CHAPTER 3

Governmental Policies and Programs

U.S. policy is "no first use" of lethal or incapacitating chemical agents by the U.S. Armed Forces. However, the right is reserved to retaliate, using lethal or incapacitating chemical agents, against an enemy that has used them on U.S. forces. The authority to order or approve the first retaliatory usage rests with the president. Risk to civilian populations is to be avoided to the maximum extent possible.

As discussed in Chapter 2 CWAs and TICs will produce harmful physiological and/or psychological effects after exposure through inhalation, direct contact, or ingestion. Because these CWAs can cause large number of casualties, the government has developed many regulations in an effort to control, safeguard, and provide safe handling protocols. For example, chemical agent workers must meet stringent qualification criteria established in the Chemical Personnel Reliability Program to qualify for working with the agents. Pertinent regulations have been developed by the Department of Defense (DoD), Department of the Army, Army Materiel Command, and Aberdeen Proving Ground. These regulations complement each other to cover multiple aspects of safely handling CWAs. In addition to complying with diverse regulations, laboratories must develop standing operational procedures (SOPs) for each operation involving CWAs. SOPs are discussed in Chapter 4.

CWAs and TICs can be disseminated using a variety of methods and available distribution systems. Incidents in places where large numbers of people congregate or travel through, such as subway systems, airport terminals, or high-rise office buildings, could lead to hundreds or thousands of casualties and deaths (direct and indirect) and the disruption of crucial services. The U.S. government has developed numerous initiatives to deal with such incidents as part of the Domestic Preparedness Program (DPP).

The DPP includes training and equipping local response teams, such as police, fire fighters, first responders, and medical support people. In 1996, this program took the initiative to test and evaluate the detection equipment that emergency responders were using to determine if they had the CWA detection capability. The

program later invited detector developers to submit products for evaluation. Evaluation results are posted on the Homeland Defense website (http://www2.sbccom.army.mil/hld/ip/reports.htm#detectors). This initiative assessed current detector capabilities as well as responders' degree of readiness. The detector evaluation program followed evaluation criteria similar to those applied in testing military CWA detection devices.

3.1 CWA DETECTION STANDARDS AND CRITERIA FOR DEPLOYMENT

Government recommendations for CWA concentration levels to be considered were prepared to serve as guidelines for the developers and researchers to meet. The recommendations are based on evaluation of previous standards to address a myriad of unique scenarios. Department of the Army pamphlet 385-61 entitled "Toxic Chemical Agent Safety Standards" details standard procedures and protective equipment for proper handling of CWAs.

3.1.1 Low-Level Exposure and Operational Risk Management

DoD policy and doctrine are based on a uniformly defined "range" of low-level exposure. This range must address all military scenarios to appropriately determine policy, doctrine, research, and technological needs. Policy and doctrine should not arbitrarily dictate either the number or percentage of casualties that a commander can or should accept in order to complete a mission. The specific accepted risk should be determined by the commander(s), based on the situation and mission requirements. Operational risk management (ORM) is a fundamental aspect of military decision making. The U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) recommends using the ORM framework to define low-level exposures, and thus low-risk exposures.

The ORM process involves ranking the severity of a situation, and the probability that this exposure will occur. As Table 3.1 shows, low risk can be attributed to hazards ranging in severity from "negligible" to "marginal" to "critical," depending on the likelihood that the hazard will occur.

Table 3.1 Risk Assessment Matrix

	Probability				
Severity	**Frequent**	**Likely**	**Occasional**	**Seldom**	**Unlikely**
Catastrophic	E	E	H	H	M
Critical	E	H	H	M	L
Marginal	H	M	M	L	L
Negligible	M	L	L	L	L

E, extremely high risk; H, high risk; M, moderate risk; L, low risk.

Source: U.S. Department of the Army. USACHPPM Technical Guild 230, Chemical Exposure Guidelines for Deployed Military Personnel Version 1.3 May 2003; currently being reviewed by NRC.

The severity of health effects from chemical exposure is the direct result of dose, the product of chemical concentration and duration of exposure. It is impossible to predict responses and outcomes in all situations due to variation in environmental and exposure conditions. Therefore, generic scenarios are used to represent typical conditions for estimating the severity of effects.

3.1.1.1 Significant Adverse Effect

The "significance" of an effect depends on the severity of resulting health and operational impacts. While the threshold for lethal effects is defined as the high end of low-level exposures, the lower end can then be defined as the exposure dosage that would not cause significant immediate or delayed adverse health consequence.

To determine an exposure level that does not result in adverse health effects is complicated by the nature of the pathologic sequelae following exposures. If a temporary chemical exposure results in an immediate effect, the relationship between the exposure level and the physiologic impairment may be readily determined. A dose–response relationship could then be established. However, single or multiple exposures to a toxicant may cause cellular damage that is not reflected as overt pathology for days, weeks, or years following the exposure. Such pathologic sequelae are difficult to link quantitatively to a specific toxicant exposure.

Under circumstances where the physiologic damage is reversible, the resulting adverse health consequences will also reverse at some time after the exposure. This leads to observations of immediate, transient adverse health effects and/or delayed, transient adverse health effects. If sufficient transient damage accumulates to cause irreversible deterioration or if the cellular pathologic effects of exposure are irreversible, temporary or short-term exposure may result in permanent chronic illness. Therefore, adverse health effects following a chemical exposure may be a mixture of immediate, delayed, transient, or chronic symptoms. Each symptom may be characteristically associated with a different exposure level.

3.1.1.2 Duration of Exposure

The time period that personnel may be exposed to CWAs or other hazards cannot be precisely estimated. Duration periods listed in Table 3.2 describe generalized

Table 3.2 Designation of Reference Exposure Duration for Deployments

Temporary exposure duration	Brief, one-time occurrence. Such occurrence may only last minutes or up to a few hours.
Short-term exposure duration	In general, this term applies to exposures that exceed the "temporary" duration and continue daily up to 2 weeks. This includes continuous exposures and repeated, intermittent exposures.
Long-term exposure duration	Long-term exposures include continuous exposures or repeated, intermittent exposures that continue daily for more than 2 weeks.

Source: U.S. Department of the Army (see p. 34).

duration of exposure that deployed forces may encounter. This grouping provides a systematic means of focusing research. For example, the primary focus of research will be to identify low-level concentrations and associated effects for temporary exposures, as this is the most probable exposure duration anticipated. Long-term exposures to chemical agents, however, are relatively unlikely, and thus of lower priority for research. The time period of interest used by planners at the U.S. Army Center for Health Promotion and Preventive Medicine (Aberdeen Proving Ground, Maryland) is generally between 6 and 48 hr. As previously noted, duration of exposure will be variable for almost any scenario. One area of research interest is to further investigate the relationship of the concentration and time (Ct) variables to provide more accurate information to the operational and developer community.

3.1.1.3 Low-Level Exposure Concentration

A low-level exposure represents the level(s) below which there is low risk to human health. For purposes of evaluating and establishing DoD policies, doctrine, and research needs, "benchmark" concentrations are developed in accordance with the best available scientific data and risk assessment techniques. A methodology has been developed by a national advisory committee, which was established under Public Law 92-463 for interpreting toxicological data and deriving acute human exposure concentrations, referred to as acute exposure guideline levels (AEGLs). The committee is responsible for developing AEGLs for TICs. AEGLs are designed to make protective action decisions for the general public in the event of chemical releases — accidental occurrences or intentional terrorist acts. AEGLs reflect temporary exposure duration (10 min to 8 hr) for three levels of severity that are compatible with the range of military low-risk operational definitions (Table 3.3).

3.1.2 Uncertainties in Risk Assessment and Research Considerations

A key challenge for the scientific community is to develop a valid methodology and appropriate toxicological principles for predicting CWA dose–response effects over longer exposure times and at lower concentrations. A valid methodology requires developing techniques that are verifiable and defensible aimed at providing consistent and accurately measuring agents in a test chamber. To date, researchers have encountered technical challenges in generating a constant low level of chemical agents for long exposure periods and developing sampling and analysis methods to verify low-level exposure concentrations within a test chamber throughout the exposure period. Table 3.4 describes several risk assessment uncertainties that will have to be addressed when applying laboratory data to real-world scenarios.

