrated disciplinary or motivational problems that interfere with your full participation in the test.

If you have any questions regarding this program, you may contact the Principal Investigator, _____(NAME) at (___)-__-. If you have any questions regarding the rights of research subjects or problems resulting from the research, you may contact _____(NAME) at (__)-__-. Questions related to health may be directed to _____(NAME) at (__)-__-. A copy of the complete plan of this study, called the protocol, will be available to you upon request.

You have been provided a copy of a statement that describes the safeguards available to you because of the Privacy Act of 1974. You have been given the opportunity to review the statement, to ask questions, and to retain a personal copy. You understand that information gained from this protocol may be used as part of a scientific publication in professional journals, but you will in no way be personally identified.

Your signature below indicates that the purposes and procedures of the aerosol challenge of chemical-protective garments" have been explained to you and that you consent to participate.

Participant's Name – Printed

Participant's Signature and Date

Signature of Person Obtaining Consent

Date

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

1. STANDARDIZED POSTURE

The purpose of a standardized test participant posture is to ensure that the differences found in body sizes within a group are not because of variations in body posture. Most body-posture descriptions are self explanatory, but the frequently used phrase "anthropometric standing" requires clarification. For anthropometric standing, test participants are asked to stand erect with their weight evenly distributed on both feet, heels together as much as possible, legs and trunk straight without stiffness, and the head erect and looking straight ahead. The arms are to hang relaxed with the elbows lightly touching the sides with the palms of the hands beside, but not touching the thighs. This posture is similar to that of the position of military attention but without the stiffness and bracing with which it is often associated. A number of dimensions and landmarks require that the participant's head be in the Frankfort plane (also known as the Frankfort horizontal, Figure E.1). This head position is quite similar to having the participant look straight ahead with the head erect. However, when the Frankfort plane is called for, the anthropometrist will position the participant's head so that an imaginary line connecting the drawn landmarks at right tragion and right infraorbitale is horizontal.

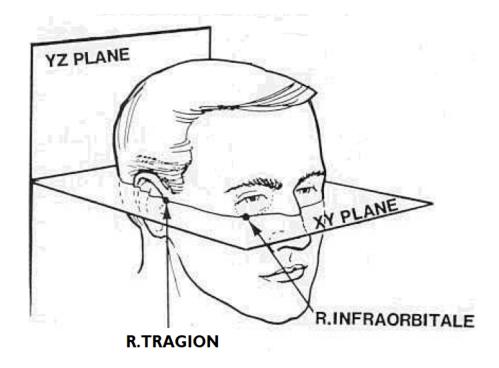


Figure E.1. Frankfort Plane.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

2. TERMS OF ORIENTATION

a. Anatomical Position – a standard position of the body to which all anatomical directions (e.g., superior, medial, anterior) are referenced (Figure E.2).

b. Anterior – pertaining to the front of the body; as opposed to posterior (Figure E.2).

c. Coronal Plane – any vertical plane at right angles to the midsagittal plane (Figure E.2).

d. Distal – the end of a bone or body segment farthest from the head, as opposed to proximal (Figure E.2).

e. Dorsal – pertaining to the back of the body or one of its parts (on the hand, its top surface as opposed to its palmar surface).

f. Frankfort Plane – the standard horizontal plane or orientation of the head. The plane is established by a line passing through the right tragion (approximate earhole) and the lowest point of the right orbit (eye socket, Figure E.1).

g. Inferior – below, in relation to another structure; lower (Figure E.2).

h. Lateral – lying near or toward the sides of the body; as opposed to medial (Figure E.2).

i. Medial – lying near or toward the midline of the body; as opposed to lateral. (Figure E.2).

j. Midsagittal Plane – the vertical plane which divides the body into right and left halves (Figure E.2).

k. Transverse Plane – the horizontal plane which divides the body into top and bottom halves (Figure E.2).

1. Posterior – pertaining to the back of the body; as opposed to anterior (Figure E.2).

m. Proximal – the end of a bone or body segment nearest the head; as opposed to distal (Figure E.2).

n. Superior – above, in relation to another structure; higher (Figure E.2).

o. Supra - prefix designating above or on.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

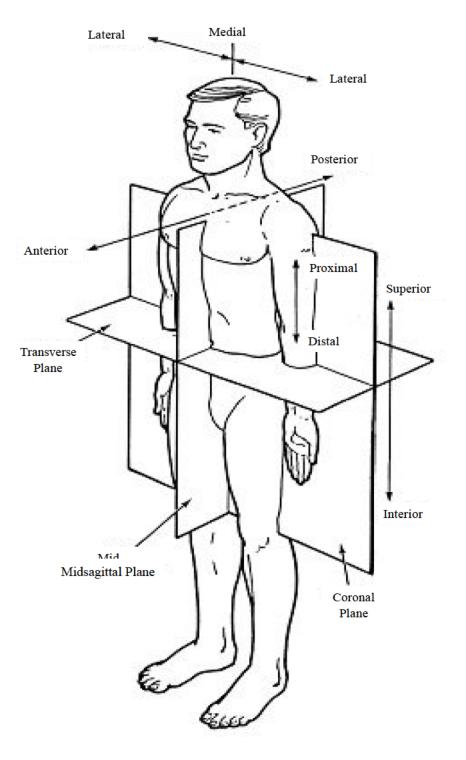


Figure E.2. The Body in Anatomical Position.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

3. GLOSSARY OF ANATOMICAL AND ANTHROPOMETRIC TERMS

a. Anterior superior iliac spine (ASIS) – the anterior terminal point of the iliac crest of the pelvis. It can be located by palpation. A line drawn between the right and left ASIS defines the superior boundary of the pubic region.

b. Landmark – a landmark (auxiliary landmark or another passive absorbent device (PAD) location) which is used to determine the position of a given PAD location of interest.

c. Biceps – the large muscle on the anterior surface of the upper arm.

d. Femur – long bone of the upper thigh (thigh bone).

e. Inguinal crease – the crease at the junction of the inner part of the thigh with the trunk.

f. Mastoid process – lowest bony projection behind and below the ear. The mastoid process can be easily located behind the earlobe.

g. Omphalion – the navel or bellybutton.

h. Palpate – to locate or explore an area of the body by touch or feel. They are often used in reference to identification of an underlying bony landmark.

i. Mandible – the jaw bone.

j. Radius – long bone of the forearm, located laterally (thumb side) when in anatomical

standing posture.

k. Scye – points at the junction of the upper arm and torso. Scye can typically be referred to as anterior or posterior.

1. Tibia – primary long bone of the lower leg (shin bone), located medially (big toe side).

m. Triceps – the large muscle on the posterior surface of the upper arm.

n. Ulna – long bone of the forearm located medially (little finger side) when in anatomical standing posture.

4. IDENTIFYING LANDMARKS AND PAD MARKERS (Tables E.1 and E.2)

a. STEP 1:

(1) LANDMARK 1: Infraorbitale, the lowest point on the border of the bony eye socket (Figure E.3).

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

(2) PROCEDURE: Direct the participant to stand, looking straight ahead. Stand in front of the participant and palpate the bony eye socket under the eye to locate its lowest point. Draw a dot on the landmark.

Landmarks	Anatomic Location
1	Infraorbitale (bony eye socket)
2	Tragion (ear flap juncture)
3	Infrathyroid (bottom point of the Adam's apple)
4	Biceps point, left
5	Elbow crease, left
6	Stylion, left (bony wrist point – thumb side)
7	Wrist, dorsal, left
8	Anterior superior iliac spine (ASIS), right and left
9	Waist (venter of the navel)
10	Left inside knee, flexed knee
11	Fifth metatarsophalangeal protrusion, left
12	First metatarsophalangeal protrusion, left

Table L.I. Landinark Checklist.	Table E.1.	Landmark Checklist
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Table E.2.	Passive Absorbent Device	(PAD) Marker Checklist.

PAD Markers	Anatomic Location
P1	Left ear
P2	Chin (left and right anterior neck)
P3	Chest
P4	Inner upper arm, left
P5	Forearm, volar, left
P6, P6D	Pubic region
P8	Crotch
Р9	Inner thigh, left
P10, P10D	Inner shin, left
P11	Boot (foot)
P13, P13D	Nape
P14	Armpit, left
P15	Outer upper arm, left
P16, P16D	Mid-back. (mid-back at the level of the waist (center of the navel))
P17	Hip (hip point, left side)
P18	Glove (hand)

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.



Figure E.3. LANDMARK 1, Infraorbitale.

(3) CAUTION: Participants may be apprehensive when you palpate near their eyes. Care must be taken in locating this landmark to reduce the participant's concern.

b. STEP 2:

(1) LANDMARK 2: Tragion, left and right, it is the point where the flap of the ear meets with the head (Figure E.4).

(2) PROCEDURE: Palpate each tragus to find the upper point of attachment to the head. Place a dot on each landmark.

(3) CAUTION: Avoid distorting the soft tissue in this area while drawing the landmark.

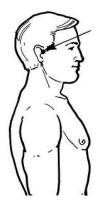


Figure E.4. LANDMARK 2, Tragion.

c. STEP 3:

- (1) PAD MARKER P1: Left ear (Figure E.5).
- (2) DESCRIPTION: Point posterior to the ear at the level of tragion (Figure E.5).

(3) LANDMARK: Tragion.

(4) PROCEDURE: Direct the participant to stand in anthropometric standing position with the head in Frankfort plane. Behind the ear, draw a short horizontal line (the ear landmark line) on the head at the level of tragion.

d. STEP 4:

(1) LANDMARK 3: Infrathyroid (bottom point of the Adam's apple, Figure E.6).

(2) PROCEDURE: Direct the participant to stand with the head in the Frankfort plane. Stand in front of the participant and palpate the smooth surface of the thyroid cartilage moving downwards until you locate the bottom point of the thyroid cartilage (Adam's apple) in the midsagittal plane. Draw a short horizontal line through the landmark.

(3) CAUTION: Be sure the participant's head is in the Frankfort plane.

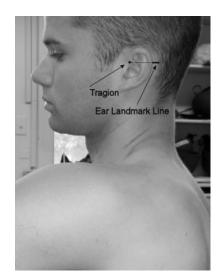


Figure E.5. PAD MARKER P1, Left Ear.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.



Figure E.6. LANDMARK 3, Infrathyroid.

e. STEP 5:

(1) PAD MARKERS P2L and P2R: Chin (left and right anterior neck, Figure E.7).

(2) DESCRIPTION: The left and right sides of the neck lateral to the Adam's apple at the level of the neck circumference line (Figure E.7).

(3) LANDMARK: Infrathyroid (bottom of the Adam's apple)

(4) PROCEDURE: Direct the participant to stand, looking straight ahead, with the teeth together and the head in Frankfort plane. Stand to the rear of the participant and place the measuring tape around the neck with the upper edge at the level of the drawn Infrathyroid landmark (bottom of the Adam's apple) as if measuring the neck circumference. The plane of the tape is perpendicular to the long axis of the neck. Draw a 4- to 5-cm (2-in) line on each side of the neck from the infrathyroid landmark posteriorly along the top edge of the tape. Intersect these lines on each side of the neck, with vertical lines at the lateral base of the laryngeal prominence. **NOTE**: Maintain tape position for next step.



Figure E.7. PAD MARKERS P2L and P2R, Chin (Left and Right Anterior Neck).

f. STEP 6:

(1) PAD MARKERS P13 and P13D: Nape (Figure E.8).

(2) LANDMARK: Infrathyroid (bottom of the Adam's apple, Figure E.8).

(3) PROCEDURE: Same procedure as used in Step 5 (Appendix E, Paragraph 4.e). Now, standing behind the participant, draw a 6-cm, horizontal line along the upper edge of the tape across the back of the neck. At the intersection of the drawn line and the spinal column, draw a short vertical line across the horizontal line.

(4) CAUTION: Be sure that the participant's head is in the Frankfort plane.

g. STEP 7:

(1) PAD MARKER P14: Scye (armpit), left and right (Figure E.9).

(2) DESCRIPTION: Points on the posterior upper arm and torso associated with the armhole of a garment (Figure E.9).

(3) PROCEDURE: Direct the participant to stand in the anthropometric standing position. Direct the participant to place the left hand on the hip. Begin by standing in front of the participant and move around the participant as needed. Place the edge of a plastic ruler firmly into the armpit in a horizontal position and then ask the participant to carefully lower the arm to the side, thus clamping the ruler in place. Make sure the ruler is level. Draw a short horizontal line on the torso at the top of the ruler on the anterior and posterior junction where the arm and torso intersect. With the arm hanging naturally to the side, cross this line with a short vertical line at the posterior edge of the arm. Repeat this procedure for the right side.

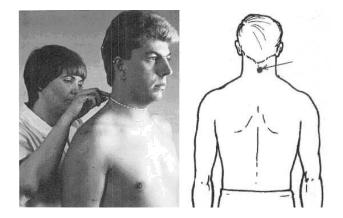


Figure E.8. PAD MARKERS P13 and P13D, Nape.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

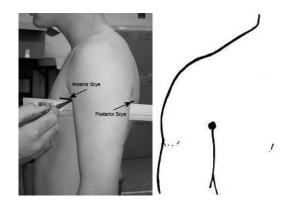


Figure E.9. PAD MARKER P14, Scye (Armpit), Left and Right.

(4) CAUTION: These are some of the more difficult landmarks to locate accurately and consistently. On some participants, the arms must be held farther away from the body than the hands-on-hips position to place the ruler in its proper position. Be sure that the ruler is level when the arm is lowered to the side. If it is not, begin the process of placing the ruler again. Do not try to level the ruler while the participant's arm is down.

h. STEP 8:

- (1) PAD MARKER P3: Chest (Figure E.10).
- (2) DESCRIPTION: Mid-chest at the level of scye (Figure E.10).
- (3) LANDMARK: Anterior scye, left and right.

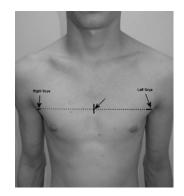


Figure E.10. PAD MARKER P3, Chest.

(4) PROCEDURE: Place tape horizontally across the torso between the left and right anterior scye landmarks. The tape should be tight against the chest. Align the top edge of the tape with the right and left anterior scye landmarks. Draw a horizontal line along the top edge of the tape at mid-chest. Bisect this line with a short vertical line on the sternum at the midsagittal plane.

i. STEP 9:

(1) LANDMARK 4: Biceps point, left, the highest point of the left flexed biceps as viewed from the participant's left side (Figure E.11).

(2) PROCEDURE: Direct the participant to stand with the left upper arm extended forward horizontally and the elbow flexed about 90 degrees. The participant's fist will be tightly clenched and held facing the head. Stand to the right of the participant and locate the highest point on the flexed biceps by inspection. Draw a short line perpendicular to the long axis of the upper arm passing through the landmark. **NOTE**: Maintain position for next step.

j. STEP 10:

(1) PAD MARKER P4: Inner upper arm, left (Figure E.12).

(2) DESCRIPTION: Inside of the upper arm between the biceps and triceps muscles at level of biceps circumference, flexed (Figure E.12).

(3) LANDMARK: Biceps point, left.

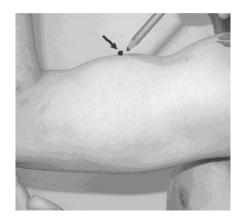


Figure E.11. LANDMARK 4, Biceps Point, Left.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

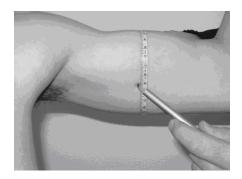


Figure E.12. PAD MARKER P4, Inner Upper Arm, Left.

(4) PROCEDURE: Direct the participant to stand with the left upper arm extended forward horizontally and the elbow flexed about 90 degrees. Place a tape around the upper arm (as if measuring biceps circumference) at the level of the drawn biceps point landmark. The fist will be clenched and held facing the head. The participant will be urged to exert maximum effort in "making a muscle." The tape should be in a plane perpendicular to the long axis of the upper arm. Exert only enough tension on the tape to maintain contact between the tape and the skin. Palpate downward on the biceps along the tape to the groove between the biceps and the triceps brachii muscle. Place a mark at the point where the tape intersects this groove. <u>NOTE</u>: Maintain tape position for the next step.

k. STEP 11:

(1) PAD MARKER P15: Outer upper arm, left (Figure E.13).

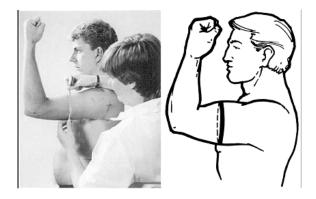


Figure E.13. PAD MARKER P15, Outer Upper Arm, Left.

(2) DESCRIPTION: Outside of the upper arm at the level of the biceps circumference,

flexed (Figure E.13).

(3) LANDMARK: Biceps point, left.

(4) PROCEDURE: Use the same procedure used in Step 10 [Appendix E, Paragraph 4.j(4)]. Place a mark on the left outer upper arm at the most lateral point of the biceps muscle that is crossed by the tape.

1. STEP 12:

(1) LANDMARK 5: Elbow crease, left, the skin crease on the inside of the elbow joint when the elbow is flexed 90 degrees (Figure E.14).

(2) PROCEDURE: Direct the participant to stand with the upper left arm hanging naturally to the side, the lower arm extended forward horizontally, the elbow flexed about 90 degrees, and the palm of the hand facing upward. Place a horizontal mark along the primary elbow crease.

m. STEP 13:

(1) LANDMARK 6: Stylion, left, the lowest point of the bottom of the radius (Figure E.15).

(2) PROCEDURE: Direct the participant to stand. Stand in front of the participant and grasp the participant's hand. Place your thumb on the thumb side of the participant's hand and palpate up toward the wrist until you locate the end of the radius. Draw a line over the landmark.



Figure E.14. LANDMARK 5, Elbow Crease, Left.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

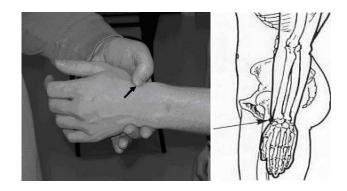


Figure E.15. LANDMARK 6, Stylion, Left, the Lowest Point of the Bottom of the Radius.