3.1.3 Summary of Existing/Recently Proposed Air Standards

Tables 3.5 and 3.6 summarize the current status of various existing standards and provide the concentration levels and their designated application by type of population and designated time period for which the concentration applies. Very simply, the shorter the duration, the higher the concentration of a given substance

Table 3.3 Range of Low-Level Concentration and Corresponding Effects

Critical (C), AEGL-3

Above critical concentration level:
Significant fatalities (this is above low-level range).

At critical concentration:
Defines threshold for fatalities (few personnel impacted this severely, immediate effects). High end of "low-level" range.

Between critical and marginal concentration levels:
Severe immediate effects (functional decrement, may require medical attention); and/or severe transient effects, and/or probable concern for permanent/chronic health effects.

Marginal (M), AEGL-3

At marginal concentration level:
Threshold for which initial cases of severe and/or permanent health effects may occur in exposed population.

Between marginal and negligible concentration levels:
Some immediate/transient effects with mild functional decrement, limited medical attention required, and/or possible concern for permanent/chronic health effects.

Negligible (N), AEGL-1

At negligible concentration level:
Threshold for where initial signs/symptoms are initially anticipated in some members of exposed population.

Below the negligible concentration level indicates no anticipated biologically significant effects (below low-level exposure range). Biological markers for exposure are not by themselves considered significant effects.

Source: U.S. Department of the Army (see p. 34).

Table 3.4 Laboratory vs. Battlefield Exposure Conditions

Conditions	Laboratory	Battlefield
Weather (wind, humidity, temperature, air stability, precipitation)	Controlled, simple	Uncontrolled, complex
Sunlight	Artificial or none	Present (variable)
Topography	Fixed, simple	Variable, complex
Vegetation/soil	None	Varieties present
Chemical state	Vapors, aerosols, liquids (pure)	Vapors, aerosols, and liquids (likely to be contaminated)
Rate of exposure	Intermittent, continuous, sustained	Variable and intermittent
Personnel	None; animal models used	Personnel exposed and stressed (physiologically and psychologically)

Source: U.S. Department of the Army (see p. 34).

Table 3.5 Current Proposed Exposure Standards for General Population

Standard	Population	Exposure	H/HD/HT	GA	GB	GD/GF	VX	Lewisite
IDLH (immediately dangerous to life or health)	Civilian/DoD worker	One-time exposure	2	0.1	0.1	0.05	0.01	0.003
STEL (short-term exposure limit)	Civilian/DoD worker	Occasional 15-min exposure (4 times/day)	0.0004	0.0004	0.0004	0.0002	0.00004	NA
WPL (worker population limit)	Civilian/DoD worker	8 hr/day for 30 years, time-weighted average	0.003	0.0001	0.0001	0.00003	0.00001	0.003
GPL (general population limit)	Civilian population	24 hr/day, lifetime, time-weighted average	0.00002	0.000003	0.000003	0.000001	0.0000003	0.0001

NA, not available. Concentrations are listed as mg/m^3.

Source: U.S. Department of the Army (see p. 34).

Table 3.6 Proposed AEGLs: One-Time Exposures for Emergency Planning

Duration of One-time Exposure	H/HD/HT (mg/m^3)	GA (mg/m^3)	GB (mg/m^3)	GD/GF (mg/m^3)	VX (mg/m^3)
AEGL, Level 1 (Nonsignificant but possibly noticeable effects)					
10 min	0.4	(0.0069)	(0.0069)	(0.0035)	(0.001)
30 min	0.13	(0.0040)	(0.0040)	(0.0020)	(0.00033)
1 hr	0.067	(0.0028)	(0.0028)	(0.0014)	(0.00017)
4 hr	0.017	(0.0014)	(0.0014)	(0.0007)	(0.000041)
8 hr	0.008	(0.0010)	(0.0010)	(0.0005)	(0.000021)
AEGL, Level 2 (Could cause casualties)					
10 min	0.6	(0.087)	(0.087)	((0.044)	(0.015)
30 min	0.2	(0.05)	(0.05)	(0.025)	(0.0050)
1 hr	0.1	(0.035)	(0.035)	(0.018)	(0.0025)
4 hr	0.025	(0.017)	(0.017)	(0.0085)	(0.00063)
8 hr	0.013	(0.013)	(0.013)	(0.00065)	(0.00031)
AEGL, Level 3 (Could cause fatalities)					
10 min	6.1	(0.76)	(0.38)	(0.38)	(0.38)
30 min	4.2	(0.38)	(0.19)	(0.19)	(0.19)
1 hr	2.1	(0.26)	(0.13)	(0.13)	(0.13)
4 hr	0.53	(0.14)	(0.070)	(0.070)	(0.070)
8 hr	0.27	(0.010)	(0.051)	(0.051)	(0.051)

Note: Values in parentheses are taken from draft documents not yet published.

AEGL, acute emergency guideline level.

Source: U.S. Department of the Army (see p. 34).

that a person can tolerate. If repeated exposures over a long period of time are anticipated, the resulting daily average dosage will be lower than the stated average over a short period of time. AEGL levels are most pertinent to military applications.

3.1.4 Recommended Chemical Agent Concentration Criteria for Detectors

There are both scientific and political reasons that justify reassessment of current criteria. The USACHPPM has been careful to focus on realistic operational scenarios in this assessment. Current military detector capabilities may not immediately be able to meet all levels of the expanding range of what may constitute a "low-level" risk during military operations. Current equipment capabilities are generally adequate to identify and thus allow decision making regarding chemical agent exposures at the high end of the low-risk range. The lower end of that range, which would

include conservative estimates of the threshold for significant biological effects in the general population, is not yet achievable for all agents.

Therefore, the 10-min AEGL Level-1 concentration values for each agent should be established as alarm trigger points in developing new detectors. These concentrations should be detected in 10 min or less. The proposed capabilities of equipment currently in development (e.g., the U.S. military's Joint Chemical Agent Detector, a multimission chemical agent point detection system [JCAD]) aim to be near the low extreme of the low-level concentration range.

For equipment that is designated specifically for wartime use, setting alarms at higher thresholds may be warranted. The use of AEGL-2 or AEGL-3 values should be considered as thresholds and objectives. Future detectors should be able to continuously monitor airborne concentrations down to the designated 8-hr AEGL concentration. Table 3.7 lists capabilities and objectives of selected existing and development-stage detectors. The rationales for these recommended criteria include the following:

1. The values are scientifically defensible. These AEGLs are based on a scientifically acceptable method currently used for assessing other TICs.
2. The AEGLs are derived for scenarios that parallel military deployment scenarios. Exposure durations address the highest-probability exposure scenarios of military interest. Anticipated scenarios where military troops may be exposed to CWAs include a rare, if not one-time brief event, where exposure would last minutes to a maximum of hours. The three AEGL levels provide the necessary flexibility for military ORM decision making. Use of AEGLs prevents establishing a single, conservative "acceptable level" for each chemical, such as those designed for chronic lifetime exposure periods that are unlikely in military applications.
3. These values are protective of the general population. The AEGLs are designed for the general public, and thus are an appropriate way to ensure that more sensitive members of the deployed military population are being protected.

3.2 JOINT SERVICES OPERATIONAL REQUIREMENTS FOR CHEMICAL AGENT DETECTORS

The purpose of the Joint Services Operational Requirements (JSOR) (Table 3.8) for CWA detectors is to permit timely warning for people to don protective gear. Criteria for the Automated Chemical Agent Detection Alarm (ACADA), in use by the U.S. military, are based on the JSORs, which were established without considering airborne exposure limits (AELs). The JSOR values consider adequate advance warning time to escape the area without significant harm when the air contains a particular concentration of a target chemical. Detection technologies have not yet been developed to permit detection of lowest-level concentrations under the AEL criteria.

Another set of criteria for the Joint Chemical Agent Detector (JCAD) has been proposed. The JCAD includes the ACADA JSOR requirements. Detector sensitivity down to the AEL is being considered as technology progresses.