(3) CAUTION: This area is crossed by tendons so it may be necessary to bend the hand up and down at the wrist to find the landmark.

n. STEP 14:

(1) LANDMARK 7: Wrist, dorsal, left (Figure E.16). A line across the back of the wrist originating at the stylion landmark and perpendicular to the long axis of the arm.

(2) PROCEDURE: Direct the participant to stand. Direct the participant to make fists and bring them together as shown in the Figure E.16. With the back of the hand facing outward and the palm sides facing inward, direct the participant raise the arms until they are in a horizontal position roughly parallel to the standing surface. The forearms and fists will be in a straight line. Stand in front of the participant looking directly at the stylion landmark to eliminate errors in sighting. Draw a line across the dorsal (back) surface of the wrist beginning below the stylion.

(3) CAUTION: Be sure the line is vertical and that its origin is at the stylion.

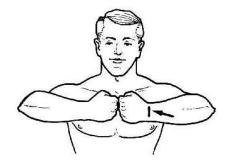


Figure E.16. LANDMARK 7, Wrist, Dorsal, Left.

o. STEP 15:

(1) PAD MARKER P5: Forearm, volar, left (Figure E.17).

(2) DESCRIPTION: Point centered on the inner surface of the lower left arm at a level midway between the elbow crease and the wrist crease (Figure E.17).

(3) LANDMARKS: Elbow crease, wrist, dorsal.

(4) PROCEDURE: Direct the participant to stand with the upper left arm hanging naturally to the side, the lower arm extended forward horizontally, the elbow flexed about 90 degrees, and the palm of the hand faceing upward. Mark a line on the arm midway between the elbow crease and the wrist, dorsal landmarks. Visually estimate the point along this line that is midway between the lateral and medial sides of the lower arm. At this point, draw a line that bisects the first line.

p. STEP 16:

(1) PAD MARKER P18: Glove (hand), left (Figure E.18).

(2) DESCRIPTION: A point on back of hand midway between the knuckle of the third finger and the back wrist crease (Figure E.18).

(3) LANDMARKS: Stylion, wrist, dorsal.

(4) PROCEDURE: Direct the participant to rest a forearm on a table while extended forward horizontally, with the hand extended straight with dorsal side facing up. Take a perpendicular measurement from the wrist, dorsal landmark to the first knuckle of the third finger. Mark a point midway along the line.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.



Figure E.17. PAD MARKER P5, Forearm, Volar, Left.



Figure E.18. PAD MARKER P18, Glove (Hand), Left.

q. STEP 17:

(1) LANDMARK 8: ASIS, left and right (Figure E.19).

(2) PROCEDURE: Direct the participant to stand in the anthropometric standing position. Stand in front of the participant. Locate each iliac crest (the top of the pelvis) by palpation, and then bring the thumb to the anterior points of the crests. Mark each landmark. In most cases you will have to ask the participant to lower the waistband of the shorts somewhat to reveal these points.

(3) CAUTION: Do not distort the skin when drawing the cross.

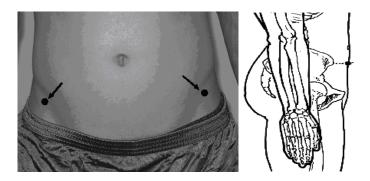


Figure E.19. LANDMARK 8, Anterior Superior Iliac Spine (ASIS), Left and Right.

r. STEP 18:

(1) PAD MARKERS P6 and P6D: Pubic region (Figure E.20).

(2) DESCRIPTION: Point below the navel on line between the left and right ASIS (Figure E.20).

(3) LANDMARKS: ASIS, left and right

(4) PROCEDURES: Direct the participant to stand in the anthropometric standing position. Stand in front of the participant. Stretch a tape between the left and right ASIS landmark. Draw a short horizontal line along the tape below the navel. From the center of the navel, visually project a vertical line downward and draw a short vertical line where it crosses the horizontal line.

(5) CAUTION: Do not distort the skin when drawing the cross.

s. STEP 19:

(1) LANDMARK 9, PAD Markers P16 and P16D: Waist (center of the navel, omphalion), anterior and posterior (Figure E.21).

(2) PROCEDURE: Direct the participant to stand in the anthropometric standing position. Stand in front of the participant and locate the center of the navel by inspection. Draw a 4-cm horizontal line across navel. Stand in back of the participant. With the top edge of the tape passing over the center of the navel, place tape horizontally around the waist as if measuring waist circumference. Draw a 4-cm horizontal line across the spine of the participant at the upper edge of the tape. Draw a vertical line at the spine that crosses the horizontal line. The landmarks are drawn at the maximum point of quiet respiration.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

(3) CAUTION: The participant must not tense the abdominal muscles or change body position during location and marking of these points. The tape must be horizontal around the waist.

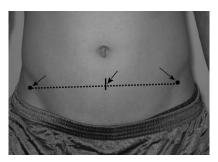


Figure E.20. PAD MARKERS P6 and P6D, Pubic Region.



Figure E.21. LANDMARK 9, PAD MARKERS P16 and P16D, Waist (Center of The Navel, Omphalion), Anterior and Posterior.

t. STEP 20:

(1) PAD MARKER P17: Hip (hip point, left side, (Figure E.22).

(2) DESCRIPTION: Hip point at the level of the maximum buttock protrusion (Figure E.22).

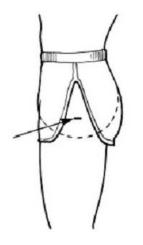


Figure E.22. PAD Marker P17, Hip (Hip Point, Left Side).

(3) PROCEDURE: Direct the participant to stand in the anthropometric standing position with the left leg of the shorts hiked above the level of maximum buttock protrusion. Stand to the left of the participant and position the tape loosely around the hips. Sight the point of maximum protrusion of the left buttock (hip point, posterior) and position the tape over the left hip at this point. The tester's assistant will adjust the tape so it is horizontal all the way around the hip region. The tester will place a horizontal line on the left thigh at the lower edge of the tape. The tester will then cross this horizontal line with a short vertical line, visually located along the vertical axis of the femur (upper thigh bone). Be careful because this vertical plane may or may not be located midway between the front and back of the thigh. The posterior and right lateral points of the hip point landmark will not be marked.

(4) CAUTION: The participant should exercise care to avoid stretching the soft tissue of the upper thigh when hiking the leg of the shorts.

u. STEP 21:

(1) LANDMARK 10: Left inside knee, flexed knee, inside of the left knee pivot point (medial femoral epicondyle) when the knee is flexed about 90 degrees (Figure E.23).

(2) PROCEDURE: Direct the participant to stand on the right foot with the left foot placed on a low bench so that the left thigh extends forward horizontally and the knee is flexed about 90 degrees. Stand in front of the participant and, with one hand, grasp the bony prominences of the bottom of the femur (femoral epicondyles) located to the left and right of the knee. Direct the participant to flex the knee, if necessary, to help locate the medial epicondyle. When you have located the medial point of the medial femoral epicondyle, use the thumb or index finger of the other hand to mark its place and draw a point on the landmark. <u>NOTE</u>: Maintain position for next step.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

(3) CAUTION: This landmark is difficult or impossible to locate accurately in heavily muscled participants. Use your best judgment in these cases.



Figure E.23. LANDMARK 10, Left Inside Knee, Flexed Knee.

v. STEP 22:

(1) PAD MARKER P9: Inner thigh, left (Figure E.24).

(2) DESCRIPTION: Point on the inner thigh midway between the medial femoral epicondyle and the crotch (Figure E.24).

(3) LANDMARK: Medial femoral epicondyle.

(4) PROCEDURE: Direct the participant to stand erect with the right foot on the floor, the left foot positioned on a low stool so that the left thigh extends forward horizontally, and the lower leg flexes downward approximately 90 degrees. Place an 18-in ruler along the length of the inner thigh with the "zero" end toward the crotch. At the knee, the ruler edge is placed at the medial femoral epicondyle landmark and the ruler is visually aligned with the long axis of the thigh. Ask the participant to slide the ruler up the leg until firm but light contact is made with the crotch. Mark a point on the thigh midway between the crotch and medial femoral epicondyle.

w. STEP 23:

(1) PAD MARKER P8: Crotch (Figure E.25).

(2) DESCRIPTION: A vertical line halfway between the front and back of the left inner thigh and extending downward from the level of the gluteal furrow (Figure E.25).

(3) PROCEDURE: Direct the participant to stand erect, looking straight ahead with the right foot on a platform so that the right knee is flexed about 90 degrees. Stand at the right of the participant and locate the landmark by inspection. Draw a vertical line approximately 4 cm long down the middle of the inner left thigh, beginning at the level of the gluteal furrow (posterior juncture of the buttock and thigh). Place a 4-cm wide straight-edge horizontally between the legs and in contact with the crotch. At the bottom of the straight-edge, cross the vertical line with a short horizontal line

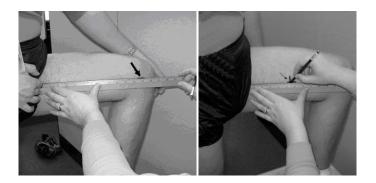


Figure E.24. PAD MARKER P9, Inner Thigh, Left.

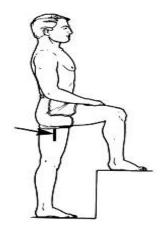


Figure E.25. PAD Marker P8, Crotch.

x. STEP 24:

(1) PAD MARKERS P10 and P10D: Inner shin, left (Figure E.26).

(2) DESCRIPTION: Point on the inside of the left tibia at the level that maximum calf circumference is measured (Figure E.26).

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

(3) PROCEDURE: Direct the participant to stand erect with the weight distributed equally on both feet. Wrap a tape around the calf, crossing it at the side, and slide it up and down to establish the maximum circumference of the calf. Be sure the tape is in a horizontal plane. Draw a short horizontal line along the bottom of the tape on the medial side of the calf. Palpate along this line to locate the groove between the calf muscle and the tibia, and mark this point on the calf muscle.

(4) CAUTION: On some participants, the level of maximum circumference of the calf may extend vertically more than 1 cm. In such cases, the landmark is drawn at the level of the lowest maximum circumference of the calf.

y. STEP 25:

(1) LANDMARK 11: Fifth metatarsophalangeal protrusion, left (Figure E.27).

(2) DESCRIPTION: The most lateral protrusion of the left foot in the region of the fifth metatarsophalangeal joint (Figure E.27).

(3) PROCEDURE: Direct the participant to stand on a table with the weight distributed equally on both feet. Stand in front of the participant and, by visual inspection and palpation of the metatarsophalangeal joint, locate the maximum protrusion on the outside of the foot near the little toe. Draw a short vertical line through the landmark. Be sure the mark is placed on or near the joint on the end of the foot and not on the toe.

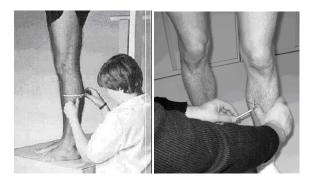


Figure E.26. PAD MARKERS P10 and P10D, Inner Shin, Left.



Figure E.27. LANDMARK 11, Fifth Metatarsophalangeal Protrusion, Most Lateral Protrusion of the Left Foot.

z. STEP 26:

(1) LANDMARK 12: First metatarsophalangeal protrusion, left (Figure E.28)

(2) DEFINITION: The most medial protrusion of the left foot in the region of the first metatarsophalangeal joint (Figure E.28).



Figure E.28. LANDMARK 12, First Metatarsophalangeal Protrusion, Most Medial Protrusion of the Left Foot.

(3) PROCEDURE: Direct the participant to stand on a table with weight distributed equally on both feet. Stand in front of the participant and, by visual inspection and palpation inspection, locate the maximum protrusion of the inside of the foot near the metatarsophalangeal joint. Draw a short vertical line through the landmark. Be sure the mark is placed on or near the joint on the end of the foot and not on the toe.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

aa. STEP 27:

(1) PAD MARKER P11: Boot foot (Figure E.29).

(2) DESCRIPTION: Point where the ball of foot circumference intersects the tendon of the second toe (Figure E.29).

(3) LANDMARKS: First metatarsophalangeal protrusion, fifth metatarsophalangeal protrusion.



Figure E.29. PAD MARKER P11, Boot (Foot).

(4) PROCEDURE: Direct the participant to stand with the feet about 10 cm apart and the weight distributed equally on both feet. Stand in front of the participant and position a tape as if measuring the circumference of the foot at the drawn first and fifth metatarsophalangeal landmarks on the ball of the foot. At the point where the tape crosses the tendon of the second toe, mark the foot on the side of the tape closest to the ankle.

5. PAD PLACEMENT WITH RESPECT TO PAD MARKERS

a. The locations of the PAD placement on the test participant are listed in Table E.3 and are illustrated in Figures E.30 and E.31. Detailed instruction on the locations of the PAD and the placement techniques are in Paragraphs 5.b through 5.v of Appendix E of this document.

<u>NOTE</u>: Some individuals may experience skin irritation from PAD adhesive following multiple man-in-simulant testing (MIST) trials. In such cases, varying PAD placement slightly to avoid further irritation is acceptable.

Table E.S. Passive Absorbent Device	(PAD) Placement Location Descriptions for WIST.
Position Number ^a	Description
P1	Left ear
P2L, P2R ^b	Chin (left and right anterior neck)
P3	Chest
P4	Inner upper arm
P5	Forearm, volar
P6, P6D ^b	Pubic region
P7	External genitalia
P8	Crotch
Р9	Inner thigh
P10, P10D ^b	Inner shin
P11	Boot (foot)
P12	Scalp
P13, P13D ^b	Nape
P14	Armpit
P15	Outer upper arm
P16, P16D ^b	Mid-back
P17	Hip point, left lateral
P18	Glove (hand)
P30	Nose cup
P31	Mask

Table E 3 Passive Absorbent Device (PAD) Placement Location Descriptions for MIST.

^aSee Figures E.30 and E.31 ^bIndicates duplicate PADs at these locations.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

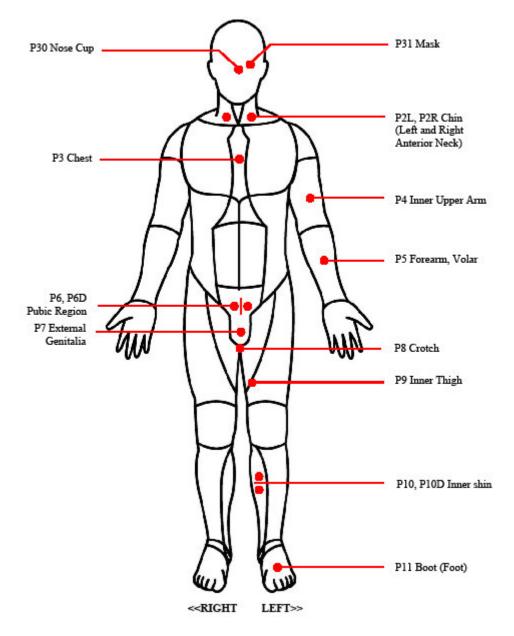


Figure E.30. Man-in-Simulant Test (MIST) Passive Absorbent Device (PAD) Placement Diagram (Front).

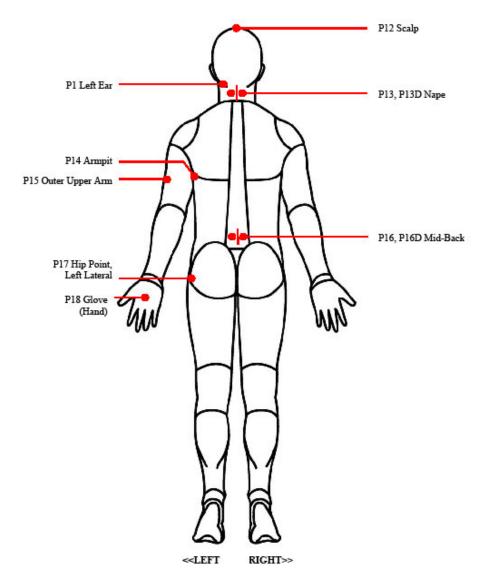


Figure E.31. Man-in-Simulant Test (MIST) Passive Absorbent Device (PAD) Placement Diagram (Back).

b. <u>Left Ear (Position Number P1, Figure E.32)</u>. PAD PLACEMENT: Orientate the long axis of the PAD vertically. Align the upper edge of the PAD with the ear landmark line, and position the anterior edge of the PAD so it lightly touches the back of the ear at its base. For some individuals and some mask styles, it may be necessary to don the mask before the best location can be determined. <u>NOTE</u>: Be sure to maintain the vertical orientation of the PAD long axis.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

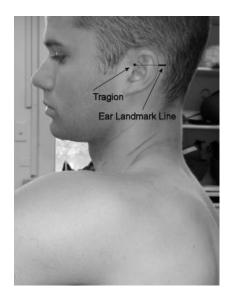


Figure E.32. Left Ear, Position Number P1.

c. <u>Chin (Left and Right Anterior Neck, Position Numbers P2L and P2R, Figure E.33)</u>. PAD PLACEMENT: Orientate the long axis of the PAD parallel to the long axis of the neck. Center the PAD vertically over the P2L, P2R PAD marker with its anterior edge aligned with the vertical laryngeal prominence line. Place the P2L PAD on the left neck and the P2R on the right neck. <u>NOTE</u>: P2R PAD (not illustrated) is located to the right of the crossed PAD marker location.



Figure E.33. Chin (Left and Right Anterior Neck, Position Numbers P2L and P2R).

d. <u>Chest (Position Number P3, Figure E.34)</u>. PAD PLACEMENT: Center the PAD over the P3 PAD marker, at the intersection of the horizontal and vertical lines, with the long axis of the PAD aligned parallel to the long axis of the torso.

e. <u>Inner Upper Arm, Left (Position Number P4, Figure E.35)</u>. PAD PLACEMENT: Center PAD over the P4 PAD Marker with the long axis of the PAD running parallel to the long axis of the upper arm.

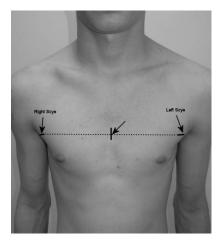


Figure E.34. Chest, Position Number P3.

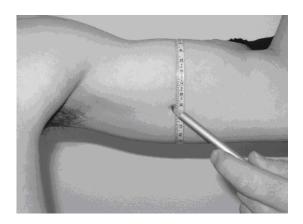


Figure E.35. Inner Upper Arm, Left, Position Number P4.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

f. <u>Forearm, Volar, Left (Position Number P5, Figure E.36)</u>. PAD PLACEMENT: Center PAD over the P5 PAD marker with the long axis of the PAD running parallel to the long axis of the lower arm.

g. <u>Pubic Region (Position Numbers P6 and P6D, Figure E.37)</u>. PAD PLACEMENT: Position P6 1 cm to the left and P6D 1 cm to the right of the P6, P6D PAD marker. Align the long axis of each PAD with the vertical axis of the torso. Place the top edge of each PAD along the horizontal line.



Figure E.36. Forearm, Volar, Left, Position Number P5.

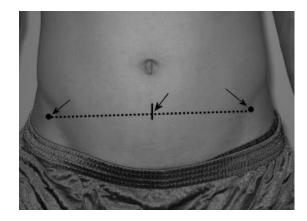


Figure E.37. Pubic Region, Position Number P6 and P6D.

h. <u>External Genitalia (Position Number P7)</u>. Instruct the test participant to make a fist with the hand. Participant will put the fist inside the exercise shorts, on the inner lining. Using the fist as a hard surface, place the PAD on the outer lining of the exercise shorts in the crotch/scrotum region.

i. <u>Crotch (Position Number P8, Figure E.38)</u>. PAD PLACEMENT: With the long axis of the PAD parallel to the long axis of the thigh, center the upper edge of the PAD at the P8 PAD marker.

j. <u>Inner Thigh, Left (Position Number P9, Figure E.39)</u>. PAD PLACEMENT: Center the PAD over the P9 PAD marker with the long axis of the PAD parallel to the long axis of the thigh.



Figure E.38. Crotch, Position Number P8.



Figure E.39. Inner Thigh, Left, Position Number P9.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

k. <u>Inner Shin, Left (Position Numbers P10 and P10D, Figure E.40)</u>. PAD PLACEMENT: Orient the long axis of the PAD parallel to the long axis of the lower leg. Position P10 with its posterior edge aligned with the vertical line on the tibia (shin bone) just above the horizontal line. Position P10D with its posterior edge aligned with the vertical line on the tibia (shin bone), just below the horizontal line. Separate the two PADs slightly so they do not rub against each other as the participant moves while performing various exercises during MIST testing. Position both PADs above the footwear.

l. <u>Boot (Foot, Position Number P11, Figure E.41)</u>. PAD PLACEMENT: Place the long axis of the PAD is placed horizontally on the top of the foot so that the lower PAD edge is centered at the P11 PAD marker drawn at the intersection of the second toe tendon and the tape. Align the lower edge of the PAD with the foot circumference line.



Figure E.40. Inner Shin, Left, Position Numbers P10 and P10D.



Figure E.41. Boot (Foot), Position Number P11.

m. <u>Scalp (Top of Head, Position Number P12, Figure E.42)</u>

(1) PROCEDURE AND PAD PLACEMENT: Direct the participant to stand in the anthropometric standing position with the head in the Frankfort plane. Stand to one side of the participant and palpate the top of the head to determine its highest point. Place PAD at the highest point along the midsagittal plane with the long axis of the PAD oriented from front to back. For some individuals and some mask styles, it may be necessary to don the mask before the best location can be determined. If the mask strap interferes with PAD placement, place the PAD immediately anterior or posterior to the strap along the midsagittal plane. When the PAD is attached to long hair, be sure to secure the hair so the position of the PAD will not move. With certain hair styles in women, it may be necessary to shift the pad location slightly in order to seat the pad securely.

(2) CAUTION: Be sure that the head is in the Frankfort plane.

n. <u>Nape (Position Numbers P13 and P13D, Figure E.43)</u>. PAD PLACEMENT: Place the P13 PAD 1 cm to the left and P13D 1 cm to the right of the P13 PAD marker with the long axis of each PAD running parallel to the long axis of the upper neck. Center both PADs vertically on the drawn neck circumference line in back.

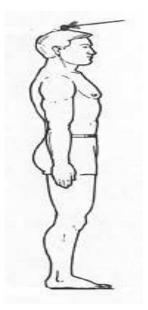


Figure E.42. Scalp (Top of Head), Position Number P12.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

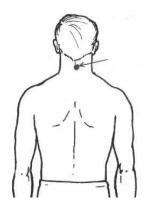


Figure E.43. Nape, Position Numbers P13 and P13D.

o. <u>Scye (Armpit), Left (Position Number P14, Figure E.44)</u>. PAD PLACEMENT: Long axis of the PAD should be parallel to the long axis of the torso. Position the PAD so that the upper right corner is at the posterior scye landmark.

p. <u>Outer Upper Arm, Left (Position Number P15, Figure E.45)</u>. PAD PLACEMENT: Center PAD over the P15 PAD marker with the long axis of the PAD running parallel to the long axis of the upper arm.

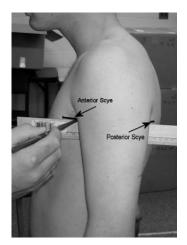


Figure E.44. P14, Scye (Armpit), Left.



Figure E.45. P15, Outer Upper Arm, Left.

q. <u>Mid-Back (Position Numbers P16 and P16D, Figure E.46)</u>. PAD PLACEMENT: Place the P16 PAD 1 cm to the left and P16D PAD 1 cm to the right of the P16, P16D PAD Marker with the long axis of each PAD running parallel to the long axis of the torso. Center both pads vertically on the horizontal line that was drawn through the PAD Marker. <u>NOTE</u>: P16D PAD (not illustrated) is located to the right of the crossed PAD marker location.

r. <u>Hip Point, Left (Position Number P17, Figure E.47)</u>. PAD PLACEMENT: Center the PAD over the left lateral hip point P17 PAD marker such that the long axis of the PAD is vertical.

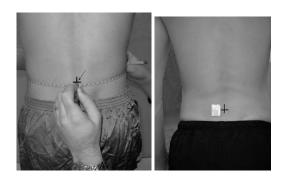


Figure E.46. P16 and P16D, Mid-Back.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

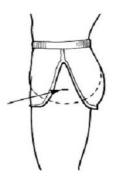


Figure E.47. P17, Hip Point, Left.

s. <u>Glove (Hand, Position Number P18, Figure E.48)</u>. PAD PLACEMENT: Center pad over the P18 PAD marker with long axis of the PAD parallel to the long axes of the hand and arm.

t. <u>Nose Cup (Position Number P30)</u>. PAD PLACEMENT: Place PAD inside the mask, in the nose cup area such that there is no interference with breathing or chaffing during wear.

u. <u>Mask (Position Number P31, Figure E.49)</u>. PAD PLACEMENT: Place PADS inside the mask just below the eye-lens, outside the viewing area, and in such a location as to not chafe the wearer.



Figure E.48. P18, Glove (Hand).



Figure E.49. Inside View of M40 Mask, P30 and P31 PAD Locations.

v. <u>P50</u>, Abdomen Pass-through (Table E.4 and Figure E.50)

Table E.4.	Man-in-Simulant Test (MIST) Ensemble Unique	
	Passive Absorbent Device (PAD).	

Position Number	Description
P50	Abdomen Pass-Through

<u>NOTE</u>: This PAD is not included in standard MIST protocols.

APPENDIX E. VAPOR MAN-IN-SIMULANT TEST PASSIVE ABSORBENT DEVICE (PAD) PLACEMENT LOCATIONS.

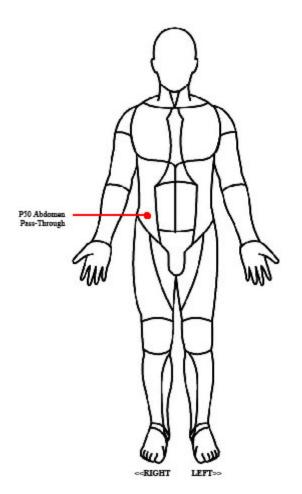


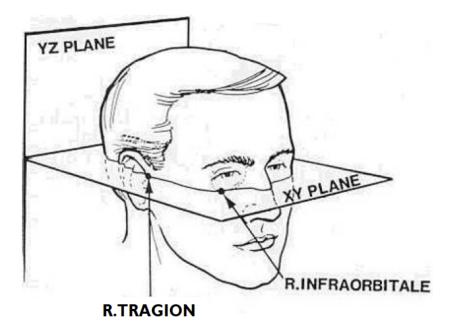
Figure E.50. Man-In-Simulant Test (MIST) Ensemble Unique Passive Absorbent Device (PAD) Diagram.

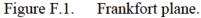
APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

1. STANDARDIZED POSTURE

a. The purpose of a standardized participant posture is to ensure that the differences found in body sizes within a group are not because of variations in body posture. Most body-posture descriptions are self explanatory, but the frequently used phrase "anthropometric standing" requires clarification. For anthropometric standing, test participants are asked to stand erect with their weight evenly distributed on both feet, heels together as much as possible, legs and trunk straight without stiffness, and the head erect and looking straight ahead. The arms are to hang relaxed with the elbows lightly touching the sides with the palms of the hands beside, but not touching the thighs. This posture is similar to that of the position of military attention but without the stiffness and bracing with which it is often associated (see Reference A).

b. In the anthropometric sitting position, the participant sits on a flat surface with the long axes of the thighs parallel and the knees flexed approximately 90 degrees. The torso is straight but not ridged, the arms hang naturally to the sides, and the participant looks straight ahead. This definition for sitting position is greatly abbreviated from the definition given for the 1988 Anthropometric Survey of U.S. Army Personnel (ANSUR) (see Reference A). A number of dimensions and landmarks require that the participant's head be in the Frankfort plane (also known as the Frankfort horizontal, Figure F.1). This head position is quite similar to having the participant look straight ahead with the head erect. However, when the Frankfort plane is called for, the tester will position the participant's head so that an imaginary line connecting the drawn landmarks at right tragion and right infraorbitale is horizontal (see Reference A).





APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

2. TERMS OF ORIENTATION

a. Anatomical position – a standard position of the body to which all anatomical directions (e.g., superior, medial, anterior) are referenced (Figure F.2).

b. Anterior – pertaining to the front of the body; as opposed to posterior (Figure F.2).

c. Coronal plane – any vertical plane at right angles to the midsagittal plane (Figure F.2).

d. Distal – the end of a bone or body segment farthest from the head, as opposed to proximal (Figure F.2).

e. Dorsal – pertaining to the back of the body or one of its parts (on the hand, its top surface as opposed to its palmar surface).

f. Frankfort plane – the standard horizontal plane or orientation of the head. The plane is established by a line passing through the right [and left] tragion (approximate ear hole) and the lowest point of the right orbit (eye socket, Figure F.1).

g. Inferior – below, in relation to another structure; lower (Figure F.2).

h. Lateral – lying near or toward the sides of the body; as opposed to medial (Figure F.2).

i. Medial – lying near or toward the midline of the body; as opposed to lateral. (Figure F.2).

j. Midsagittal plane – the vertical plane which divides the body into right and left halves (Figure F.2).

k. Posterior – pertaining to the back of the body; as opposed to anterior (Figure F.2).

l. Proximal – the end of a bone or body segment nearest to the head; as opposed to distal (FigureE.2).

m. Superior – above, in relation to another structure; higher (Figure F.2).

n. Supra – prefix designating above or on.

3. GLOSSARY OF ANATOMICAL AND ANTHROPOMETRIC TERMS

a. Auxiliary landmark – an anthropometric or anatomical landmark used to determine the position of a given aerosol system-level testing (AST) sampling location.

b. Elbow Crease – the skin crease on the inside of the elbow joint when the elbow is flexed 90 degrees.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

c. Biceps - the large muscle on the anterior surface of the upper arm.

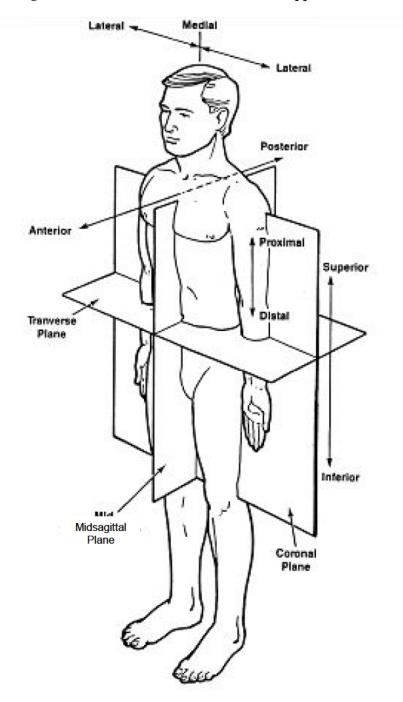


Figure F.2. Anatomical Positions.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

d. Cricoid cartilage – a small ring-like cartilage of the laryngeal skeleton. Its position is inferior to the thyroid cartilage. It can be located by palpation.

e. Femur – long bone of the upper thigh (thigh bone).

f. Laryngeal prominence (Adam's apple) – the anterior prominence on the thyroid cartilage.

g. Lateral malleolus – the lateral-distal prominence of the fibula. The "lateral ankle bone."

h. Medial malleolus – the medial-distal prominence of the tibia. The "inside ankle bone."

i. Omphalion – the navel or bellybutton.

j. Palpate – to locate or explore an area of the body by touch or feel. Often used in reference to identification of an underlying bony landmark.

k. Mandible – the jaw bone.

l. Radius – long bone of the forearm located laterally (thumb side) when in anatomical standing posture.

m. Scye – points at the junction of the upper arm and torso. Scye can typically be referred to as anterior or posterior.

n. Thyroid cartilage – the largest cartilage of the laryngeal skeleton. It is easily palpated at the front of the neck, and it is visible in many individuals.

o. Thelion – the nipple.

p. Tibia – primary long bone of the lower leg located medially (big toe side).

q. Triceps – the large muscles on the posterior surface of the upper arm.

r. Ulna – long bone of the forearm located medially (little finger side) when in anatomical standing position.

s. Volar – pertaining to the sole or the palm.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

4. LANDMARKS AND PRESAMPLING MARKERS (Tables F.1 and F.2)

Tuble 1.1. Euromatiks and Anatomic Elocations.			
Landmarks	Anatomic Location		
1	Infraorbitale		
2	Tragion		
3	Infrathyroid (bottom point of the Adam's apple)		
4	Neck base, lateral left and right		
5	Trapezius, left and right		
6	Medial scapular border at spine, left and right		
7	Substernale		
8	Biceps point, left and right		
9	Waist (omphalion)		
10	Medial femoral epicondyle, left and right		
11	Mid-thigh, left and right		

 Table F.1.
 Landmarks and Anatomic Locations.

 Table F.2.
 Pre-Sampling Markers and Anatomic Locations.

Pre-Sampling Markers	Anatomic Location
3a, 3b, 3c, 3d, 3e, 3f, and 3g	Neck circumference lines
4 and 5	Upper chest, right and left
6	Substernale
31	Mid-back
42 and 43	Side of torso, right and left
34	Back of upper arm, right
32 and 33	Lower back, left and right
7 and 8	Abdomen (lower chest), lateral right and left
18	Inside upper leg, left
16	Outside upper leg, right
38 and 39	Mid-leg, back left and right
22, 23, 24, and 25	Outside/inside lower leg, right and left

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

a. STEP 1:

(1) LANDMARK 1: Infraorbitale, the lowest point on the border of the bony eye socket (Figure F.3).

(2) PROCEDURE: Direct the participant to stand, looking straight ahead. Stand in front of the participant and palpate the bony eye socket under the eye to locate its lowest point. Draw a dot on the landmark.

(3) CAUTION: Participants may be apprehensive when you palpate near their eyes. Care must be taken in locating this landmark to reduce the participant's concern.

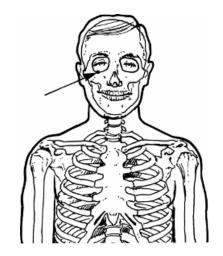


Figure F.3. LANDMARK 1, Infraorbitale.

b. STEP 2:

(1) LANDMARK 2: Tragion, left and right, it is the point where the flap of the ear meets with the head (Figure F.4).

(2) PROCEDURE: Palpate each tragus to find the upper point of attachment to the head. Place a dot on each landmark.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(3) CAUTION: Avoid distorting the soft tissue in this area while drawing the landmark.



Figure F.4. LANDMARK 2, Tragion, Left and Right.

c. STEP 3:

(1) LANDMARK 3: Infrathyroid (Adam's apple, Figure F.5).

(2) PROCEDURE: Direct the participant to stand with the head in the Frankfort plane. Stand in front of the participant and palpate the smooth surface of the thyroid cartilage moving downwards until you locate the bottom point of the thyroid cartilage (Adam's apple) in the mid-sagittal plane. Draw a short horizontal line through the landmark.

(3) CAUTION: Be sure the participant's head is in the Frankfort plane.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

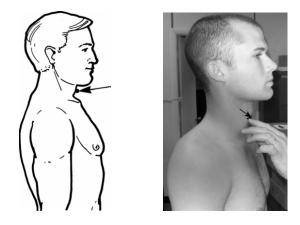


Figure F.5. LANDMARK 3, Infrathyroid (Adam's Apple).

d. STEP 4:

(1) LANDMARK 4: Neck, left and right lateral points at the base of the neck (Figure F.6).