Table 3.7 Existing Detector Capabilities and Proposed Thresholds and Objectives Compared to AEGLs

Detector	Agent						
	GA	GB	GD	GF	VX	HD	Lewisite
Minicams/RTAP	—	0.0001	0.00003	0.00003	0.00001	0.00003	0.0006
ACAMs	—	0.0001	—	—	0.00001	0.001	—
DAAMs	—	0.0001	—	—	0.00001	0.001	—
Bubbler	—	0.0001	—	—	0.000001	0.003	0.003
CAM	0.03	0.03	0.03	0.03	0.01	0.1	2.0
Draeger	—	—	—	—	3–2.5	—	—
ICAD	0.5	0.5	0.5	—	—	10.0	10.0
M18A2	—	0.02	—	—	0.1	0.5	10.0
M21	3.0	3.0	3.0	—	—	150	150
M90	0.04	0.04	0.04	0.04	0.04	0.2	0.2
M256	—	0.05 mg/m^3	—	—	0.1	1–3	14
M256A1	—	0.005 mg/m^3	—	—	0.02	3.0	14
JCAD (Proposed)	0.001; <30 min (T); <15 min (O)	0.001; <30 min (T); <15 min (O); 0.001 mg/m^3 in <30 min (T); <15 min (O)	0.001; <30 min (T); <15 min (O)	0.001; <30 min (T); <15 min (O)		0.02; <30 min (T); 0.003 mg/m^3 in 15 min (O)	0.02; <30 min (T); 0.003 mg/m^3 in 15 min (O)

Note: Concentration values are listed as milligrams per cubic meter.

AEGL, acute emergency guideline level; O, objective; T, threshold.

Source: U.S. Department of the Army. Army Regulation AR-385-61: The Army Chemical Agent Safety Program, Safety, 28 February 1997.

Table 3.8 Joint Services Operational Requirements for Point Sampling Detectors

Agent	Threshold Exposure Concentration (mg/m^3)	Threshold Exposure Response Time Maximum(s)	Relative Humidity (% RH) Range	Temperature Range (°C)
VX	1	10		
	0.04	90	5 to 100	–10 to +49
	0.1	30		
GA, GB, GD, GF	1	10	5 to 100	–30 to +49
	0.1	30		
HD, L, HN3	50	10	5 to 100	–18 to +49 (for HD)
	2	120		–18 to +49 (for L)
				+15 to +49 (for HN3)
AC	2500	10	5 to 100	–32 to +49
	22	60		
CK	20	60	5 to 100	–32 to +49

Source: U.S. Department of the Army. Proposed JCAD operational requirements Appendix A of JCAD Study Plan (Draft) 6/11/1998 modified for contractor distribution.

The JSORs are frequently mentioned in this chapter. These figures are used as guidelines for developers of modern detection instruments, and also serve as evaluation guidelines under most test programs.

3.2.1 JCAD Requirements and Rationales

The JCAD is expected to replace ACADA detectors used in the field. In order to develop a methodology for testing the JCAD, it was necessary to establish specific test temperatures and associated relative humidity levels. JCAD performance specifications are based on the aforementioned recommended criteria. The operational temperature range is from −32°C to 49°C together with relative humidity ranging from 5% to 100%.

The JCAD also has performance requirements to simultaneously detect, identify, and quantify CWA vapors at various concentration levels while in the presence of chemical interferents. This detector's performance requirements integrate dynamic agent concentration profiles and provide dosage measurements. As of this writing, a completely verified test system for evaluating JCAD performance does not exist.

To meet that goal, the government formed the Test Implementation Working Group that in turn established the Test Methodology Working Group (TMWG) to determine the methodology to be developed, validated, and verified in JCAD testing. Test methodology development (TMD) addresses chemical agent identification and detection requirements under JCAD performance specifications.

After reviewing existing and required test facility capabilities, the TMWG identified TMD in the following areas:

- Simultaneous generation of two agent vapors at two or more constant concentration levels with one or more chemical interferents at two or more concentration levels
- Simultaneous generation of two agent vapors at two or more dynamic concentration profiles with one or more chemical interferents at two or more levels
- Characterization of chemical interferents at two or more concentration levels
- Quantification of agent concentrations and dosage (integration of concentration over time) to the best available accuracy at the time of measurement with chemical interferents present
- Quantification of moving integration of agent concentrations and monitoring of hazard levels to the best available accuracy at the time of measurement with chemical interferents present
- Monitoring and recording of unit-under-test performance attribute data
- Quantification of TICs

In addition, the test system shall collect and process test data to calculate estimates of the following:

- Accuracy of measured agent concentrations and dosages
- Mean and standard deviation of exposure response times for controlled exposure agent concentration levels
- Magnitudes of any interactions and effects of controlled factors (humidity, temperature, agent type, agent concentration, dynamic profile, chemical interferent type, chemical interferent concentration) on observed performance (measurement of agent concentrations, dosage, hazard level, detection and identification response times, and time needed for reset after alerts) of the unit under test
- Probability of detection and identification of each agent or simulant as a function of agent or simulant concentration
- Probability of a false alarm and estimate of the mean time between false alarms (MTBFAs)
- Characteristics of conditions related to false alert events

3.3 OBJECTIVE AND APPROACHES AT DUGWAY PROVING GROUND

Approaches to address the above needs are included here as examples to illustrate critical requirements for proper detector evaluation. The basic technical approach to vapor generation and monitoring at Dugway Proving Ground (DPG; under the U.S. Army Test and Evaluation Command, located in Utah) is to use an evaporative disseminator for vapor generation with MINICAMS® and/or MIRAN® for "real-time" monitoring. Sorbent tubes and gas chromatography (GC) analysis are used for obtaining integrated vapor concentration measurements.

A limited amount of engineering takes place prior to each validation and verification phase. This involves determining agent–air mixtures, control settings, and instrument configurations required to achieve desired vapor concentrations. Modifications to the detector testing system (DTS) could include reconfiguring

instrumentation and controls, changing dilution airflow rates, or modifying the vapor dissemination device currently in use.

JCAD performance specifications cover a wide range of agents, concentrations, temperatures, humidity, and chemical interferents. A complete matrix to test the full envelope of performance would be impractical and cost prohibitive. Therefore, the statistical experimental design is crucial for reducing the matrix without sacrificing statistical validity, while also ensuring validity of the developed test methodology. The seven TMD areas stated earlier are discussed below.

3.3.1 Simultaneous Constant Agent Vapor Concentration Generation

Objective: To generate and maintain constant vapor concentrations for two agents simultaneously. Concentrations will be at the key performance and threshold detection levels for testing. Generation of objective levels will be evaluated in follow-up testing.

Approach: The DTS is currently configured to generate key performance level concentrations, which were demonstrated individually during ACADA testing. Generating the threshold and objective concentration levels will be achieved by increasing the quantity of dilution air, reducing the surface area of evaporating agent, and/or using a diffusion-tube disseminator. Simultaneous generation of two agent vapors at key performance concentration levels is of primary concern; simultaneous generation of two agent vapors at threshold concentration levels is of secondary concern; simultaneous generation of two agent vapors at objective concentration levels is of tertiary concern. Simultaneous generation of two agent vapors will be accomplished using evaporative vapor generators or diffusion tube generators in parallel.

3.3.2 Simultaneous Dynamic Agent Vapor Concentration Generation

Objective: Simultaneously generate two agent vapors with independently varying concentration profiles. Concentration profiles will include key performance and threshold detection levels for Phase I testing; generation of objective levels will be evaluated for Phase II testing.

Approach: Dugway Proving Ground proposes to use two evaporative vapor generators operated in parallel to generate agent vapors. Agent vapor concentrations will be controlled by adjustments of dilution air feed rates.

3.3.3 Characterization of Chemical Interferents

Objective: To generate and adequately control concentration levels of chemical interferent vapors.

Approach: DPG proposes the use of an evaporative disseminator to generate chemical interference vapors. DPG proposes to use either MIRAN or other organic vapor analyzer to monitor the chemical interferent, which will enable DPG to generate chemical interferent vapors reproducibly.

3.3.4 Quantification of Dosages

Objective: The test system will quantify agent dosages independently of the item under test.

Approach: DPG will use the data from near-real-time agent monitors and supplemental sorbent tube and/or bubbler samples to quantify the dosages presented to the units under test. This data will be collected, stored in the test database, and compared to the values reported by the units under test.

3.3.5 Quantification of Hazard Levels

Objective: The test system will quantify agent hazard levels independently of the unit under test.

Approach: DPG will use data from the near-real-time agent monitors along with the algorithm for calculating hazard levels to quantify the hazard level for the agent presented to the units under test.

3.3.6 Data Monitoring and Recording

Objective: The test system will monitor and record appropriate test data and data from the units under test, and then store the data in a database. The data will be organized and reported in a fashion that will support and simplify assessment of the performance of the unit under test.

Approach: DPG will use the existing DTS data collection system to collect all test data and item-under-test data. The system will be customized for the JCAD test. The data will be stored in the existing database system. Data may also be stored in a relational database system to aid in data analysis. Data reporting formats will be developed specifically for the JCAD test project.

3.3.7 Quantification of TICs

Objective: The test fixture will be capable of generating and quantifying vapors of TICs to determine the ability of the unit under test to detect and quantify the vapor.

Approach: DPG proposes to treat the requirement for TICs as if they were additional CWAs. The test system will have the same capabilities for the TICs as for the CWAs.

3.4 JCAD REQUIREMENTS FOR DETECTION AND IDENTIFICATION FUNCTIONS

Appearing below are selected requirements for the development of future detection devices such as the JCAD. As mentioned previously, the JCAD is intended to be widely deployable to replace or complement the ACADA. The JCAD must be able to detect and identify numerous CWAs and selected TICs.

3.4.1 Detection and Identification

The JCAD shall automatically and simultaneously detect, identify, and quantify chemical vapor by class (nerve, blister, and blood, and TIC) and specific agent (GA, GB, GD, GF, VX, HD, L, HN3, AC, CK, and possibly some TICs). It shall detect and provide an alert for nerve agent vapors, blister agent vapors, and blood agent vapors within the response times at constant concentration exposures listed in Table 3.9. These requirements are to be incorporated in requirements for future detector certification. TICs' alerts are not a requirement at present. Ability to detect TICs may be desirable however.

3.4.2 Sampling Requirements and Additional Challenges

Sampling, although seemingly simple, is perhaps one of the most difficult steps in chemical and biological agent detection. Problems arise in ensuring that the sample taken represents the media sampled, which in turn depends on proper mixing. Concentrators must be developed that can circulate great quantities of air without clogging or losing effectiveness, and that can concentrate the desired molecules. Recognizing and removing environmental interference and background effects, such as those due to geographical and temperature variability, are also necessary.

Sensors and detectors require different technology according to usage. Even the smallest tabletop mass spectrometer in a standard research laboratory cannot be converted into a rugged, lightweight model that a soldier, HAZMAT team member, or first responder could carry. Room-temperature detectors; label-free detection (e.g., without fluorescent beads); and low-cost, real-time analysis of airborne particles are barriers to widespread monitoring of chemical and biological weapons in public areas. Other obstacles that need to be surmounted by chemists and chemical engineers include improved nanoscale fabrication methods, better microfluidics and macro–micro scale interfaces, better high-throughput screening, more efficient heat exchangers, and lighter batteries. Engineering challenges include integrating new technological components into a useful finished product.

To develop robust sensors, a multidisciplinary systems approach must be taken. Experimentalists, statisticians, engineers, and data analysts must be included from the beginning (conceptual stage) to the end (using the sensor in the field). Well-designed experiments are crucial in developing sensor field worthiness, with statisticians as close collaborators of chemical and biological scientists. Actual and potential interference must be identified and dealt with through hardware design, multiple sensor types, or multivariate techniques, or through software development such as statistical analysis. Sensor calibration and drift caused by environment conditions must be addressed and corrected either mathematically or through hardware design.

Once developed, detectors and sensors must be tested according to strict criteria. A well-defined and very demanding set of test standards initiated by the DoD, including limits of detection, has been in place for the last 15 years. The U.S. Army periodically offers the opportunity for realistic field testing, and wind tunnel testing is available at several sites. It is imperative that scientists take advantage of existing resources for technology validation. It would be useful to develop new, integrated

Table 3.9 Single-Dose Hazard Levels

Hazard Levels	GA	GB	GD,GF	VX	HD
None: 2–10-min exposure in mg-min/m^3	≤0.05[a]: concentration is ≤0.005 mg/m^3 for 10-min exposure; ≤0.025 mg/m^3 for 2-min exposure	≤0.05[a]: concentration is ≤0.005 mg/m^3 for 10-min exposure; ≤0.025 mg/m^3 for 2-min exposure	≤0.02[a]: concentration is ≤0.002 mg/m^3 for 10-min exposure; ≤0.01 mg/m^3 for 2-min exposure	≤0.009[a]: concentration is ≤0.0009 mg/m^3 for 10-min exposure; ≤0.0045 mg/m^3 for 2-min exposure	≤2.5[a]: concentration is ≤0.25 mg/m^3 for 10-min exposure; ≤1.25 mg/m^3 for 2-min exposure
Low: Protection from symptoms, including miosis, conjunctivitis, rhinorrhea, and tightness in chest; 2–10-min exposure in mg-min/m^3	>0.05 and <0.5: For alert — minimum concentration to detect is 0.005 mg/m^3 for 10-min exposure; maximum concentration is 0.25 mg/m^3 for 2-min exposure	>0.05 and <0.5: For alert — minimum concentration to detect is 0.005 mg/m^3 for 10-min exposure; maximum concentration is 0.25 mg/m^3 for 2-min exposure	>0.02 and <0.2: For alert — minimum concentration to detect is 0.002 mg/m^3 for 10-min exposure; maximum concentration is 0.1 mg/m^3 for 2-min exposure	>0.009 and <0.09: For alert — minimum concentration to detect is 0.0009 mg/m^3 for 10-min exposure; maximum concentration is 0.045 mg/m^3 for 2-min exposure	>2.5 and <25: For alert — minimum concentration to detect is 0.25 mg/m^3 for 10-min exposure; maximum concentration is 12.5 mg/m^3 for 2-min exposure
Medium: Mask to protecting lungs; 2–10-min exposure in mg-min/m^3	≥0.5: For alert — concentration is >0.05 mg/m^3 for 10-min exposure; >0.25 mg/m^3 for 2-min exposure	≥0.5: For alert — concentration is >0.05 mg/m^3 for 10-min exposure; >0.25 mg/m^3 for 2-min exposure	≥0.2: For alert — concentration is >0.02 mg/m^3 for 10-min exposure; >0.1 mg/m^3 for 2-min exposure	≥0.09: For alert — concentration is >0.009 mg/m^3 for 10-min exposure; >0.045 mg/m^3 for 2-min exposure	≥25: For alert — concentration is >2.5 mg/m^3 for 10-min exposure; >12.5 mg/m^3 for 2-min exposure
High: Suit protecting skin; to 30–50-min exposure in mg-min/m^3	≥1000: For alert — concentration is ≥20 mg/m^3 for 50-min exposure; ≥33 mg/m^3 for 30-min exposure	≥600: For alert — concentration is ≥12 mg/m^3 for 50-min exposure; ≥20 mg/m^3 for 30-min exposure	≥150: For alert — concentration is ≥3 mg/m^3 for 50-min exposure; ≥5 mg/m^3 for 30-min exposure	≥5: For alert — concentration is ≥0.1 mg/m^3 for 50-min exposure; ≥0.17 mg/m^3 for 30-min exposure	≥25: For alert — concentration is ≥0.5 mg/m^3 for 50-min exposure; ≥0.83 mg/m^3 for 30-min exposure

[a] No observable adverse effect level.