(2) PROCEDURE: Direct the participant to stand looking straight ahead. Stand behind the participant. Place a tape around the base of the neck, laying it first in front, then on the sides, and finally, across the back, as if to measure neck circumference at the base of the neck. Note that this circumference would fall lower on the neck than the circumference at the infrathyroid landmark. The participant places a finger on the tape in front to help hold the tape in place. The right and left lateral landmarks are located at the bottom of the tape on both sides. Draw roughly 4-cm (1.5-in) horizontal lines through both landmarks following the bottom of the tape. It is up to the tester's discretion on whether or not to mark the anterior point.

e. STEP 5:

(1) LANDMARK 5: Trapezius point, left and right (Figure F.7). The point at which the anterior border of the trapezius muscle crosses the lateral neck landmark.

(2) PROCEDURE:

(a) Left trapezius point: Direct the participant to stand looking straight ahead. Ask the participant to place the left hand on the right shoulder to help outline the trapezius muscle on the left shoulder. Stand at the side of the participant. Moving from the shoulder to the neck, palpate the mass of the trapezius muscle to locate its anterior border. Draw a short line from the neck toward the shoulder at the point where the anterior border of the muscle crosses the lateral neck landmark.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(b) Right trapezius point: Repeat the procedures in Paragraph 4.e(2)(a) on the right trapezius point. In Figure F.7, "T" is the trapezius point which is located under the tip of the tester's index finger; "A" is the anterior point for determining the lateral neck landmark (unmarked).

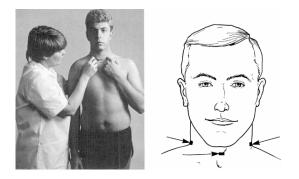


Figure F.6. LANDMARK 4, Neck, Lateral Points at the Base of the Neck, Left and Right.

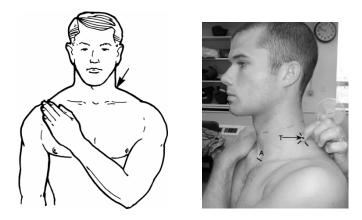


Figure F.7. LANDMARK 5, Trapezius Point, Left and Right.

f. STEP 6:

(1) PRE-SAMPLING MARKER 3: Neck circumference lines (Figure F.8). These are seven short lines along the neck circumference line that correspond to the sampling locations 3-a, 3-b, 3-c, 3-d, 3-e, 3-f, and 3-g (Table F.2). The sampling locations for the numbers are:

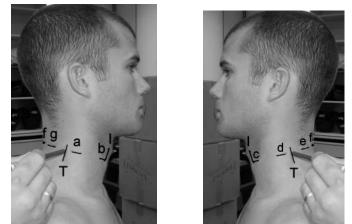
- (a) Neck front, left 3-a lateral and 3-b medial.
- (b) Neck font, right 3-c medial and 3-d lateral.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(c) Neck back – 3-e left, 3-f center, and 3-g right.

(2) PROCEDURE: Direct the participant to stand in the anthropometric standing position with the head in the Frankfort plane. Stand behind the participant and position a tape around the participant's neck as if measuring neck circumference at the level of the infrathyroid landmark. The position of the tape around the neck should be perpendicular to the long axis of the neck with the top edge of the tape in front, placed at the infrathyroid landmark. To help keep the tape from slipping, ask the participant to place a finger over the tape in front. While the tape is in place, mark all seven locations with 1.3- to 2.5-cm (0.5- to 1-in) lines along the upper edge of the tape. The lines for numbers 3-b and 3-c are located just lateral of the Adam's apple on their respective sides. Numbers 3-a and 3-d are located above the left and right trapezius landmark, respectively. Number 3-f crosses the spine in the back of the neck. Draw a short vertical line across 3-f at the spine. Numbers 3-e and 3-g are located approximately 1 in to the left and right, respectively, from the cross at 3-f. At this time, project the left and right trapezius landmark upward, along the long axis of the neck until they intersect the 3-a and 3-d lines, respectively. Also, if necessary, extend the lateral laryngeal prominence (Adam's apple) lines downward until they intersect the neck circumference lines.

(3) CAUTION: Be sure that the head is in the Frankfort plane (Figure F.1) when determining the locations.



NOTE: The neck-sampling lines are shown along the neck circumference at the infrathyroid. The left and right photographs show the pre-sampling marks for the neck-sampling locations on the right and left sides, respectively. The vertical line, designated as "T", is the upward projection of the trapezius landmark. As illustrated in Figure F.2, locations posterior to the "T" are designated as the back of the neck, and locations anterior to the "T" are designated as the front of the neck. Lines designated by lower case letters fall along the neck circumference taken at infrathyroid. The specific sampling locations are listed in Table F.3.

Figure F.8. PRE-SAMPLING MARKER 3, Neck Circumference Lines.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

g. STEP 7:

(1) LANDMARK 6: Medial scapular border at spine, left and right (Figure F.9). Medial border of the scapula at the straight line projection of the inferior ridge of the scapular spine.

(2) PROCEDURE, LEFT: Direct the participant to stand in anthropometric standing position. Locate by palpation the inferior ridge of the scapular spine of the left scapula, and project this point medially to the medial edge of the scapula. Near the medial edge of the scapula the inferior edge of the spine will curve downward. Do not follow this downward line, but project the general course of the medial 1/3 of the inferior edge of the spine to the medial border of the scapula. Mark this point with a cross (+) or a dot approximately 0.125 in (3 mm) in diameter. Draw a vertical 3.8- to 5-cm (1.5- to 2-in) line inferiorly from this point. Repeat the procedure for the upper back, right.

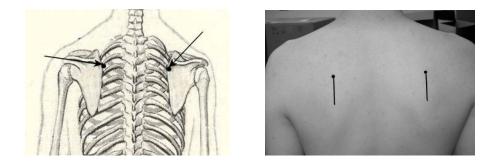


Figure F.9. LANDMARK 6, Medial Scapular Border at Spine, Left and Right.

h. STEP 8:

(1) PRE-SAMPLING MARKERS 4 and 5: Upper Chest, Right and Left (Figure F.10). Superior and medial to the nipple, on the chest.

(2) PROCEDURE: Direct the participant to stand. Draw a short line on each side of the chest approximately .5 in medial to the areola at the level of the lower edge of the nipple.

i. STEP 9:

(1) LANDMARK 7, PRE-SAMPLING MARKER 6: Substemale (Figure F.11). The lowest point of the sternum (xiphoid process).

(2) PROCEDURE, RIGHT: Direct the participant to stand erect. Stand in front of the participant and begin palpating the bottom of the rib cage on both sides simultaneously. Work toward the front along the bottom of the ribs as they curve upward until they meet the bottom of the sternum in the midsagittal plane. Draw a short horizontal line through the landmark.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.10. PRE-SAMPLING MARKERS 4 and 5, Upper Chest, Left and Right.





Figure F.11. LANDMARK 7, PRE-SAMPLING MARKER 6, Substernale.

(3) CAUTION: Subjects are often sensitive to touch in the waist area. Use firm pressure to find the deep bony structure. Avoid prolonged palpation of this area if possible.

j. STEP 10:

(1) PRE-SAMPLING MARKER 31: Mid-back below the horizontal plane passing through the substernale (Figure F.12).

(2) PROCEDURE: Direct the participant to stand in anthropometric standing position. Place a tape horizontally around the participant's torso with the upper edge of the tape at substernale landmark. Mark a short horizontal line along the top edge of the tape on the center of the back. Cross the horizontal line at the vertebral spine with a short vertical line. <u>NOTE</u>: Maintain tape position for next step.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.12. PRE-SAMPLING MARKER 31, Mid-back Below the Horizontal Plane Passing Through the Substernale.

k. STEP 11:

(1) PRE-SAMPLING MARKERS 42 and 43: Side of torso, right and left, centered at the level of substernale (Figure F.13).

(2) PROCEDURE: Direct the participant to stand in anthropometric standing position. Place a tape horizontally around the participant's torso with the upper edge of the tape at the substernale landmark. Mark a short horizontal line along the top edge of the tape on the center of the left side. Also, mark the right side of the torso while the tape is in this position. Cross the right and left lines with short vertical lines at their most lateral points along the substernale circumference.

1. STEP 12:

(1) LANDMARK 8: Biceps point, left and right (Figure F.14). The highest point of the right flexed biceps as viewed from the participant's right side.

(2) PROCEDURE, RIGHT: Direct the participant to stand with the right upper arm extended forward horizontally, the elbow flexed about 90 degrees, and the fist tightly clenched and held facing the head. Stand to the right of the participant and locate the highest point on the flexed biceps by inspection. Lower arm and draw a short line perpendicular to the long axis of the upper arm passing through the landmark. Repeat procedure for left biceps point.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.13. PRE-SAMPLING MARKERS 42 and 43, Side of Torso, Right and Left, Centered at the Level of Substernale.



Figure F.14. LANDMARK 8, Biceps Point, Left and Right.

m. STEP 13:

(1) PRE-SAMPLING MARKER 34: Back of upper arm, right (Figure F.15). A point centered on the back of the upper arm at the level that biceps circumference, flexed is measured.

(2) PROCEDURE: Direct the participant to stand in anthropometric standing posture. Locate biceps point landmark. Place tape around upper arm as if measuring biceps circumference, and draw a short line along the tape on the triceps muscles in back. Have participant straighten arm; then bisect this line with a short vertical line midway between the medial and lateral sides of the arm as visually estimated.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.15. PRE-SAMPLING MARKER 34, Back of Upper Arm, Right

n. STEP 14:

(1) LANDMARK 9: Waist (omphalion), anterior and posterior (center of the navel, Figure F.16).

(2) PROCEDURE: Direct the participant to stand in the anthropometric standing position. Stand in front of the participant and locate the landmark by inspection. Draw a 3.8-cm (1.5-in) horizontal line across omphalion. Place tape around waist with the upper edge of the tape at the omphalion landmark and draw two short lines along the top of the tape directly below the nipples. Also, mark this level with a 2.5-cm (1-in) line at the center of the back and cross it with a short vertical line at the spine. On each side of the back, draw a 3.8- to 5-cm (1.5- to 2-in) horizontal line along the top edge of the tape directly below the medial scapular border at spine point. **NOTE**: Maintain tape position for next step.

o. STEP 15:

(1) PRE-SAMPLING MARKERS 32 and 33: Lower back, left and right, inferior to the waist circumference line and centered on a vertical line extending downward from the medial scapular border at spine point (Figure F.17).

(2) PROCEDURE, LEFT: Direct the participant to stand in anthropometric standing position. Stand behind the participant. Place a tape around the participant's waist at the level of omphalion (navel). Make sure the position of the tape is on a horizontal plane. On each side of the back, draw a 3.8- to 5-cm (1.5- to-2 in) horizontal line along the top edge of the tape directly below the medial scapular border at spine point. Take a horizontal measurement from the medial scapular border at spine point to the midsagittal plane on the vertebrae (number 1 in Figure F.17). Measure the amount of this distance laterally to the left from the posterior waist at omphalion point, and draw a short vertical line (number 2 in Figure F.17) across the waist line at this point. Repeat procedure for right side. **NOTE**: Maintain tape position for next step.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

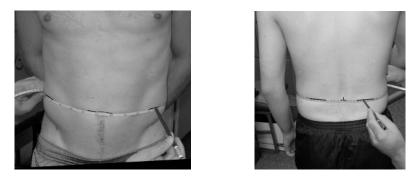


Figure F.16. LANDMARK 9, Waist (Omphalion), Anterior and Posterior (Center of the Navel).



Figure F.17. PRE-SAMPLING MARKERS 32 and 33, Lower Back, Left and Right.

p. STEP 16:

(1) PRE-SAMPLING MARKERS 7 and 8: Abdomen (lower chest), lateral right and lateral left (Figure F.18). On the right abdomen at the intersection of a horizontal line passing through omphalion and a perpendicular vertical line passing to the medial edge of the right areola.

(2) PROCEDURE, RIGHT: Direct the participant to stand in anthropometric standing position. Position the tape horizontally around the waist at the level of omphalion landmark. Draw a short horizontal line along the top edge of the tape near the lateral edge of the right abdomen and straight down from the right nipple. Take a horizontal measurement from the medial edge of the right areola to the midsagittal plane on the sternum (number 1 in Figure F.18). Measure the amount of this distance laterally to the right from omphalion, and draw a short vertical line (number 2 in Figure F.18) across the waist line at this point. Repeat procedure for left side.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

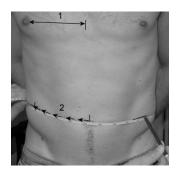


Figure F.18. PRE-SAMPLING MARKERS 7 and 8, Abdomen (Lower Chest), Lateral Left and Lateral Right.

q. STEP 17:

(1) LANDMARK 10: Medial femoral epicondyle, left and right (Figure F.19). Medial point of the femoral epicondyle (knee pivot point) when the knee is flexed about 90 degrees.

(2) PROCEDURE: Direct the participant to stand on the right foot with the left foot placed on a low bench so that the left thigh extends forward horizontally and the knee is flexed about 90 degrees. Stand in front of the participant, and with one hand, grasp the bony prominences of the bottom of the femur (femoral epicondyles) located to the left and right of the knee. Direct the participant to flex the knee, if necessary, to help locate the medial epicondyle. When you have located the medial point of the medial femoral epicondyle, use the thumb or index finger of the other hand to mark its place, and draw a point on the landmark.

(3) CAUTION: This landmark is difficult or impossible to locate accurately in heavily muscled subjects. Use your best judgment in these cases.

r. STEP 18:

(1) LANDMARK 11, PRE-SAMPLING MARKER 18: Mid-thigh, left medial and right medial (Figure F.20). Point on the medial thigh midway between the medial femoral epicondyle and the crotch.

(2) PROCEDURE, LEFT: Direct the participant to stand erect with the right foot on the floor, the left foot positioned on a low stool so that the left thigh extends forward horizontally, and the lower leg flexed downward approximately 90 degrees. Place an 18-in ruler along the length of the inner thigh with the "zero" end toward the crotch. At the knee, the ruler edge is placed at the medial femoral epicondyle landmark, and the ruler is visually aligned with the long axis of the thigh. Ask the participant to slide the ruler up the leg until firm but light contact is made with the crotch. Mark a point on the thigh midway between the crotch and medial femoral epicondyle with a cross (+). Repeat procedure for the right medial femoral epicondyle.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.19. LANDMARK 10, Medial Femoral Epicondyle, Left and Right.





Figure F.20. LANDMARK 11, PRE-SAMPLING MARKER 18, Mid-Thigh, Left Medial and Right Medial.

s. STEP 19:

(1) PRE-SAMPLING MARKER 16: Outside upper leg, right, on the lateral mid-thigh (Figure F.21).

(2) PROCEDURE, RIGHT: Direct the participant to stand erect with left foot on the floor, the right foot is positioned on a low stool so that the left thigh extends forward horizontally, and the lower leg is flexed downward approximately 90 degrees. Determine the medial midthigh location. While the leg is still positioned for determining the medial mid-thigh location, place a tape around the thigh at this location as if measuring mid-thigh circumference. Draw a short line along the tape that falls midway between the front and back of the leg on the lateral side of the thigh. Visually determine the anterior-posterior midpoint of the thigh along this line and mark this point on the line. **NOTE**: Maintain position for the next step.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

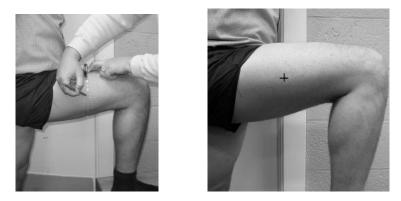


Figure F.21. PRE-SAMPLING MARKER 16, Outside Upper Leg, Right, on the Lateral Mid-thigh.

t. STEP 20:

(1) PRE-SAMPLING MARKERS 38 and 39: Mid-leg, back left and right, on the back of the left mid-thigh (Figure F.22).

(2) PROCEDURE, RIGHT: Direct the participant to stand erect with left foot on the floor, the right foot positioned on a low stool so that the right thigh extends forward horizontally, and the lower leg flexed downward approximately 90 degrees. The medial mid thigh location is determined. Place a tape around the thigh at the medial mid-thigh location as if measuring the mid-thigh circumference. Draw a short line along the tape on the back of the thigh. Direct the participant to straighten right leg by lowering left foot to floor. Visually determine the lateral-medial midpoint of the thigh along the circumference line and mark it with a short vertical line. Repeat procedure for left leg. **NOTE**: Maintain tape position for the next step.

u. STEP 21:

(1) PRE-SAMPLING MARKERS 22, 23, 24, and 25: Outside/inside lower leg, right and left (Figure F.23). Points on the lateral and medial sides of the calf at the level of the maximum circumference of the calf.

(2) PROCEDURE

(a) Right: Direct the participant to stand erect with the weight distributed equally on both feet. Wrap a tape around the calf, crossing it at the back, and slide it up and down to establish the maximum circumference of the calf. Be sure the tape is in a horizontal plane. Draw a short horizontal line along the bottom of the tape on the lateral and medial sides of the calf. Cross these two lines with short vertical lines at their most lateral and medial points, respectively.

(b) Repeat procedure for left leg.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(3) CAUTION: On some subjects the level of maximum circumference of the calf may extend vertically more than 1 cm (0.4 in). In such cases, the landmark is drawn at the level of the lowest maximum circumference of the calf.



Figure F.22. PRE-SAMPLING MARKERS 38 and 39, Mid-Leg, Back Left and Right, on the Back of the Left Mid-Thigh.



Figure F.23. PRE-SAMPLING MARKERS 22, 23, 24, and 25, Outside/Inside Lower Leg, Left and Right.