Source: U.S. Department of the Army. JCAD Study Plan for Test Methodology Development Modified for Contractor Distribution, Final Draft 6/11/1998.

multiple-source databases to create chemical and biological agent libraries for quick agent identification and access to neutralization methods. Libraries already exist in many individual agencies, and there is a need for consolidation. Sharing existed data among various agencies would prevent repetitive expenditures to seek the same information. Consolidation of data sharing is most cost effective to free funds for additional researches.

3.5 GENERAL CAPABILITIES NECESSARY TO MITIGATE VULNERABILITY

Capabilities of existing commercial sensors are limited. Most manufactured sensors are designed for use in specific environments to detect compounds of their interest. Sensor systems that can detect a large number of chemicals are needed at present. Given the high toxicity of the CWAs and TICs, detection sensitivity of many existing sensors must be improved significantly.

Sensors to assist authorities in determining when a site is safe for normal functions to resume are required for postincident management. For that to happen, detection sensors must have significantly increased specificity and sensitivity beyond any currently available systems.

Consequently, various subsystems will also be needed to support the development of these more sensitive instruments. Systems for reliable sample collection, sample processing, and presentation of chemicals to sensors are essential. Standardized methodologies are needed. Systematic quality assurance of sensor evaluations can only be achieved through standard methodologies that have proved successful. Toward this end, the National Institute of Standard Technologies (NIST) is in the process of generating the standard testing protocol under which all future detection devices shall be tested for certification.

The U.S. government supports research of these sensors mainly through the DoD, National Science Foundation, and Department of Energy. Sensor development is also heavily supported by private industry. New sensors or technology improvements are hitting the market fairly rapidly through these research efforts. However, none of the current technologies has had any real impact on emergency preparedness. For sensors to be effectively implemented, they will have to be fairly inexpensive, widely deployable, and networkable.

Development of sensors that can detect and identify the release of toxic materials must continue. Effective responses to the specific agent involved in a chemical attack can only be achieved through the correct choice of sensors for the job, which in turn is crucial for effective consequential management including orderly evacuation to minimize casualties. Therefore, a program with sustained funding to focus and coordinate research and development on sensors and sensor networks, with an emphasis on fielding systems, is needed.

The following sections provide an example of how a detection device is tested in general to qualify as a viable device. The protocol was developed specifically for the DPP for detector evaluation. Although the protocol is limited in scope, it has demonstrated effectiveness in general characterizations of devices tested thus far. It

has been well accepted, and therefore has been proposed to the NIST to serve as a platform for its detector testing protocol.

3.6 EVALUATION OF COMMERCIALLY AVAILABLE DETECTION DEVICES FOR CERTIFICATION AS CWA DETECTORS

3.6.1 Background

In 1996, the DoD established the DPP. One of its objectives is to enhance federal, state, and local emergency responders' capabilities to respond to nuclear, biological and chemical terrorism incidents. Emergency responders who encounter a potentially contaminated area must survey the area for the presence of toxic compounds, including CWAs and explosives. Vapor content detectors commonly used or commercially available must be evaluated for their ability to effectively detect and identify CWAs.

Under the DPP Expert Assistance (Test Equipment) Program, the SBCCOM established a program to address this need. The Applied Chemistry Team, formerly known as the Design Evaluation Laboratory at Aberdeen Proving Ground in Edgewood, Maryland, has been conducting detector testing for the DPP for several years. The Applied Chemistry Team is tasked with providing the necessary information to aid authorities in selecting detection equipment applicable to specific needs.

The Department of Commerce, NIST's Office of Law Enforcement Standards (OLES), and SBCCOM amended Interagency Agreement MO2398 to develop standards for testing chemical and biological detection and protective equipment for first responders. The task includes validating test methods through testing representative items, documentation of test procedures, and development of a laboratory consortium with the OLES/NIST for chemical and biological detector certification testing.

3.6.2 Proposal

A proposed protocol submitted to the NIST committee for consideration is described below. Most, if not all, elements of the protocol are expected to become requirements for future certification as a viable CWA detection device. Techniques described in this protocol serve as approaches that laboratories may follow. While suggested methodologies may not be the only or the best that are available, they have been thoroughly employed and have demonstrated highly satisfactory results for many years. Any deviation from these procedures must be thoroughly proven valid before use. That is the procedure must not cause artifacts. The ultimate objective is to evaluate the test item with the following questions in mind:

- Can the detector establish how clean the environment is? Can the measurements provide both concentration and dosage to verify concentration and degree of hazard?
- For missions of various durations, what level of decontamination is desired and does the detector provide capability to these levels?

The assessment includes identification of specifications and requirements that could improve the description of necessary detection capabilities.

3.6.3 Purpose

Techniques in CWA vapor generation, sample analytical procedures, testing procedures, and documented target detection and identification sensitivities are to serve as minimum guidelines for laboratories that conduct certification testing of detection devices. The DPP evaluation protocol is designed to characterize the CWA vapor detection capability of the candidate detector. Because covering all CWAs is impractical, agents used in testing include tabun (GA), sarin (GB), and mustard (HD) because they are believed to be the most likely threats. The protocol is limited to permit screening of devices within reasonable time and budget constraints.

Although the above three agents are to be tested only during initial screening, the candidate device must be fully programmed to include detection algorithms for all other agents that it is intended to detect. Testing for other agents will be added depending on performance of the device in the initial screening.

Test procedures and concepts used in the DPP program follow:

1. For each selected CWA, determine the minimum concentration levels (minimum detectable levels, MDLs) where repeatable readings are achieved using JSORs for point sampling devices as a guide for detection sensitivity objectives. The MDL is determined at ambient temperature and 50% relative humidity.
2. Determine the detector response for each CWA at ambient temperature at various RH levels and temperature extremes to investigate the effects of humidity and temperature on detector behaviors.
3. Observe the effects of potential interference with commonly found substance vapors to assess the ability of the detector to perform both in the laboratory and in the field.

3.6.4 General Test Protocol

A candidate device is evaluated according to the following minimum criteria.

3.6.4.1 Operating Characteristics

Startup characteristics and time required for the detection device to achieving readiness for reliable operation in various environments are observed. Total time to readiness (reliable performance) must be reasonably short. Detectors must be relatively easy to operate.

3.6.4.2 Device Sensitivity

Each device is challenged with concentrations of the CWA/compound vapor to determine its threshold sensitivity using a vapor generated under controlled atmospheric conditions. The threshold concentration is defined as the concentration of the substance at which an alarm within 2 min of exposure time or a definitive

detection is observed. CWA vapor concentrations are determined by appropriate analytical methods.

The determined threshold concentration level or minimum detectable level (i.e., MDL) is used in subsequent tests at various humidity and temperature conditions. MDL is determined based on detection occurrence with a minimal target substance dosage. For example, a longer exposure time is permissible if the device can demonstrate capacity to detect the target substance at a lower concentration to produce the lowest concentration/time relationship (Ct).

Testing the device with higher vapor concentration levels produces information on its ability to quickly provide the necessary warning to minimize exposure dosage and to clear out vapor residue after contamination. Detectors are tested at low, medium, and high concentration levels to generate response curves.

Current JSOR point-detection target sensitivities for the JCAD, as shown in Tables 3.9 through 3.13, serve as guides for candidate detector tests to follow. These targeted concentrations were developed according to the relative toxicity of each CWA and the current state-of-the-art in detectors. JCAD requirements are extensions of the JSOR requirements for the ACADA; JCAD includes even lower concentration detection, with AEL detection as an ultimate goal.

Tables 3.9 through 3.13 provide the required detection performance of devices designed for a specific sensitivity range. Table 3.9 shows the exposure dosage that will cause physiological effects. IDLH concentrations and AELs serve as guides for appropriate protective equipment requirements. AEL values are currently considered permissible exposure levels for up to 8 hr without special protection. IDLH levels for GA and GB are 0.2 mg/m^3 (0.030 ppm) and 0.2 mg/m^3 (0.035 ppm), respectively. An IDLH for HD has not been established due to concerns about carcinogenicity. AELs for GA, GB, and HD for persons without masks are 0.0001 mg/m^3 (0.00002 ppm), 0.0001 mg/m^3 (0.00002 ppm), and HD (0.003 mg/m^3 or 0.0005 ppm), respectively.

Table 3.10 Maximum Response Time at IDLH and Higher Concentrations

Agent	Threshold Exposure Concentration (mg/m^3)	Threshold Exposure Response Time Maximum(s)	Relative Humidity (% RH) Range	Temperature Range (°C)
VX	1 0.04 0.1	10 90 30	5 to 100	–10 to +49
GA, GB, GD, GF	1 0.1	10 30	5 to 100	–30 to +49
HD, L, HN3	50 2	10 120	5 to 100	–18 to +49 (for HD) –18 to +49 (for L) +15 to +49 (for HN3)
AC	2500 22	10 60	5 to 100	–32 to +49
CK	20	60	5 to 100	–32 to +49

Source: U.S. Department of the Army (see p. 42). JCAD Study Plan (draft 5/11/94).

Table 3.11 Maximum Response Time at Low Concentrations

Agent	Threshold Exposure Concentration (mg/m^3)	Threshold Exposure Response Time Maximum(s)	Relative Humidity (% RH) Range	Temperature Range (°C)
VX	0.001	1800	5 to 100	–10 to +49
GA, GB, GD, GF	0.001	1800	5 to 100	–30 to +49
HD, L, HN3	0.02	1800	5 to 100	+15 to +49
AC	NA	NA	5 to 100	–32 to +49
CK	NA	NA	5 to 100	–32 to +49

NA, not available. To be determined.

Source: U.S. Department of the Army. Appendix A of JCAD Requirements Study Plan modified for contractor distribution (draft 6/11/98).

Table 3.12 Objective Maximum Response Time at AEL Concentrations of Selected Agents

Agent	Exposure Concentration (mg/m^3)	Exposure Response Time Maximum(s)	Relative Humidity (% RH) Range	Temperature Range (°C)
VX	0.00001	900	5 to 100	–10 to +49
GA, GB, GD, GF	0.0001	900	5 to 100	–30 to +49
HD, L, HN3	0.003	900	5 to 100	+15 to +49
AC	NA	NA	5 to 100	–32 to +49
CK	NA	NA	5 to 100	–32 to +49

AEL, airborne exposure limits; NA, not available. To be determined.

Source: U.S. Department of the Army. Appendix A of JCAD Requirement Study Plan modified for contractor distribution (draft 6/11/98).

Tables 3.10 through 3.12 show desired maximum detection time versus concentration levels ranging from the IDLH to targeted detection capability at AEL concentrations for respective CWAs. Table 3.13 lists the desired minimum concentration level applicable to the general public. These numbers are considered wishful thinking at this time. Efforts should be focused on the more realistic goal of reaching AEL detection and verification with reliability.

Results from certification testing will be compared to the above values to assess the relative usefulness of the detection device in general. The MDL determined places the device in its proper category.

To compare detector sensitivities, respective LDL concentrations and detection times are plotted along the vertical and horizontal axes, respectively. Constant dosage measurements are plotted along the lines determined by the following equation:

$$K_d = \text{Dosage} = \text{Concentration (C)} \times \text{Time} = \text{Ct (mg-min/m}^3) \qquad (3.1)$$

The following single-dose hazard levels are related to various observed effects on humans:

1. The concentration level that has no observed effect over a 1- to 14-day period. This is the short-term level for ocular or nasal vapor prescribed in military air

Table 3.13 Minimum Effect Concentrations of Selected Agents

Concentration (mg/m^3)	GA	GB	GD	VX	HD	L
Military air guideline — short-term, ocular or nasal vapor 1- to 14-day exposure	0.00001	0.00001	0.000003	0.000003	0.003	NA
Unmasked agent worker — 8-hr time-weighted average in any work shift (demonstration standard)	0.0001	0.0001	0.00003	0.00001	0.003	0.003
No effects concentrations in any environment	0.000003	0.000003	0.000003	0.000003	NA	NA
General population, 3-day time-weighted average	0.000003	0.000003	0.000003	0.000003	0.0001	0.003

NA, not available.

Source: U.S. Department of the Army. AR 385-61 The Army Chemical Agent Safety Program, Safety, 28 February 1997.

contamination guidelines. This level is plotted as the cut-off value for longer exposure time of hazard dosage level "none." It is this hazard dosage value that detectors should measure in a given environment.

2. The concentration level that has no observed effect over an 8-hr shift in an airborne agent work environment. This level is plotted as the 8-hr time weighted average (TWA) value that the detector should measure in work environments.
3. The single-dose hazard level after a 2- to 10-min exposure in which a soldier's fighting capability is not measurably affected. This level is the upper boundary of the "none" range.
4. The single-dose hazard level after a 2- to 10-min exposure below which miosis, conjunctivitis, rhinorrhea, and tightness in chest occur if the general population is exposed to the agent. This level is the upper boundary of the "low" range.
5. The single-dose hazard level in a 2- to 10-min exposure below which 50% of exposed soldiers show effects (ECt_{50}) if eyes and lungs are not protected. This level is the upper boundary of the "medium" range. This same dosage is the lower boundary of the "high" range in which dosages during a 30- to 50-min exposure will affect 50% of the population if eyes, lungs, and skin are not protected.

To our knowledge, there is no detector at present that has the capability of measuring guideline concentrations over a 1- to 14-day period or the safe exposure level developed for the general public. No instrument is specified at this level of detection. The 1- to 14-day exposures appear to be extremely low considering that the 8-hr TWA for workers in an environment where toxic agent(s) are used is 10 to 33 times higher.

3.6.4.3 Relative Humidity and Temperature Effects

Testing of detection capability at RH levels of less than 10%, 50%, and more than 90% and at temperature extremes (determined by the candidate's operable range) using the determined threshold concentrations are done to gain insights on the device's ability to perform in various environmental conditions. Desired performance targets are also listed in Tables 3.9–3.13. Targets are current JSORs in

developing the JCAD. Commercial detectors may not be able to meet military requirements. It is important to avoid exceeding the operable temperature and humidity range that the device was designed for during any evaluation.

3.6.4.4 Field Interference Test

The ability to detect a substance in the laboratory under clean, controlled conditions is insufficient to determine whether a detection device is useful. The units need to be tested in the field with common potential interference substances such as engine exhaust, burning fuels, and other burning materials such as common clothing and building materials. Such tests reveal potential problems under real-world operational conditions. Table 3.14 lists potential field interference substances tested.

Because testing CWAs in the open air is not possible, potential interfering substances are tested in the laboratory at controlled exposure levels. The detector's ability to detect the CWA vapor is tested in combination with potential interfering vapors at the 0.1% and 1% headspace saturation concentration level of interferent vapor, providing that the interferent does not cause the detector to alarm. Such testing reveals whether the detector issues false positive or false negative results.

Substance vapors that are considered potential interferents should be screened using a controlled generation technique. The headspace vapor of the substance is blended with an airstream to produce approximately 1% concentration of the interferents. If a false alarm occurs, the concentration is lowered to approximately 0.1% and retested. If a detector does not respond to the interference vapor, then the airstream is replaced with a stream of similar air that contains the target CWA in order to assess detection of the target under the influence of the interference vapor.

Even if a particular detector has CWA detection and identification ability, its usefulness is severely diminished if it shows a similar response to too many other substances. Table 3.15 lists common potential interference substances to be tested. Others can be added as necessary.

Table 3.14 List of Potential Field Interferents to be Tested Outdoors

Gasoline exhaust, idle	Insect repellent
Gasoline Exhaust, revved	Diesel vapor
Diesel exhaust, idle	Gasoline vapor
Diesel exhaust, revved	HTH (supertropical bleach, 107, calcium hypochloride) vapor
Kerosene vapor	Bleach vapor
Kerosene on fire	Burning cardboard
JP8 (jet fuel) vapor	Burning cotton
Burning JP8 smoke	Burning woodfire smoke
Burning gasoline smoke	Doused woodfire smoke
Burning diesel smoke	Burning rubber
AFFF (Aqueous Film Forming Foam) vapor	

Source: U.S. Department of the Army. Domestic Preparedness Program. Protocol for Detector Testing and Evaluation.