5. AST SAMPLING LOCATION DESCRIPTIONS

The sampling location descriptions and diagrams for AST are in Table F.3 and Figure F.24, respectively.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

	1 5	Research Triangle Institute
Sampling Location Numbers ^a	Description	(RTI) Sampling Order
58	Palm of hand, left	1
55	Back of hand, right	2
62	Inside wrist, right	3
56	Back of wrist, left	4
36	Rump	5
44-R	Ear lobe, right	6
44-L	Ear lobe, left	7
14	Pelvic area, right	8
15	Pelvic area, left	9
45	Scrotum	10
53	Bottom of foot, right	11
48	Top of foot, left	12
47	Outside of foot, left	13
50	Inside of foot, right	14
22	Outside lower leg, right	15
23	Inside lower leg, right	16
24	Inside lower leg, left	17
25	Outside lower leg, left	18
20	Mid-leg, front right	19
21	Mid-leg, front left	20
16	Outside upper leg, right	21
18	Inside upper leg, left	22
11	Upper arm, front right	23
13	Lower arm, front left	24
34	Upper arm, left	25
35	Lower arm, right	26

Table F.3. Sampling Location Descriptions for System-Level Aerosol Testing.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

Sampling Location		Research Triangle Institute (RTI)
Numbers ^a	Description	Sampling Order
29	Upper back, left	27
30	Upper back, right	28
31	Mid-back	29
32	Lower back, left	30
33	Lower back, right	31
42	Side of torso, right	32
43	Side of torso, left	33
4	Upper chest, right	34
5	Upper chest, left	35
6	Mid-chest,	36
7	Abdomen (lower chest), lateral right	37
8	Abdomen (lower chest), lateral left	38
3-а	Neck, right lateral front	39
3-b	Neck, right medial front	40
3-с	Neck, left medial front	41
3-d	Neck, left lateral front	42
38	Mid-leg, back left	43
39	Mid-leg, back, right	44
3-е	Neck, left lateral back	45
3-f	Neck, center back	46
3-g	Neck, right lateral back	47
1	Head, top	48
2-R	Head, right side	49
2-L	Head, left side	50

Table F.3. Sampling Location Descriptions for System-Level Aerosol Testing (Cont'd).

^aSee Figure F.24.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

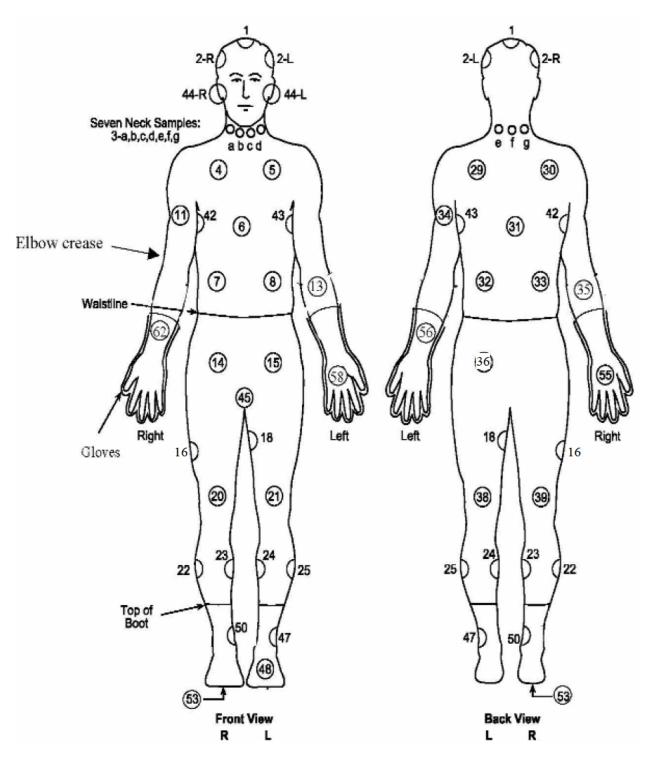


Figure F.24. Aerosol System-Level Testing (AST) Sampling Location Diagram.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

a. Palm of Hand, Left (Sampling Location 58, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter on the palm of the hand (Figure F.25).

(2) POLYVINYL CHLORIDE (PVC) TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand with the lower arm extending forward and the palm of the hand facing upward. Cup the hand slightly, and place the tube in the deepest point of this cup. Getting a tight seal is usually not a problem. If the seal is questionable, it can be improved by applying greater pressure to the tube rather than by shifting its location.

b. Back of Hand, Right (Sampling Location 55, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter on the padded area on the back of the hand between the metacarpal bones (hand bones) of the thumb and the index fingers (Figure F.26).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand with the lower arm extending forward, the hand resting palm down on a flat surface, and the thumb extending out to the side. Place the tube on the fleshy area between the metacarpal bones of the thumb (first metacarpal) and index finger (second metacarpal). Obtaining a tight seal at this location may be difficult because of the many underlying tendons and bones. The tube may be shifted, if necessary, to get a tight seal; however, the amount that the tube can be shifted in this area is minimal. Having the participant apply slight pressure with the hand to the flat surface may improve the seal by providing a firmer base on which to seat the tube. It may also be necessary for the tester to apply additional pressure on the tube in order to get a seal. Care should be exercised to minimize the discomfort to the participant's hand when pressure is applied to the sampling tube.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.25. Palm of Hand, Left (58).



Figure F.26. Back of Hand, Right (55).

c. Inside Wrist, Right (Sampling Location 62, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter on the front of the wrist (Figure F.27).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand with the forearm extending forward with the hand straight and the palm facing upward. Position the tube on the distal volar surface of the lower arm at a level just above (proximal to) the wrist crease and tendons in the wrist area. Visually center the tube between the medial and lateral sides of the wrist. The tube may be shifted, if necessary, to get a tight seal. Ensure that the area being sampled was covered by the gauntlet of the glove during the AST.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.27. Inside Wrist, Right (62).

d. Back of Wrist, Left (Sampling Location 56, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter, on the back of the wrist. (Figure F.28).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand with the forearm extended forward and the hand straight with the palm facing down. Position the tube against the lateralproximal edge of the ulnar head (the boney prominence at the distal end of the ulna). If a tight seal is not possible at this location, slide the tube along the lateral side of the ulnar head toward the hand. Ensure that the area being sampled was covered by the gauntlet of the glove during the AST. The arrow in the figure points to the ulnar head.

e. Rump, Left Buttock (Sampling Location 36, Figure F.24)].

(1) DESCRIPTION: Circle, approximately 6.1 cm (2.4 in) in diameter on the left buttocks below the waist band of the shorts (Figure F.29).

(2) PVC TUBE COUPLER SIZE: 5.08 cm (2 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand and bend over the table with the palms of the hands placed on the table. Without touching the chest and abdomen, the hands and arms support the torso so that it does not come in contact with the table. Place the superior edge of the tube just below the waist band and center the tube side to side on the left buttock. Ensure that the buttock sampling location is inferior to the level of the waist band. The tube should also be positioned entirely on the left buttock. If the tube location is too high when it is positioned just below the lower edge of the waistband, then the tube should be moved inferiorly onto the buttock. It will be necessary for the participant to lower the waist band slightly over the buttock point in order to accommodate the PVC tube. <u>NOTE</u>: Figure F.29 shows the approximate placement of the PVC tube. However, the actual sampling is performed on the participant's bare skin with the waist band of the shorts lowered slightly.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.





Figure F.28. Back of Wrist, Left (56).



Figure F.29. Left Rump (Left Buttock, 36).

f. Ear Lobes, Right and Left, Sampled by Participant (Sampling Locations 44-L and 44-R, Figure F.24).

(1) DESCRIPTION: All sides of the right and left ear lobes (Figure F.30).

(2) SAMPLING SWABS: Three water-moistened pads for each ear.

(3) SAMPLING PROCEDURE, RIGHT: Direct the participant to sit and take the ear lobe sample. Direct the participant to swab entire right ear lobe thoroughly with water-moistened pad and then place the pad in a vial. Direct the participant to repeat the process two more times, and then place each pad in a separate vial. Direct the participant to repeat the procedure for the left ear lobe.

(4) CAUTION: Care should be exercised to avoid swabbing skin beyond the ear lobe.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.30. Right and Left Ear Lobes Sampled, by Participant (44-L and 44-R).

g. Pelvic Area (Iliac Area), Right and Left, Sampled by Participant (Sampling Locations 14 and 15, Figure F.24).

(1) DESCRIPTION, RIGHT: Circle, approximately 6.1 cm (2.4 in) in diameter, in the right iliac area (Figure F. 31).

(2) PVC TUBE COUPLER SIZE: 5.08 cm (2 in).

(3) PVC TUBE PLACEMENT, RIGHT: Direct the participant to sit, remove shorts, and take sample according to the following instruction for taking private samples: <u>NOTE</u>: While obtaining these samples, be very careful not to touch or rub other areas of your skin that have not yet been sampled.

(a) Put on disposable gloves.

(b) While doing this, make a mental note that the samples must come from skin that was covered by the briefs.

(c) Using scissors, cut off brief by making one cut from the waist band down in line with front of left leg, and a second cut from the waist band down in line with front of right leg.

(d) Place the brief in a plastic bag.

(e) While the participant is partially sitting on the chair, extend the left leg. Press a large diameter sample tube on sample location 14 (Table F.3 and Figure F.24), add the 20 mL from the corresponding vial, swish around for 20 seconds, and then use clean pipette to suction off back to vial.

(f) Repeat the procedure for sample location 15.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.31. Right and Left Pelvic Areas, Iliac Area Sampled by Participant (14 and 15).

(4) Sampling generally occurs on the flesh overlying the pubic bone near the groin or the crease separating the leg and the abdomen. Extend the right leg. Place the lateral edge of the tube at the crease between the leg and the torso. The superior edge of the tube should fall below the level at which the waist band of the briefs was worn. Ensure that the area being sampled was completely covered by the briefs during the AST. Repeat the procedure for the right pelvic area. **<u>NOTE</u>**: Figure F.31 shows the approximate placement of the PVC tube. Recall, however, that the actual sampling is performed on the participant's bare skin with the shorts removed.

h. Scrotum, Sampled by Participant (Sampling Location 45, Figure F.24)].

- (1) DESCRIPTION: The complete scrotal sack.
- (2) SAMPLING PADS: Three water-moistened pads.

(3) SAMPLING PROCEDURE: Direct the participant to sit, cut away briefs, wipe scrotum with water-moistened pad, and place the pad in a vial. Direct the participant to repeat the process with two additional pads, placing each pad in a separate vial. <u>NOTE</u>: Take the sample using three water-moistened swabs to wipe the scrotum. These are very important samples that must be done carefully.

(a) Put on a new pair of clean disposable gloves.

(b) Take one of the unused swabs and wipe the scrotum thoroughly (for example, about 3 times). **<u>NOTE</u>**: Try not to wipe surrounding areas; just the scrotal sack.

(c) Put the swab in the appropriate vial.

(d) Repeat with the next two swabs.

(4) CAUTION: Care should be exercised to avoid swabbing skin surrounding the scrotum.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

i. Bottom of Foot, Right (Sampling Location 53, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter on the center of the arch on the bottom of the right foot (Figure F.32).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand on left foot, use a table or chair for balance, and flex the knee so that the top of the foot is resting on a low stool behind the participant with the bottom of the foot facing upward. Place the tube in the center of the arch.



Figure F.32. Bottom of Foot, Right (53).

j. Top of Foot, Left (Sampling Location 48, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter on the top of left foot lateral to the instep (Figure F.33).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT: Place tube on the top of the foot just lateral to the high point of the instep. Shift tube slightly, as needed, to obtain a tight seal.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.33. Top of Foot, Left (48).

k. Outside of Foot, Left (Lateral Ankle, Sampling Location 47, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter on the outside of the ankle superior to the lateral malleolus (Figure F.34).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand on right foot, with the left foot resting on a low stool. Position the tube on the lateral ankle superior to the lateral malleolus and centered on the leg from front to back. The distance for tube placement above the lateral malleolus should be just enough to get a good seal; this may be as much as a couple of inches or more for some individuals. Ensure that this sampling location is located under the top of the boot. Without rolling the foot sideways, tilt the lower leg inward to keep the sampling solution from running over the top of the tube.

1. Inside of Foot, Right, Medial Ankle (Sampling Location 50, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter, on the medial right ankle superior to the medial malleolus of the tibia (Figure F.35).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand on left foot, with the right foot resting on a low stool. Position the tube on the medial ankle superior to the medial malleolus and centered on the leg from front to back. The distance for tube placement above the medial malleolus should be just enough to get a good seal; this may be as much as a couple of inches or more for some individuals. Ensure that this sampling location is located under the top of the boot. Without rolling the foot sideways, tilt the lower leg outward to keep the sampling solution from running over the top of the tube.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.34. Outside of Foot, Left (Left Lateral Ankle, 47).



Figure F.35. Inside of Foot, Right (Right Medial Ankle, 50).

m. Outside Lower Leg, Right (Sampling Location 22, Figure F.24).

(1) DESCRIPTION: Circle, approximately 6.1 cm (2.4 in) in diameter at the most lateral point on the lower leg at the level of maximum calf circumference (Figure F.36).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

(3) PVC TUBE PLACEMENT, RIGHT: Direct the participant to stand on left foot, with the right foot resting on a stool so that right upper leg is extended forward horizontally, and the lower leg flexed approximately 90 degrees. Center the tube over the lateral calf landmark. Without rolling the foot sideways, tilt the lower leg inward to keep the sampling solution from running over the top of the tube. Repeat procedure for left leg.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.36. Outside Lower Leg, Right (22).

n. Inside Lower Leg, Right and Left (Sampling Locations 23 and 24, Figure F.24).

(1) DESCRIPTION: Circle, approximately 6.1 cm (2.4 in) in diameter at the most medial point on the lower leg at the level of maximum calf circumference (Figure F.37).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

(3) PVC TUBE PLACEMENT, RIGHT: Direct the participant to stand on left foot, with the right foot resting on a stool so that right upper leg is extended forward horizontally and the lower leg flexed approximately 90 degrees. Center the tube over the medial calf landmark. It will be necessary to tilt the lower leg outward to keep the sampling solution from running over the top of the tube. Repeat procedure for left leg.

o. Outside Lower Leg, Left (Sampling Location 25, Figure F.24).

(1) DESCRIPTION: Circle, approximately 6.1 cm (2.4 in) in diameter at the most lateral point on the lower leg at the level of maximum calf circumference (Figure F.38).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

(3) PVC TUBE PLACEMENT, LEFT: Direct the participant to stand on right foot with the left foot resting on a stool so that left upper leg is extended forward horizontally and the lower leg is flexed approximately 90 degrees. Center the tube over the lateral calf landmark. Without rolling the foot sideways, tilt the lower leg inward to keep the sampling solution from running over the top of the tube.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.37. Inside Lower Leg, Right and Left (23 and 24).



Figure F.38. Outside Lower Leg, Left (25).

p. Mid-Leg, Front Right and Left (Sampling Locations 20 and 21, Figure F.24).

(1) DESCRIPTION: Circle, approximately 6.1 cm (2.4 in) in diameter on the lower front of the thigh proximal to the patella (knee cap, Figure F.39).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

(3) PVC TUBE PLACEMENT, RIGHT: Direct the participant to stand on left foot, with the right foot resting on a stool so that the right upper leg is extended forward horizontally, and the lower leg is flexed approximately 90 degrees. Center the tube from side to side on the lower thigh as close to the patella as possible where a tight seal can be obtained. Shift the tube as necessary to obtain a good seal. The complex muscle and tendon configuration may require several tube placement adjustments on some subjects to locate a satisfactory sampling location. Repeat procedure for left leg.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.39. Mid-Leg, Front Right and Left (20 and 21).

q. Outside (Lateral) Upper Leg, Right (Sampling Location 16, Figure F.24).

(1) DESCRIPTION: Circle, approximately 6.1 cm (2.4 in) in diameter on the lateral midthigh (Figure F.40).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand on left foot, with the right foot resting on a stool so that right upper leg is extended forward horizontally and the lower leg is flexed approximately 90 degrees. Center the tube over the crossed landmark on the lateral thigh. It will be necessary to tilt the upper leg inward to keep the sampling solution from running over the top of the tube.

r. Inside Upper Leg, Left (Inner Thigh, Sampling Location 18, Figure F.24).

(1) DESCRIPTION: Circle, approximately 6.1 cm (2.4 in) in diameter on the medial thigh midway between the medial femoral epicondyle and the crotch (Figure F.41).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand on the right foot with the left foot resting on a stool so that left upper leg is extended forward horizontally and the lower leg is flexed approximately 90 degrees. Center the PVC tube over the crossed landmark on the medial mid-thigh. It will be necessary to tilt the upper leg outward slightly to keep the sampling solution from running over the top of the tube.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.40. Outside (Lateral) Upper Leg, Right (16).



Figure F.41. Inside Upper Leg, Left (Inner Thigh, 18).

s. Upper Arm, Front Right (Sampling Location 11, Figure F.24).

(1) DESCRIPTION: Circle, approximately 4.8 cm (1.9 in) in diameter on the lateral right biceps at the level of biceps point (Figure F.42).

(2) PVC TUBE COUPLER SIZE: 1 3.8 cm (0.5 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand with the right upper arm extended forward. Center the tube over the biceps point landmark. Take the sample at this position if there is a good seal. The tube may be shifted laterally keeping the tube centered vertically on the marked points. Keep the tube on the biceps.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.42. Upper Arm, Front Right (11).

t. Lower Arm, Front Left (Sampling Location 13, Figure F.24).

(1) DESCRIPTION: Circle, approximately 4.8 cm (1.9 in) in diameter on the volar surface of the lower arm just distal to the elbow crease (Figure F.43).

(2) PVC TUBE COUPLER SIZE: 3.8 cm (1.5 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand with the left upper arm hanging slightly to the front of the torso, and the lower arm extending forward horizontally with the palm of hand facing upward. Place the tube on the volar surface of the lower arm so that the PVC tube is centered between the medial and lateral sides of the arm. The proximal edge of the tube is approximately 1 cm distal to the elbow crease. The tube may be shifted distally or to either side slightly, if necessary, to get a tight seal.

u. Back of Upper Arm, Left (Sampling Location 34, Figure F.24).