Table 3.15 Typical Substances Tested in Laboratory as Interferents

AFFF (Aqueous Film Forming Foam)	
Antifreeze	Vinegar
Household bleach	Windex™
Diesel fuel	Floor wax
Gasoline	Spray 9 cleaner™
Jet fuel-JP8	25-ppm ammonia
Toluene	

Source: U.S. Department of the Army. Longworth et al. Domestic Preparedness Program: Report on Testing of Commercially Available Detectors against Chemical Warfare Agents. (http://hldisbccom.army.mil).

3.6.5 Stability and Reliability

General observations made during the test program are sufficient to determine the relative stability and reliability of detector devices. Abnormalities and problems are recorded. No special stability or reliability runs are necessary during this preliminary testing. The stability or reliability of the instrument will be determined only after the instrument has demonstrated potential as a CWA detection device.

3.6.6 Remarks

The extent of this type of testing is limited to the abovementioned characterization criteria. Test conditions should not exceed a device's potential as provided by the manufacturer. The evaluation protocol is intended to provide an abbreviated and yet sufficient characterization of candidate devices to assess CWA detection capabilities to aid authorities in selecting equipment for CWA detection.

The scope of this type of test program suggests that statistical analysis is not necessary because each test point will be conducted with repetitions using multiple units. The comparative data collected will provide insight on device performance.

Of primary importance is the ability to detect the target CWA within acceptable time and concentration limits to protect the users such as first responders. The alarm threshold must be able to provide sufficient time for responders to don protective gear before they become casualties. Failure to meet this criterion is grounds for termination of further testing.

Also important is the ability to resist false alarms. False alarms could be expected in high-sensitivity detectors no matter what technologies are used. The key is to assess false alarm rates and the materials that caused the false alarms. If the device responds with false alarms too frequently when exposed to common substances, its usefulness is greatly diminished. Equally if not more important is the ability of a device to function properly while under the influence of interferent vapors. If a relatively large number of interferent vapors affect a device's ability to detect the target chemicals, its usefulness is also limited.

The tested device must be easy to operate and require minimal recalibration to produce reliable results after a period of storage. The ability to achieve operational stability within a short time after setup is an important criterion for usefulness to first responders in emergency situations.

Testing should be divided into phases. The first phase screens the device for CWA sensitivity at ambient temperature and humidity conditions after a successful startup procedure. The dosage derived from the product of substance concentration and alarm time determines whether the testing should continue to the next phase.

The second phase includes testing the device in various temperature and humidity conditions. Successful completion would then lead to additional testing with potential interference substances both outdoors in the field and in the controlled laboratory environment. Given successful results in the second phase, the testing should then be expanded to cover other agents and other features of the device.

3.6.7 CWA Sensitivity Testing

Agent vapor generation methodologies are described in "Vapor Generation Methods for Chemical Warfare Agents" (U.S. Army Edgewood Chemical and Biological Center, Maryland [ECBC], Technical Report 148, March 1998). Analytical techniques specific to manual sampling of the MINICAMS® appears in "Analytical Methodology for Quantitative Determination of O-ethyl S-(2-diisopropylaminoethyl) methylphosphonothiolate (VX)" (U.S. Army Edgewood Research, Development and Engineering Center [ERDEC], Aberdeen Proving Ground, Maryland, Technical Report 476, March 1998). These methodologies, which have been used for many years, were also successfully employed in DPP testing of various detection devices. Thus, they should serve as a guide for certification testing.

For generating vapor concentrations to test IDLH detectors, "Multipurpose Chemical Agent Vapor Generation System" (ERDEC, Technical Report 424, July 1997) provides details on techniques for laboratory generation of agent vapor, including methods for generation of agent plus interference vapors. The multistaged system that is required for generating a desired vapor concentration level is described in the ECBC's Technical Report 148 for testing AEL detection devices.

The preferred method for analyzing vapor concentration is described in ERDEC's report 476 (March 1998). This method uses manual sample collection such that the sample enters directly into the preconcentrator tube of the MINICAMS. This avoids sample loss through the sampling line to achieve the most accurate measurement. The collected sample is then thermally desorbed into the GC column for separation and quantification using appropriate peak detectors.

Other thermal desorption-GC devices could be used in a similar fashion. Systems like the Agilent Dynatherm-GC-FPD/MS® will also produce similar results. This type of instrument can be used when a MINICAMS is not available. Analysis times, however, will be substantially longer than required by the described MINICAMS method.

The system to be used must be calibrated using standards made from materials of known concentration, such as the Chemical Agent Standard Analytical Reference Materiel (CASARM), if available. The calibration curve for the instrument is developed through varying the amount of the substance injected. GC output from the vapor sample collected is then correlated with the calibration curve to derive the exact vapor concentration by dividing the amount determined over the volume (sampling rate $\times$ time) of the sample collected.

The thermal desorption technique has been used with success. It is probably the only technique that is capable of analyzing the extremely low AEL concentrations within a reasonably short time. However, the thermal desorption–GC method does have limitations for analyzing high-concentration vapors. Other techniques, such as sample collection through bubbling through liquid solvent with subsequent injection into the GC instrument will be required for analyzing concentration levels that exceed the capability of thermal desorption techniques. Capability is exceeded when a reasonable sample rate and time cannot prevent the result from overwhelming the GC instrument. Under these circumstances, the sample can be collected in a solvent through bubbling. The resulting solution can then be serially diluted into the range needed for the GC analysis. Vapor transport efficiency must be properly addressed when collecting sample using all types of techniques. The preferred method for maximum accuracy is direct sampling into the collection media without use of an external transfer line.

Regardless of the sampling methodology used, techniques in sample collection are important to ensure that the sample is collected properly. For example, sample collection through bubbling solvent to analyze a low concentration level requiring an extra long sampling time is not advisable. Inefficient sample collection and solvent loss can cause large errors.

3.6.8 Detector Testing

Depending on the type of detection device, different evaluation techniques are required to provide appropriate characterization. If the item has different modes of operations, each of them needs to be addressed separately. Instruments that have alarm features are tested for minimum detectable level (MDL) using the alarm time within 2 min as a criterion. Those that do not have alarm features would also use the criterion for obtaining the maximum response signal at a certain time within the 2-min exposure. A more specific evaluation procedure for each type of detector may be required.

3.6.9 Return of Materials Exposed to CWAs

According to Department of the Army pamphlet 385-61, "Toxic Chemical Agent Safety Standards," instruments that have been exposed to CWA materials must remain under control of the government. KYO initiated a waiver request through proper channels to permit the return of materials subjected to CWA exposure to the company that developed them. The next section presents a sample risk assessment that permitted developers to retake control over materials that had been subjected to CWA testing.

3.7 SAFETY RISK ASSESSMENT FOR RELEASE OF TESTED, CONTRACTOR-OWNED MATERIALS TO CONTRACTOR

The purpose of securing a risk assessment is to allow for contractor-owned items to be tested against chemical agent vapor in an Army test facility at the U.S. Army

Edgewood Research, Development and Engineering Center (ERDEC), and to be able to return the items to contractor control. Army Regulation 385-61, Chapter 5, 5-1e(4)(a) states:

> Items decontaminated to 3X level may not be released from Government control. Some items may be released from Government control if all Federal, State, and local provisions have been met and approval is granted by the MACOM Commander.

However, there exist Command memoranda that delegate the decision authority, based on the level of risk, from the Materiel Command (MACOM) to the Chemical Biological Defense Command (CBDCOM) commander, to the ERDEC technical director for low-risk hazards.

Traditionally, contractors submitted detectors of various configurations via contract with the government, and the government would own the prototype items. Once agent testing was complete, the items would be designated as 3X and remain under government control. Given private sector interest in chemical agent detection, and the thrust of test service agreements under which government test facilities are used by private companies, companies need to conduct prototype testing that may not be associated with government agencies. For example, under the Domestic Preparedness Detector Testing Program, contractors provide their detectors for testing, and upon test completion, remove their detectors from the government site. In this case, there would be no government control (i.e., ownership) as required for chemical-agent-exposed 3X items per AR 385-61.