(1) DESCRIPTION: Circle, approximately 4.8 cm (1.9 in) in diameter at a point centered on the back of the upper arm at the level that biceps circumference, flexed is measured (Figure F.44).

(2) PVC TUBE SIZE: 3.8 cm (1.5 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand and bend forward resting the hand on a table such that the upper arm is held in a somewhat horizontal position to ensure that the sampling liquid will not spill over the top of the tube. Center the tube over the marked landmark. Direct the participant to keep the triceps relaxed so that a tighter seal can be maintained.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.



Figure F.43. Lower Arm, Front Left (13).



Figure F.44. Back of Upper Arm, Left (34).

v. Lower Arm, Lateral Right (Sampling Location 35, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.8 cm (1.5 in) in diameter on the lateral aspect of the brachioradialis muscle at the level of the maximum lower arm circumference (Figure F.45).

(2) PVC TUBE SIZE: 3.8 cm (1.5 in).

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(3) PVC TUBE PLACEMENT: Direct the participant to stand with the upper arm extended with the elbow flexed approximately 45 degrees, and the palm of the hand facing downward. Position the tube on the brachioradialis muscle at the level of the maximum forearm circumference. Proximal-distal placement of the tube on the lower arm is determined by positioning the proximal edge of the tube level with the elbow crease. Direct the participant to keep the brachioradialis muscle relaxed so that a tighter seal can be maintained.



Figure F.45. Lower Arm, Lateral Right (35).

w. Upper Back, Left and Right (Sampling Locations 29 and 30, Figure F.24).

(1) DESCRIPTION: Circle, approximately 6.1 cm (2.4 in) in diameter centered vertically on the medial edge of the scapula and below the level of the medial scapular spine (Figure F.46).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

(3) PVC TUBE PLACEMENT: Direct the participant to stand and bend over a table with the torso supported by the arms, the elbows on the table straight out from the shoulders (approximately 90 degrees from the torso), and the hands under the center of the chest. Place the left hand flat on the table under the center of the chest and the right hand flat on top of the left hand. Position the center of the tube over the line projecting down from the spine of the scapula, and place the superior edge of the tube at the inferior-medial point of the scapula spine. The tube may be shifted laterally or inferiorly a small distance, if necessary, to obtain a good seal. Repeat procedure for upper back, right.

x. Mid-Back (Sampling Location 31, Figure F.24).

(1) SAMPLING AREA DESCRIPTION: Circle, approximately 6.1 cm (2.4 in) in diameter on the mid-back below the horizontal plane passing through substernale (Figure F.47).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(3) PVC TUBE PLACEMENT: Direct the participant to stand, bend over a table, and support the torso weight on the table by folding the arms under the chest so that the torso does not come in contact with the table. Center the tube from side to side over the spinal column with the most superior edge of the tube at the substernale circumference line. It may be difficult to get a tight seal because of the groove of the back along the vertebral column. In this case, first direct the participant to arch the back by lowering the head, rolling the shoulders forward and elevating the middle of the back (thoracic vertebrae). If a good seal still cannot be obtained, then shift the tube inferiorly along the spine or medially (whichever direction requires the least movement) while keeping the back arched.



Figure F.46. Upper Back, Left and Right (29 and 30).



Figure F.47. Mid-Back (31).

y. Lower Back, Left and Right (Sampling Locations 32 and 33, Figure F.24).

(1) DESCRIPTION: Circle, approximately 6.1 cm (2.4 in) in diameter on the lower back, inferior to the waist circumference line and centered on a vertical line extending downward from the medial scapular border at spine point (Figure F.48).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(3) PVC TUBE PLACEMENT, LEFT: Direct the participant to stand and bend over a table with the palms of the hands facing down on the table so that the torso does not come in contact with the table. Place the superior edge of the tube at the waist circumference line and center the tube over the vertical line that is the downward extension of the medial scapular border at spine point. The tube may be shifted slightly, if necessary, to obtain a tight seal between the tube and the back. Repeat procedures for right side.

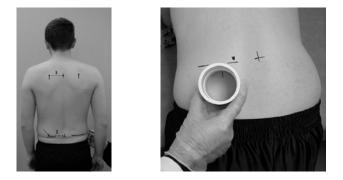


Figure F.48. Lower Back, Left and Right (32 and 33).

z. Side of Torso, Right and Left (Sampling Locations 42 and 43, Figure F.24).

(1) DESCRIPTION, RIGHT: Circle, approximately 6.1 cm (2.4 in) in diameter on right side of torso centered on the circumference line at the level of substernale (Figure F.49).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

(3) PVC TUBE PLACEMENT, RIGHT: Direct the participant to recline on left side with the upper torso elevated, resting on the left elbow, and the right arm folded across the chest. To protect the left side of torso sampling area from abrasion, it is important to keep the left side of the torso from contacting the table. Center the tube over the cross of the horizontal and vertical lines. Repeat procedure for left side.

aa. Upper Chest, Right and Left (Sampling Locations 4 and 5, Figure F.24).

(1) DESCRIPTION: Circle, approximately 6.1 cm (2.4 in) in diameter, superior and medial to the nipple, on the chest (Figure F.50).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

(3) PVC TUBE PLACEMENT, RIGHT: Direct the participant to lie face up on a table with the head resting on a 5.1-cm (2-in) thick head support. Position the PVC tube on the right chest medial to the areola with the inferior edge of the tube on a line drawn at the level of the lower edge of the nipple. Leave approximately 3 mm (0.5 in) of space separating the tube from the areola. The tube may be shifted up or down, if necessary, to get a tight seal. Repeat the procedure for the upper chest, left.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(4) CAUTION: The back of the neck should not be allowed to touch the head support or table.



Figure F.49. Side of Torso, Right and Left (42 and 43).

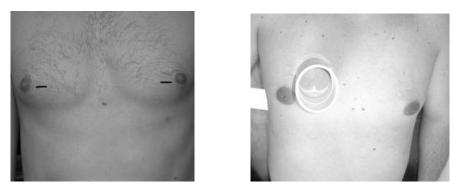


Figure F.50. Upper Chest, Right and Left (4 and 5).

bb. Mid-Chest (Sampling Location 6, Figure F.24).

(1) DESCRIPTION: Circle, approximately 6.1 cm (2.4 in) in diameter on the midsagittal plane of the chest inferior to the xiphoid process of the sternum (Figure F.51).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

(3) PVC TUBE PLACEMENT: Direct the participant to lie face up on a table with the head resting on a 5.1-cm (2-in) thick head support. Position the PVC tube on the midline of the torso with the upper edge of the tube just inferior to the substernale landmark. The tube may be shifted inferiorly, if necessary, to get a tight seal.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(4) CAUTION: The back of the neck should not be allowed to touch the head support or table.



Figure F.51. Mid-Chest (6).

cc. Abdomen (Lower Chest), Lateral Right and Lateral Left (Sampling Locations 7 and 8, Figure F.24).

(1) DESCRIPTION, RIGHT: Circle, approximately 6.1 cm (2.4 in) in diameter on the right abdomen at the intersection of a horizontal line passing through omphalion and a perpendicular vertical line passing to the medial edge of the right areola (Figure F.52).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

(3) PVC TUBE PLACEMENT, RIGHT: Direct the participant to lie face up with the back of the head resting on a 5.1-cm (2-in) thick head support. Center the PVC tube over the cross of the horizontal waist line and the lateral vertical line. The tube may be shifted slightly, if necessary, to get a tight seal. When a shift is required, the tube may be moved in a superior, inferior, or medial direction; whichever requires the least amount of movement. Everything being equal, move the tube medially.

(4) CAUTION: The back of the neck should not be allowed to touch the head support or table.

dd. Neck, Front, Right Lateral (Sampling Location 3-a, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter, where a vertical line drawn from the anterior border of the trapezius muscle intersects with the neck circumference arc (Figure F.53).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(3) PVC TUBE PLACEMENT, RIGHT LATERAL: Direct the participant to lie on back with head turned to the left. Center the PVC tube on the horizontal neck line (a) with the lateral edge of the tube at trapezius line (T). Move the tube medially along the neck line, if necessary, to get a tight seal. The tube must be placed upright enough to keep the sampling liquid from running over the top. If the angle of the tube must be adjusted, direct the participant roll slightly toward the front.



Figure F.52. Abdomen (Lower Chest), Lateral Right and Lateral Left (7 and 8).



Figure F.53. Front, Right Lateral Neck (3-a).

ee. Neck, Front, Right Medial (Sampling Location 3-b, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter on the neck circumference arc lateral to the thyroid cartilage (Adam's apple, Figure F.54).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT, RIGHT MEDIAL: Direct the participant to lie face up with head turned to the left. Center the PVC tube on the horizontal neck line (b) with the medial edge of the tube at the right laryngeal prominence line (I). Move the tube laterally along the neck line, if necessary, to get a tight seal. If the angle of the tube angle must be adjusted to keep the sampling liquid from running over, direct the participant to roll slightly toward the back

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

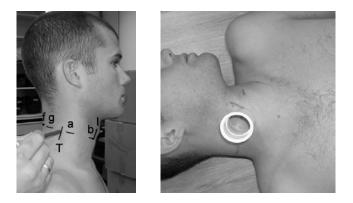


Figure F.54. Front, Right Medial Neck (3-b).

ff. Neck, Front, Left Medial (Sampling Location 3-c, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter on the neck circumference arc lateral to the thyroid cartilage (Adam's apple, Figure F.55).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT, LEFT MEDIAL: Direct the participant to lie face up with head turned to the left. Center the PVC tube on the horizontal neck line (c) with the medial edge of the tube at the right laryngeal prominence line (I). Move the tube laterally along the neck line, if necessary, to get a tight seal. If the angle of the tube angle must be adjusted to keep the sampling liquid from running over, direct the participant roll slightly toward the back.

gg. Neck, Front, Left Lateral (Sampling Location 3-d, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter, where a vertical line drawn from the anterior border of the trapezius muscle intersects with the neck circumference arc (Figure F.56).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT, LEFT LATERAL: Direct the participant to lie face up with head turned to the left. Center the PVC tube on the horizontal neck line (d) with the lateral edge of the tube at Trapezius line (T). Move the tube medially along the neck line, if necessary, to get a tight seal. The tube must be placed upright enough to keep the sampling liquid from running over the top. If the angle of the tube must be adjusted, direct the participant roll slightly toward the front.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

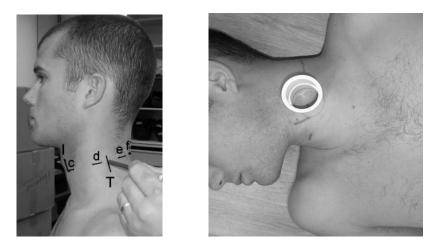


Figure F.55. Front, Left Medial Neck (3-c).



Figure F.56. Front, Left Lateral Neck (3-d).

hh. Mid-Leg, Left Back and Right Back (Sampling Locations 38 and 39, Figure F.24).

(1) DESCRIPTION: Circle, approximately 6.1 cm (2.4 in) in diameter on the back of the left mid-thigh (Figure F.57).

(2) PVC TUBE COUPLER SIZE: 5.1 cm (2 in).

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(3) PVC TUBE PLACEMENT, LEFT: Direct the participant to lie on table face down. Center the tube over the crossed landmark on the posterior left thigh. Repeat procedure for right leg.



Figure F.57. Mid-Leg, Left Back and Right Back (38 and 39).

ii. Neck, Back, Left Lateral (Sampling Location 3-e, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter on the neck circumference arc lateral to the neck (Figure F.58).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT, LEFT: Direct the participant to lie face down on a table, looking straight ahead. Center the PVC tube vertically on the drawn neck circumference line. Place the medial edge of the tube at the vertical line located 2.5 cm (1 in) lateral to the 3-f mark (Figure F.59). Figure F.58 shows the relative positions of the three sampling locations at the back of the neck. <u>NOTE</u>: These areas are sampled one at a time, not simultaneously as might be inferred from Figure F.58.

jj. Neck, Back, Center (Sampling Location 3-f, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter at the point where the midsagittal plane of the back of the neck intersects with the neck circumference arc (Figure F.59).

(2) CAUTION: Be sure that the head is in the Frankfort plane when determining the location.

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(3) PVC TUBE SIZE: 2.5 cm (1 in).

(4) PVC TUBE PLACEMENT: Direct the participant to lie face down on a table, looking straight ahead. Center the PVC tube on the drawn landmark. The tube may be shifted up or down, if necessary, to get a tight seal.

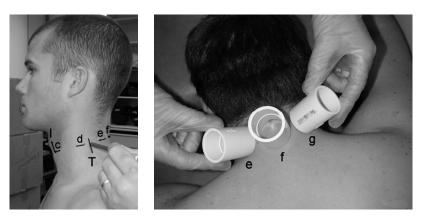


Figure F.58. Back, Left Lateral Neck (3-e).



Figure F.59. Neck, Back, Center (3-f).

kk. Neck, Back, Right Lateral (Sampling Location 3-g, Figure F.24).

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter on the neck circumference arc lateral to the neck (Figure F.60).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT: Direct the participant to lie face down on a table looking straight ahead. Center the PVC tube vertically on the drawn neck circumference line. Place the medial edge of the tube at the vertical line located 2.5 cm (1 in) lateral to the 3-f mark (Figure F.59). Figure F.58 shows the relative positions of the three sampling locations at the back of the neck. Repeat procedure for right side. <u>NOTE</u>: These areas are sampled one at a time, not simultaneously as might be inferred from Figure F.58.



Figure F.60. Neck, Back, Right Lateral (3-g).

II. Head, Top (Sampling Location 1, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter on the midsagittal plane at the posteriosuperior area of the head (Figure F.61).

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT: Direct the participant to sit with the torso and head tilted slightly forward. Stand to one side of the participant and determine the point closest to the top of the head along the midsagittal plane where the head is flat enough to allow a tight seal. It may be necessary to place the PVC tube to the side of the midsagittal plane to get a better seal.

mm. Head, Right Side and Left Side (Sampling Locations 2-R and 2-L, Figure F.24).

(1) DESCRIPTION: Circle, approximately 3.3 cm (1.3 in) in diameter at the most lateral point on the side of the head above the level of the ears when the head is in the Frankfort position (Figure F.62).

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

(2) PVC TUBE COUPLER SIZE: 2.5 cm (1 in).

(3) PVC TUBE PLACEMENT, RIGHT: Direct the participant to sit with the head in the Frankfort plane. Stand to the right of the participant and determine by visual inspection or palpation the lateral most point on the right side of the head above the ears. Position the PVC tube over the sampling location and hold it in position as the participant slowly leans and tilts the head to the left. Adjust the tube, if necessary, so that a tight seal can be maintained. Repeat procedure for head, left side.



Figure F.61. Head, Top (1).



Figure F.62. Head, Right Side and Left Side (2-R and 2-L).

APPENDIX F. AEROSOL MAN-IN-SIMULANT TEST (MIST) SKIN-RINSE SAMPLE LOCATIONS.

6. REFERENCE

A. U.S. Army Natick Research Development and Engineering Center, Natick, Massachusetts, 1988 Anthropometric Survey of U.S. Army Personnel (Methods and Summary Statistics), 1989.

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1. OVERVIEW

a. The BRHA is a model that measures the protective performance of protective ensembles against percutaneous threats for configurations tested in the vapor and aerosol man-in-simulant testing (MIST).

b. The input to the model depends on the test type.

(1) For vapor tests, the input is the amount of methyl salicylate (MeS) collected on the standard passive adsorbent devices (PADs, Figure G.1 and Table G.1).

(2) For aerosol, the input is the deposition velocity (V_d) calculated from the aerosol deposition on the skin (Figure G.2 and Table G.2).

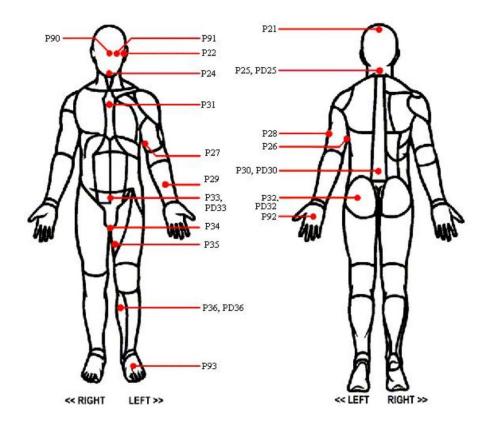


Figure G.1. Standard Passive Absorbent Device (PAD) Placement for Vapor Man-in-Simulant Testing (MIST).

APPENDIX G. BODY REGION HAZARD ANALYSIS (BRHA)

(3) Missing values are estimated as the geometric mean of all other PADs or deposition velocities from the same location for the individual configuration. This usually only applies to vapor MIST, as PADs sometimes fall off during testing. As the aerosol MIST data are from skin rinse samples, it is very rare to have a missing value.

c. There are two standard outputs for vapor and aerosol MIST. Although the outputs theoretically represent the highest agent dosage to which the configuration could be exposed before 50 percent of the population experienced the onset of nausea and vomiting (for systemic agents) or burns and blisters (local agents), the correlation between the output and true protection is not known. Therefore, the outputs are used to relatively rank and compare configuration performance. Because the outputs theoretically represent the challenge dosage the ensemble protects against, higher values are better. The outputs are the systemic agent minimum exposure dosage (MED_{SYS}) and local minimum exposure dosage (MED_{HD}).

(1) The MED_{SYS} value uses the body region sensitivities and the body regions area to calculate the ability of the configuration to protect against systemic agents. This value can be thought of as a type of weighted average of performance over the entire body.

(2) The MED_{HD} value compares all of the body regions and chooses the region that is most susceptible to the outside challenge based on the protection in the region and the sensitivity of the region to agent. This means that the most susceptible region may not necessarily be the region with the most breakthrough. It could be a region that had less breakthrough but is more sensitive to agent. Typically, the most susceptible regions are in the head/mask/suit interface or the crotch/groin region.

Table G.1.	Passive Absorbent Device (PAD) Placement for		
Vapor Man-in-Simulant Testing (MIST).			

Position Number ^a	Description
P21	Scalp
P22	Left ear
P24	Chin
P25, PD25 ^b	Nape
P26	Armpit
P27	Inner upper arm
P28	Outer upper arm
P29	Forearm, volar
P30, PD30 ^b	Mid-back
P31	Abdomen
P32, PD32 ^b	Buttocks
P33, PD33 ^b	Groin
P34	Crotch/scrotum
P35	Inner thigh
P36, PD36 ^b	Inner shin
P90	Nose cup
P91 ^c	Mask
P92	Glove (hand)
P93	Boot (foot)

^aSee Figure G.1. ^bIndicates duplicate passive sampling device (PSD) at these locations.

°PSD placed in mask, not on the test participant's body.

APPENDIX G. BODY REGION HAZARD ANALYSIS (BRHA)

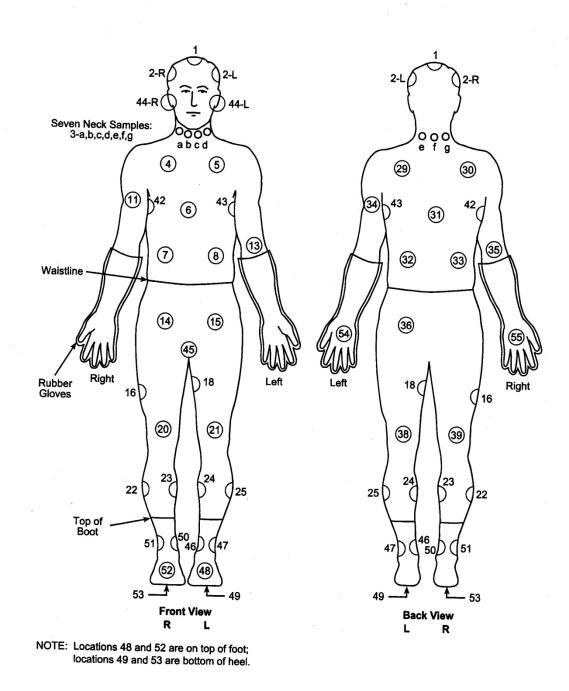




Table G.2.	Sampling Locations for Aerosol Man-in-Simulant Testing (MIST).
Position Number ^a	Description
1	Head, top
2-R	Head, right side
2-L	Head, left side
3-а	Neck
3-b	Neck
3-с	Neck
3-d	Neck
3-е	Neck
3-f	Neck
3-д	Neck
4	Upper chest, right
5	Upper chest, left
6	Mid-chest
7	Lower chest, right
8	Lower chest, left
11	Upper arm, front right
13	Lower arm, front left
14	Pelvic area, right
15	Pelvic area, left
16	Outside upper leg, right
18	Inside upper leg, left
20	Mid-leg, front right
21	Mid-leg, front left
22	Outside lower leg, right
23	Inside lower leg, right
24	Inside lower leg, left
25	Outside lower leg, left
29	Upper back, left
30	Upper back, right
31	Mid-back

Table G.2. Sampling Locations for Aerosol Man-In-Simulant Testing (MIST).

APPENDIX G. BODY REGION HAZARD ANALYSIS (BRHA)

Position Number ^a	Description		
32	Lower back, left		
33	Low back, right		
34	Upper arm, back left		
35	Lower arm, back right		
36	Rump		
38	Mid-leg, back left		
39	Mid-leg, back right		
42	Side of torso, right		
43	Side of torso, left		
44-R	Ear lobe, right		
44-L	Ear lobe, left		
45	Scrotum		
46	Inside of foot, left		
47	Outside of foot, left		
48	Top of foot, left		
49	Bottom of foot, left		
50	Inside of foot, right		
51	Outside of foot, right		
52	Top of foot, right		
53	Bottom of foot, right		
54	Back of hand, left		
55	Back of hand, right		

Table G.2. Sampling Locations for Aerosol Man-In-Simulant Testing (MIST) (Cont'd).

^aSee Figure G.2.

d. Additional, optional outputs can be produced that are similar to the MED_{HD} value. For instance, a program for investigating closures may want to look specifically at the closure areas (wrists, ankles, waist, neck, etc). Localized exposure dosages are produced for 27 different body regions that can all be reported as desired. Past specialized outputs include minimum exposure dosages for the glove interface (MED_{GLOVEI}), boot interface (MED_{BOOTI}), and crotch (MED_{CROTCH}) which are calculated from the clothed effective concentration × time (CE_{Ct}) in the interface region. A more detailed explanation of the calculations is given in Paragraphs G.2 and G.3.

e. An integral part of the BRHA is the sensitivity estimate of the body region to the agent. The current BRHA estimates are based on persistent nerve agent (VX) ED_{50} values (i.e., the amount of a substance required to produce a specific effect in 50 percent of the test subjects) from a 1962 study (Reference A).

(1) The ED_{50} values for VX represent the mass of liquid VX that would cause a 70 percent depression in red blood cell cholinesterase in a 70-kg human. Each of the body regions in the BRHA model has an associated VX ED_{50} (Table G.3).

(2) The BRHA uses the assumption that the ratio between the sensitivities of different regions is the same for liquid VX, vapor VX, vapor HD, etc. In other words, if one region is twice as sensitive as another to liquid VX, it is assumed that the region will also be twice as sensitive to other agent challenges.

(3) This assumption and the idea of using liquid VX data for analysis of vapor threats have been criticized. Currently, there are efforts under way to update the body region sensitivity data in the BRHA. As better estimates of the body region sensitivities are completed, they will be included in future updates.

f. For a more detailed explanation of BRHA, see References A through C.

2. VAPOR MIST

a. The input for the vapor BRHA is the complete set of masses from the standard PAD locations.

(1) A complete data set for each ensemble is required to perform the BRHA. There are 17 PAD locations included in this data set (the nose cup and mask PADs are not included in the BRHA because it applies only to percutaneous effects, not inhalation or ocular effects.

(2) Missing values are estimated as the geometric mean of all other PADs from the same location of the other ensembles in the configuration.

(3) Values below the PAD detection limit of 50 ng are set to 50 ng.

b. The PAD masses are normalized to correspond to a standard 12,000 mg·min/m³ challenge concentration × time (Ct). This means that the PAD will be challenged with 100 mg/m³ MeS during a 2-hour trial (Table G.3 and Equation 1).

APPENDIX G. BODY REGION HAZARD ANALYSIS (BRHA)

Body Region	Area (cm ²)	VX ^a ED ₅₀ ^b (mg/Individual)
		, e /
Scalp	350	0.76
Ears	50	0.46
Cheeks and neck	100	0.48
Chin and neck	200	0.36
Nape	100	1.72
Abdomen	2858	2.23
Back	2540	2.65
Axillae	200	2.07
Inner upper arm	488	2.80
Outer upper arm	706	6.57
Elbow fold	50	2.09
Elbow	50	2.25
Forearm, volar	487	2.80
Forearm, dorsum	706	6.57
Hands, dorsum	200	2.91
Hands, palmer	200	9.24
Buttocks	953	4.26
Groin	300	1.22
Scrotum	200	0.11
Thigh, dorsum	2845	6.57
Thigh, plantar	1422	4.26
Knee	200	7.14
Popliteal spaces	100	2.09
Shins	1897	6.57
Calves	948	2.80
Feet, dorsum	500	6.60
Feet, plantar	300	7.14

Table G.3. Body Region Hazard Analysis (BRHA) Estimates of Body Region Sensitivities.

^aVX – persistent nerve agent.

 ${}^{b}ED_{50}$ – Amount of a substance required to produce a specific effect in 50 percent of the test subjects.

Equation 1

$$mass_{normalized} = mass_{original} \times \frac{12000}{Challenge CT}$$

Where:

 $mass_{normalized} = normalized mass (ng).$ $mass_{original} = mass (ng) \text{ of MeS reported for PAD.}$ $Challenge \ CT = \text{dosage of MeS (mg \cdot min/m^3)} \text{ measured during time the ensemble was}$ tested.

c. Regions not measured directly by PADs are estimated using nearby or surrounding PADs. For example:

(1) The calf is estimated using masses from the inner shin.

(2) The elbow is estimated as the average of the forearm and outer upper arm masses.

(3) A total of 27 body regions (14 are directly measured, and 13 are estimated) are included in the model (Table G.4).

d. A local protection factor (PF) is then calculated for each of the 27 body regions by comparing the amount of MeS on the outside of the ensemble to the amount on the inside of the ensemble (Equation 2). The current model uses an estimate of 200,000 ng for the mass on the outside of the suit during a two-hour trial in a 100 mg/m³ challenge. This value could be measured directly by using PADs on the outside of the suit, but past measurements have shown that for a well controlled challenge, the estimate is accurate.

Equation 2

 $PF_{body\,region} = \frac{200,000}{mass_{body\,region}}$

Where:

 $PF_{body region}$ = the protection factor for the given body region. $Mass_{body region}$ = mass (ng) of MeS reported for PAD for the given body region. 200,000 = estimate of mass of MeS (ng) that would be collected on the outside of the ensemble during the trial.

APPENDIX G. BODY REGION HAZARD ANALYSIS (BRHA)

e. The PFs and body region sensitivities (Table G.4) are used to estimate the MED_{SYS} and MED_{HD} values.

Table G.4.	Body Regions	Calculations from	n Passive Abso	orbent Devices (PADs).

	PAD(s) From Which the Mass of Methyl Salicylate (MeS) Reported is Used, Alone or in the Calculations,		
Region	to Estimate Permeation		
Scalp	Scalp		
Ears	Left ear		
Cheeks and neck	Left ear		
Chin and neck	Chin		
Nape	Nape		
Abdomen	$[2 \times (\text{chest} + \text{armpit} + \text{groin})]/4$		
Back	$[2 \times (nape + mid back + buttocks)/3 + armpit]/3$		
Axillae	Armpit		
Inner upper arm	Inner upper arm		
Outer upper arm	Outer upper arm		
Elbowfold	(Inner upper arm + forearm, volar)/2		
Elbow	(Outer upper arm + forearm, volar)/2		
Forearm, dorsum	Forearm, volar		
Forearm, volar	Forearm, volar		
Hands, dorsum	Glove		
Hands, palmer	Glove		
Buttocks	Buttocks		
Groin	(Groin + crotch) / 2		
Crotch	Crotch		
Thigh, dorsum	Inner thigh		
Thigh, plantar	Inner thigh		
Knee	(Inner thigh + inner shin) / 2		
Popliteal spaces	(Inner thigh + inner shin) / 2		
Shins	Inner shin		
Calves	Inner shin		
Feet, dorsum	Boot		
Feet, plantar	Boot		

f. Vapor MED_{SYS}

(1) The MED_{SYS} is a cumulative effect summed over all of the 27 body regions.

(2) It is a function of the ED_{50} of VX, local PF, and local surface area for each body region.

(3) The first step in determining the MED_{SYS} is to calculate an overall systemic PF (Equation 3) for the ensemble.

Equation 3

$$Systemic PF = \sum_{i} \frac{\frac{area_{i}}{VX ED_{50i}}}{\frac{area_{j}}{VX ED_{50j} \times PF_{j}}}$$

Where:

Systemic PF = protection factor for entire enemble. $area_i = \text{local surface area (cm²) of the ith body region.}$ $area_j = \text{local surface area (cm²) of the jth body region.}$ $VX ED_{50i} = \text{local VX ED}_{50}$ (mg/individual) for the ith body region. $VX ED_{50j} = \text{local VX ED}_{50}$ (mg/individual) for the jth body region. $PF_i = \text{local PF}$ for the jth body region.

(4) Equation 3 is based on the assumption that the response of the population to agent exposure can be characterized as a function of dose, and that the response curve follows a lognormal distribution. A detailed derivation of Equation 3 is found in References A through D.

(5) The systemic PF is multiplied by 25 mg·min/m³ to calculate the MED_{SYS} for the ensemble. The 25 mg·min/m³ value is the challenge that would cause effects for unprotected individuals (Reference A).

g. <u>Vapor MED_{HD}</u>

(1) Based on the assumption that the ratios of agent sensitivity are the same for a given body region for different agents (Paragraph G.1.e), the ratio of the VX ED_{50} for each body region to the VX ED_{50} for the volar forearm (VX ED_{50}) is calculated. This gives a relative ratio of sensitivities. For example, the scalp (VX $ED_{50} = 0.76$ mg) would have effects from agent at a dosage of about 27.1 percent of what the forearm would, or the outer upper arm (VX $ED_{50} =$ 6.57) would not see effects until the dosage was about 235.6 percent of the forearm critical dosage.

APPENDIX G. BODY REGION HAZARD ANALYSIS (BRHA)

(2) The ratios are calculated using the forearm because that was thought to be the most understood area and had a good dosage value for HD effects. The estimated dosage is $1,000 \text{ mg} \cdot \text{min/m}^3$, and is the dosage that would cause severe burns in hot, humid conditions (Reference A). As with other toxicological values in the BRHA, this value is currently being studied and may be updated.

(3) A local agent cytotoxicity 50 percent (CT_{50}) (i.e., the concentration with 50 percent cell mortality) is calculated for each body region by multiplying the calculated ratios by 1,000 mg·min/m³. For example, the vapor challenge necessary to cause burns in the scalp is 271 mg·min/m³, or the calculated ratio of 27.1 percent multiplied by 1,000 mg·min/m³. This is meant to correspond to the vapor challenge to which the bare skin in a given body region could be exposed before experiencing severe burns.

(4) A CE_{Ct} is then calculated for each body region by multiplying the local agent CT_{50} for each body region by the corresponding local PF (Paragraph G.2.d). For each body region, this represents the challenge Ct outside the protective ensemble that would cause burns on the skin at that body region.

(5) Equation 4 shows this process for a given body region.

Equation 4

$$CE_{CT \, region} = \left(\frac{VX \, ED_{50 \, region}}{VX \, ED_{50 \, forearm}}\right) \times 1000 \times Local \, PF$$

Where:

CE_{CT region} =clothed effective Ct (mg·min/m³) for a given body region.
VX ED_{50 region} = VX ED₅₀ (mg/individual) for a given body region.
VX ED_{50 forearm} = 2.8 mg·min/m³ = volar forearm VX ED₅₀.
1000 = HD dosage (mg·min/m³) resulting in severe burns on the forearm in hot, humid weather.
Local PF = local PF for a given body region.

(6) The minimum of all the clothed effective Cts is the ensemble MED_{HD} . This represents the challenge Ct outside the protective ensemble that would cause burns on the skin in 50 percent of the population at the most susceptible body region of the ensemble.

(7) Additional local summary values can be calculated from these clothed effective CTs by taking the minimum value from the body regions in question. For example, MED_{GLOVEI} is calculated as the minimum clothed effective Ct from the forearm and hand body regions.

3. AEROSOL MIST

a. The aerosol analysis follows a similar structure as the vapor analysis, but is based on deposition velocity (V_d) instead of PF.

(1) The V_d is the rate of aerosol deposition on the TP's skin. It is calculated using the results of the skin sample swap (Equation 5, Figure G.2, and Table G.2,).

Equation 5

$$V_d = \frac{M_{Aerosol} - M_{Background}}{A \times C_m \times T}$$

Where:

 V_d = deposition velocity. $M_{Aerosol}$ = Mass of deposited aerosol. $M_{Background}$ = Background mass. A = Sample area. C_m = Aerosol mass concentration (mg/m³). T = Sample duration (minutes).

(2) Because the fluorescence of the samples is directly related to the mass of the aerosol in the samples, the fluorescence of the samples will be used instead of determining the mass of aerosol in the samples. Therefore, V_d will be computed as shown in Equation 6.

Equation 6

$$V_d = \frac{F_{Aerosol} - F_{Background}}{A \times C_f \times T}$$

Where:

 V_d = deposition velocity. $F_{Aerosol}$ = Fluorescence of deposited aerosol. $F_{Background}$ = Background fluorescence. A = Sample area. C_f = Aerosol fluorescence concentration (F/m³). T = Sample duration (minutes).

APPENDIX G. BODY REGION HAZARD ANALYSIS (BRHA)

(3) For samples where the measured fluorescence is less than or equal to twice the background fluorescence, the V_d will be computed using the background level (Equation 7).

Equation 7

$$V_d = \frac{F_{Background}}{A \times C_f \times T}$$

Where:

 V_d = deposition velocity. $F_{Background}$ = Background fluorescence. A = Sample area. C_f = Aerosol fluorescence concentration (F/m³). T = Sample duration (minutes).

b. Because aerosol testing allows for skin rinse samples, as opposed to the PADs in the vapor test, samples are taken at each of the body regions. However, there are only 23 body regions instead of the 27 in the vapor test. This is because historically samples have not been taken under the gloves and boots because little to no aerosol deposition was seen in those areas. Glove and boot samples are now taken, but any analysis performed on those values is based on the V_d ; they are still not included in the BRHA.

c. For many regions, multiple samples are taken and averaged together (Table G.5).

Table G.5.	Body Region and Corresponding Skin Rinse Samples for Aerosol
	Man-in-Simulant Testing (MIST).

Body Region	Skin Rinse Samples	
Chin and neck	3a through d	
Ears	44 right and left	
Cheeks and neck	3a, 3d, 3e, and 3g	
Nape	3e through g	
Scalp	1, 2 right, and 2 left	
Abdomen	4 through 8, 14, 15, 42, and 43	
Axillae	42 through 43	
Back	29 through 33, 42, and 43	
Inner upper arm	11	
Outer upper arm	34	
Elbow fold	13	
Elbow	35	
Forearm, volar	13	
Foearm dorsum	35	
Buttocks	36	
Groin	14, 15, and 45	
Scrotum	45	
Thigh, dorsum	18	
Thigh, plantar	16	
Knee	20 and 21	
Popliteal spaces	38 and 39	
Shins	22 and 25	
Calves 23 and 24		

<u>NOTES</u>: 1.

: 1. See Table 2 and Figure 2 for a description of the skin rinse sample areas.

For body regions with more than one sample, the multiple samples are averaged to give a single value.

APPENDIX G. BODY REGION HAZARD ANALYSIS (BRHA)

d. Aerosol MED_{SYS}

(1) The MED_{SYS} is a cumulative effect summed over all of the 23 body regions.

(2) It is a function of the VX ED_{50} , Vd, and local surface area for each body region.

(3) Equation 8 gives the calculation for MED_{SYS} for aerosol.

(4) The MED_{SYS} equation for aerosol (Equation 8) is a step in the process for the derivation of the systemic PF equation for vapor (Equation 3). However, because aerosol uses Vd, it can be calculated directly from Equation 8 rather than using systemic PFs (Reference A).

Equation 8

$$MED_{SYS} = \left(\sum_{j} \frac{V_{d_j} \times A_j}{VX ED_{50j} \times 10^6}\right)^{-1}$$

Where:

 V_{d_i} = deposition velocity (cm/min) at the jth body region.

 $A_i = \text{local surface area (cm²) of the jth body region.}$

 $VX ED_{50j}$ = local VX ED₅₀ (mg/individual) for the jth body region.

 10^6 = conversion factor so that MED_{SYS} units are mg·min/m³.

e. Aerosol MED_{HD}

(1) MED_{HD} is calculated using the VX ED₅₀ and V_d for each body region.

(2) The first step is to calculate an effective dose for each body region. Similar to the vapor analysis, these doses are hypothesized to be proportional to VX ED_{50} , so the ratio of the VX ED_{50} of each body region to the VX ED_{50} of the volar forearm is multiplied by 50 µg/cm² (the effective deposition level for the volar forearm).

(3) This value is then multiplied by 1,000 mg·min/m³ (the critical dosage for the volar forearm) and divided by V_d . The resulting value is the clothed effective Ct for the given body region (Equation 9).

Equation 9

$$CE_{CT \ region} = \left(\frac{VX \ ED_{50 \ region} \times 50}{VX \ ED_{50 \ forearm}}\right) \times \frac{1000}{V_{d_{region}}}$$

Where:

 $CE_{Ct region} = \text{clothed effective Ct (mg·min/m³) for a given body region}$ $VX ED_{50 region} = VX ED_{50}$ (mg/individual) for a given body region $VX ED_{50 forearm} = 2.8 \text{ mg·min/m}^3 = \text{volar forearm VX ED}_{50}$ 50 = effective deposition level (µg/cm2) for the volar forearm $1000 = \text{HD dosage (mg·min/m}^3)$ resulting in severe burns on the forearm in hot, humid weather $V_{d_{region}} = \text{deposition velocity (cm/min) for a given body region}$

(4) The minimum of all the clothed effective CTs is the ensemble MED_{HD} . This represents the challenge Ct outside the protective ensemble that would cause burns on the skin in 50 percent of the population at the most susceptible body region of the ensemble.

(5) Additional local summary values can be calculated from these clothed effective CTs by taking the minimum value from the body regions in question. For example, MED_{GLOVEI} is calculated as the minimum clothed effective Ct from the forearm and hand body regions.

4. FURTHER ANALYSIS

a. It is important to remember that the BRHA output values indicated ensemble protective performance, so higher numbers are better.

b. A natural log transformation is performed. Historically, this helps most chemical testing data conform better to the necessary assumptions for statistical testing.

c. An outlier test is performed. An outlier will be defined as a point having a studentized residual with an absolute value greater than 3.

(1) If any outliers are identified, those values will be reviewed to determine if there is a discernible cause for each outlier.

(a) If there is a discernible cause, the values will be adjusted, if possible, to reflect the true value; otherwise, the value will be replaced with the geometric mean of the same body point from all ensembles of the same configuration.

(b) If there is not a discernible cause for the outlier, the original value will be used.

APPENDIX G. BODY REGION HAZARD ANALYSIS (BRHA)

(2) The outlier analysis will be conducted only once.

d. Descriptive statistics, including geometric mean, logarithmic standard deviation, and the 95 percent confidence intervals on the mean, are calculated.

e. A comparison of means is performed (typically analysis of variance) to compare results among configurations or to compare candidates with a standard. For MIST results, comparisons with a standard are strongly encouraged, as opposed to using some sort of pass/fail value, such as a target performance value (TPV).

f. Graphical summaries of the results are often helpful to find patterns and illustrate findings. A line plot of the geometric mean of each clothed effective CT by body region is a standard plot that has been created.

<u>NOTE</u>: The MED_{SYS} and MED_{HD} values for vapor and aerosol MIST are typically analyzed the same way. The typical data analysis procedures are described in Paragraphs G.4.a through G.4.f. However, the analysis methods can be adapted to the needs of a specific program.

5. POTENTIAL IMPROVEMENTS

a. The area of improvement that has received the most attention is updating the toxicological values in the BRHA. The current use of VX ED_{50} values and assuming that ratios of sensitivity hold constant is thought to be invalid. Updated toxicological values could be inserted into the BRHA with relatively little effort.

b. Another idea for improvement would be to change the type of output of the BRHA. Instead of reporting a value that theoretically gives the challenge dosage that would result in the median population experiencing severe symptoms (e.g., MED_{SYS} and MED_{HD}), a better output would be the proportion of the population experiencing symptoms given a challenge dosage. This would require including the population sensitivity to agent variability in the BRHA. These variabilities would likely be calculated with the updated toxicological values. This change to the BRHA would require significantly more effort than just updating the toxicological values but would provide a much more useful and understandable answer to decision makers.

c. The ultimate goal of the BRHA should be to provide results that correspond directly to toxicological effects. This will only be possible once the toxicological data in the BRHA are improved, along with minimizing the overall variability in the MIST process.

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- AEHA U.S. Army Environmental Hygiene Agency
- ANOVA analysis of variance
- ANSUR Anthropometric Survey
- AR Army Regulation
- ASIS -- anterior superior iliac spine
- AST –aerosol system-level testing
- ATEC U. S Army Test and Evaluation Command
- BRHA Body Region Hazard Analysis
- CAPAT Commodity Area Process Action Team
- CB chemical/biological
- CE_{Ct region} clothed effective Ct (mg·min/m³) for a given body region
- CPU chemical-protective undergarment
- Ct concentration × time
- CT cytotoxicity
- CT₅₀ cytotoxicity 50 percent (concentration with 50 percent cell mortality)
- CWA chemical warfare agent
- DA Department of The Army
- DEM diethyl malonate
- DMMP dimethyl methylphosphonate
- DTIC Defense Technical Information Center
- DTP detailed test plan
- EA environmental assessment
- ED_{50} Amount of a substance required to produce a specific effect in 50 percent of the test subjects

- EIALC environmental impact assessment for life cycle
- EIS environmental impact statement
- EMT emergency medical technician
- FEP fluorinated ethylene propylene
- FM -field manual
- GB sarin
- GC gas chromatograph
- HD distilled mustard
- HFE human factors engineering
- HHA health hazard assessment
- HUC Human Use Committee
- IAW in accordance with
- IP individual protection
- JSLIST Joint Services Lightweight Integrated Suit Technology
- LDL lower detection limit
- LED local exposure dosage
- MED minimum effective dosage
- MED_{BOOTI} minimum exposure dosage for the boot interface
- MED_{CROTCH} minimum exposure dosage for the crotch
- MED_{GLOVEI} minimum exposure dosage for the glove interface
- MED_{HD} minimum effective dosage of HD
- MED_{SYS} systemic agent minimum effective dosage
- MeS methyl salicylate
- MINICAMS® -miniature, automatic, continuous air-monitoring system

- MIRAN[®] Miniature Infrared Analyzer[®]
- MIST man-in-simulant test(ing)
- MSDS material safety data sheet
- NaOH sodium hydroxide
- NEPA National Environmental Policy Act
- NET new equipment training
- NRDEC U.S. Army Natick Soldier Research, Development, and Engineering Center
- ORI operational readiness inspection
- PAD passive absorbent device
- PAM pamphlet
- PF protection factor
- PFA perfluoroalkoxy
- POC point of contact
- PSD passive sampling device
- PTFE polytetrafluoroethylene
- PVC –polyvinyl chloride
- PVSMS personal vital signs monitoring system
- QA quality assurance
- QC quality control
- REC record of environmental consideration
- RH relative humidity
- RSD relative standard deviation
- RTI Research Triangle Institute
- RTM real-time monitor

- SAR safety assessment report
- SEP system evaluation plan
- SF₆ sulfur hexafluoride
- SOP standing operating procedure
- SSP system support package
- SSPL system support package list
- TEMP test and evaluation master plan
- TICN test item control number
- TIIN test item identification number
- TO test officer
- TOP test operations procedure
- TP test participant
- TPV target performance value
- Vd deposition velocity
- VX persistent nerve agent

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APPENDIX J. APPROVAL AUTHORITY.

TECMIPT Test Operations Procedures (TTOP) 10-2-022, Chemical Vapor and Aerosol System-Level Testing of Chemical/Biological Protective Suits

Individual Protection Capability Area Process Action Team (CAPAT):

Dr. Charles Walker, Dugway Proving Ground

CAPAT Review & Concurrence: October 2013



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REFERENCES:

(a) Chemical and Biological Defense Program (CBDP) Test and Evaluation (T&E) Standards Development Plan, dated 19 July 2010.

(b) Memorandum of Understanding (MOU) Among the Department of National Defence of Canada the Secretary of State for Defense of the United Kingdom of Great Britain and Northern Ireland and the Secretary of Defense on Behalf of the Department of Defense of the United State of America concerning the Research, Development and Acquisition of Chemical, Biological and Radiological Defense Materiel, dated June 2000. Amendment One, dated August 2006.

APPENDIX J. APPROVAL AUTHORITY.

The Individual Protection (IP) Capability Area Process Action Team (CAPAT) of the Test and Evaluation Capabilities and Methodologies Integrated Process Action Team (TECMIPT) has completed review of this document. The CAPAT recommends approval of this document. If a representative non-concurs, a dissenting position paper will be attached.

Concurrence Sheet for the Test Operating Procedures (TOP) 10-2-022 Chemical Vapor and Aerosol System-Level Testing of Chemical/Biological Protective Suits			
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		US Army Test and Evalua	tion Command
US Marine Corps Operational Test &		(ATEC)/US Army Evaluation	
Evaluation Activity (MCOTEA)		(ATEC)/05 ATTIY Evaluation	on Center (ALC)
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Signature	Date	Signature	Date
Nevin K. Elden, USAF		Laurie K. Richter, Lt Col,	JSAF
Director of Operations		Joint Requirements Office	
US Air Force Operation	al Test and	Chemical, Biological, Rad	
Evaluation Center (AFC		Nuclear Defense-	
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Signature	Date	Signature	Date
Jeffery Bobrow		Deborah Shuping	
Assistant Chief of Staff,		CBRN Defense (CBRND)	T&E Executive
Warfare, Commander	Operational Test and		
Evaluation Force (CON	IOPTEVFOR)		
01	1704201L	Deborah B Stuping	25F-6-013
Signature	Date	Signature	Date
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Joint Program Executiv	e Office for	Joint Science and Technology Office	
Chemical and Biological Defense (JPEO		(JSTO)	
CBD)			
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Charlie Walker			
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Note: CAPAT members' Signature represents an O6 level concurrence from their organization. If the CAPAT representative is not empowered at this level, he/she must coordinate the concurrence/non-concurrence process within his/her organization, and prior to the specified suspense date for the document.

APPENDIX J. APPROVAL AUTHORITY.

TECMIPT Chair Endorsement

AMXAA-CD

6 January 2014

MEMORANDUM FOR

Chemical, Biological, Radiological and Nuclear Defense (CBRND) Test and Evaluation (T&E) Executive, Office of the Deputy Under Secretary of the Army, Taylor Building, Suite 8070, 2530 Crystal Drive, Arlington, VA 22202

SUBJECT: Test and Evaluation Capabilities and Methodologies Integrated Process Team (TECMIPT) Test Operations Procedure (TTOP) 10-2-022, Chemical Vapor and Aerosol System-Level Testing of Chemical/Biological Protective Suits

1. The Individual Protection Capability Area Process Action Team (CAPAT) has completed their review of the subject TTOP in accordance with the DUSA-TE Instructions to the TECMIPT, the Standards and Development Plan, and the TECMIPT Standard Operating Procedure (SOP). All signatory members of the CAPAT have provided their concurrence to this TTOP. The CAPAT signature sheets and the ATEC Approval for Publication memorandum are enclosed.

2. Based on the concurrence of the CAPAT, I recommend the CBRND T&E Executive endorse this TTOP as a Department of Defense (DoD) Test and Evaluation (T&E) Standard.

Encl

RONALD O. PRESCOTT TECMIPT Chair

APPENDIX J. APPROVAL AUTHORITY.

Office of the Deputy Under Secretary of the Army Endorsement



DEPARTMENT OF THE ARMY OFFICE OF THE DEPUTY UNDER SECRETARY OF THE ARMY 102 ARMY PENTAGON WASHINGTON, DC 20310-0102

DUSA-TE

JAN 1 6 2014

MEMORANDUM FOR DISTRIBUTION

SUBJECT: Endorsement of TECMIPT Test Operations Procedure (TTOP) 10-2-022A, Chemical Vapor and Aerosol System-Level Testing of Chemical/Biological Protective Suits

1. Reference: Memorandum, DUSA-TE, 19 July 10, subject: Chemical and Biological Defense Program (CBDP) Test and Evaluation (T&E) Standards Development Plan

2. TTOP 10-2-022A was developed, coordinated, and approved by the members of the Individual Protection (IP) Capability Area Process Action Team (CAPAT) in accordance with the reference. The U.S. Army Test and Evaluation Command (ATEC) approved according to their TOP approval process.

3. I endorse this TTOP as a DoD T&E Standard for Individual Protection testing and encourage its broad use across all test phases. All T&E Standards are for government associated program access and use. They are stored in Army Knowledge Online (AKO), in the TECMIPT Share point site and on the National Institute of Standards and Technology (NIST) website at http://gsi.nist.gov/global/index.cfm/L1-4/L2-19/A-664.

4. My point of contact for this action is Ms. Deborah Shuping, (703) 545-1119, deborah.f.shuping.civ@mail.mil.

JAMES C. COOKE CBRN Defense T&E Executive

Encl

DISTRIBUTION: DASD(CBD) DASD(DT&E) DOT&E, Deputy for Land and Expeditionary Warfare Army G3/5/7 Army G8 (DAPR-FDZ-I) AF-TE CNO, N091 Commanding General, ATEC Commander, AFOTEC

APPENDIX J. APPROVAL AUTHORITY.

Office of the Deputy Under Secretary of the Army Endorsement

DUSA-TE SUBJECT: Endorsement of TECMIPT Test Operations Procedure (TTOP) 10-2-022A, Chemical Vapor and Aerosol System-Level Testing of Chemical/Biological Protective Suits

DISTRIBUTION (CONT) JSTO-CBD Commander, OPTEVFOR JPEO-CBD JRO CBRND Director, NSRDEC Director, USANCA DTRA/JSTO-CB Director, ARL/SLAD Technical Director, ECBC Director, MCOTEA Director, CBDP PAIO Commander, NSWC-DD

APPENDIX J. APPROVAL AUTHORITY.

CSTE-TM

16 December 2013

MEMORANDUM FOR

Commanders, All Test Centers Technical Directors, All Test Centers Directors, U.S. Army Evaluation Center Commander, U.S. Army Operational Test Command

SUBJECT: Test Operations Procedure (TOP) 10-2-022A, Chemical Vapor and Aerosol System-Level Testing of Chemical/Biological Protective Suits, Approved for Publication

1. TOP 10-2-022A, Chemical Vapor and Aerosol System-Level Testing of Chemical/Biological Protective Suits, has been reviewed by the U.S. Army Test and Evaluation Command (ATEC) Test Centers, the U.S. Army Operational Test Command, and the U.S. Army Evaluation Center. All comments received during the formal coordination period have been adjudicated by the preparing agency. The scope of the document is as follows:

This TOP provides the standard for designing and conducting tests estimating penetration of chemical agent vapor and aerosol simulant through chemical/biological protective suit systems while the suits are worn. Methyl salicylate is used to simulate a chemical agent vapor challenge. Nontoxic, fluorescent-tagged silica aerosol particles are used to simulate an aerosol chemical agent challenge. For the vapor tests, personal sampling devices, such as passive absorbent devices, are used to monitor chemical concentration inside the suits. For the aerosol tests, a discussion is offered of the sampling methods used to determine aerosolized chemical concentration inside the suits.

2. This document is approved for publication and has been posted to the Reference Library of the ATEC Vision Digital Library System (VDLS). The VDLS website can be accessed at https://vdls.atc.army.mil/.

3. Comments, suggestions, or questions on this document should be addressed to U.S. Army Test and Evaluation Command (CSTE-TM), 2202 Aberdeen Boulevard-Third Floor, Aberdeen Proving Ground, MD 21005-5001; or e-mailed to usarmy.apg.atec.mbx.atecstandards@mail.mil.

> FONTAINE.RAYMO ND.G.1228812770 ND.G.1228812770

MICHAEL J. ZWIEBEL Director, Test Management Directorate (G9) Forward comments, recommended changes, or any pertinent data which may be of use in improving this publication to the following address: Range Infrastructure Division (CSTE-TM), U.S. Army Test and Evaluation Command, 2202 Aberdeen Boulevard, Aberdeen Proving Ground, Maryland 21005-5001. Technical information may be obtained from the preparing activity: Commander, West Desert Test Center, U.S. Army Dugway Proving Ground, ATTN: TEDT-DPW, Dugway, UT 84022-5000. Additional copies can be requested through the following website: <u>http://itops.dtc.army.mil/RequestForDocuments.aspx</u>, or through the Defense Technical Information Center, 8725 John J. Kingman Rd., STE 0944, Fort Belvoir, VA 22060-6218. This document is identified by the accession number (AD No.) printed on the first page.