This author, KYO, requested the ERDEC Safety Office to develop an avenue for risk assessment to address hazards associated with unrestricted release of detectors to be exposed to chemical agents under SOP #CR9-ISP022-97C. This SOP details how the detectors are exposed to the laboratory-generated agent vapors.

The ERDEC Safety Office has since performed risk assessments on various detectors brought to government facilities for testing. Such procedures, when followed, permit the return of contaminated items to manufacturers. In the following, assessments of two detectors, the MiniRae and the M43A1® upgrade, are used as examples of how risks were assessed. Tables 3.16 and 3.17 define hazard severity and probability levels used as the criteria for assessing risk.

Table 3.16 Hazard Severity

Description	Category	Definition
Catastrophic	I	Death, system loss, or severe environmental damage
Critical	II	Severe injury, severe occupational illness, or major system or environmental damage
Marginal	III	Minor injury, minor occupational illness, or minor system or environmental damage
Negligible	IV	Less than minor injury, occupational illness, or less than minor system or environmental damage

Source: U.S. Department of the Army. Army Regulation 385-61.

Table 3.17 Hazard Probability

Description	Category	Definition
Frequent	A	Likely to occur frequently
Probable	B	Will occur several times in lifetime
Occasional	C	Likely to occur during lifetime
Remote	D	Unlikely but possible to occur during lifetime
Improbable	E	So unlikely that it can be assumed hazard will not be experienced

Source: U.S. Department of the Army. Army Regulation 385-61.

3.7.1 Assessment Scenario

All detectors are subjected to vapor challenge with HD, VX, and at least one G-agent (GD, GB, or GA). The maximum detector sampling rate is 2.0 l/min. Trials for each agent will be conducted at 25°C with low, medium, and high humidity, as well as at high temperature (52°C), low temperature (−10°C to −30°C), and room temperature (25°C) with ambient humidity. There are three repetitive trials per detector for a total of 54 exposures (27 at low concentrations and 27 at higher concentrations) for each agent. The maximum exposure for each trial is 15 sec. The sequence of test temperatures is from low (first) to high (last). After testing, each detector will be operated in a clean hood for 24 hours and then monitored.

The following assumptions are made:

- All tube structures are in proper working condition, that is, there are no cracks, broken parts, or defects, such that the only components to come into contact with agent vapors are within the tubing assembly.
- All parts that come in contact with agent vapors and cannot be decontaminated, such as filters, sieve packs, and so on, are removed and disposed of accordingly after testing per the operational SOP.
- There are no new porous or highly absorptive or adsorptive materials being introduced into the detector that can come into contact with the agent in the airstream.
- No detector has been exposed to chemical agents prior to testing.

Internal components that contact the vapor stream in the MiniRae:

- 6 in. of Teflon® tubing in the inlet probe
- 1 in. of stainless steel connector
- Disposable filter consisting of a Teflon membrane supported by an aluminum ring
- 0.5-in.-thick Teflon sensor containing two thin stainless steel grids
- 3 in. of Tygon® tubing
- Hard plastic pump with ethylene propylene diene monomer (EPDM) diaphragm
- 3 in. of Tygon tubing
- 0.5 in. exit port of acrylonitrile-butadiene-styrene type (ABS) plastic

Internal components that contact the vapor stream in the M43A1 upgrade:

- Sieve pack assembly
- Cell module assembly
- Manifold assembly
- Inlet housing assembly
- Two pump assemblies
- Charcoal filter assembly
- Silicone tubing, gaskets, seals

Low-temperature testing presents the greatest likelihood of agent deposition on the internal tubing assembly. However, because high-temperature testing will be performed last and each detector will be run for 24 hr in a clean hood to flush the system, any agent deposition on the inside surface of the tubes will likely evaporate. Any residual hazards will most likely be from sorption of agent vapor or liquid agent deposited through the wall of the tube materials. Thus, during any subsequent disassembly, there is a chance of off-gassing chemical agents posing a potential hazard. Studies have shown that negligible sorption of chemical agents occurs in Teflon and hard plastic. In addition, tests carried out at Arthur D. Little laboratory suggest that plasticization by agents is unlikely, especially in low agent concentrations. The only source of agent sorption would be from the silicone and Tygon tubing.

In the MiniRae detector, the Tygon tube dimensions are 3/16 in. × 6 in., or 22.8 cm^2. Data from a previous study showed that for concentrations less than 100 µg/l approximately 60% of agents were sorbed in 3 min over the tube's 64.52 cm^2 surface area. Even though the experimental number was recorded only at 3 min, and the amount of sorption is probably not a linear function of time, initially the sorption would be slow until a steady state is achieved. The rate will then decrease when approaching saturation state. For safety purposes and to simplify the analysis, an average rate will be used even though the exposure duration per trial is relatively short (15 sec). By interpolation, the sorption rate for each agent at the "challenge concentration" is calculated as:

$$\text{Sorption rate } (\mu g/\text{min-cm}^2) = (0.6 \times (\text{amount of agent } (\mu g) \text{ in 1 liter})) / (64.52\ \text{cm}^2 \times 3\ \text{min}) \quad (3.2)$$

Results are tabulated in column three of Table 3.18.

Using the maximum sampling rate at 2.0 l/min and the maximum exposure time is 15 sec, the amount of sorption per trial is calculated by multiplying the sorption rate by the total inner surface area of the tube exposed (22.8 cm^2) and the exposure time (0.25 min). Results are shown in column four of Table 3.18.

After each test cycle, the detector is run on the average of 3 min at room temperature to clear out residues and reset for the next trial. Previous studies show that sweeping a contaminated surface with air will remove chemical agent deposited on the surface and/or dissolved in the matrix of the material. Therefore, it is reasonable to assume that some agent off-gasses from the tube. Assuming 80% retention

Table 3.18 Calculated Results for MiniRae Detector

Agent	Challenge Concentration (μg/l)	Sorption Rate (μg/min/cm²)	Amount of Sorption per Trial, *N* (μg)	$\sum_{i=1}^{27} N(8^i)$ (μg)	Total Sorption (μg)
G	0.1 (low)	0.00031	0.00177	0.00706	0.0777
G	1 (high)	0.0031	0.0177	0.0706	
HD	2 (low)	0.0062	0.0353	0.141	3.671
HD	50 (high)	0.155	0.884	3.53	
VX	0.04 (low)	0.000124	0.000707	0.00282	0.0734
VX	1 (high)	0.0031	0.0177	0.0706	

Source: U.S. Department of the Army. Safety Risk Assessment for Release of Tested, Contractor-Owned Material to Contractor, 1997.

Table 3.19 Calculated Results for M43A1 Detector

Agent	Challenge Concentration (μg/l)	Sorption Rate (μg/min/cm²)	Amount of Sorption per Trial, *N* (μg)	$\sum_{i=1}^{27} N(8^i)$ (μg)	Total Sorption (μg)
G	0.1 (low)	0.000233	0.00177	0.0071	0.0781
G	1 (high)	0.00233	0.0177	0.0710	
HD	2 (low)	0.00465	0.0354	0.141	3.66
HD	50 (high)	0.116	0.880	3.52	
VX	0.04 (low)	0.000093	0.00071	0.00282	0.038
VX	1 (high)	0.00233	0.0177	0.0710	

Source: U.S. Department of the Army. Safety Risk Assessment for Release of Tested, Contractor-Owned Material to Contractor, 1997.

of the sorbed agent, the total amount remaining in the Tygon is $\sum_{i=1}^{27} N(.8^i)$ for each test concentration level, where N is the amount being sorbed after each trial. Results are showed in column 5 of Table 3.18.

In the M43A1 detector, the silicon tube dimensions are 3/16 in. × 4 in. or 15.2 cm². Using the same analysis as for the MiniRae detector, the sorption rate for the silicone tube can be calculated based on a previous study, which showed 90% retention of agents for silicone (Table 3.19). The calculated dosages from exposures are listed in Table 3.20.

For the MiniRae detector, in worst-case scenarios, 0.0777 μg of G-agent, 3.68 μg of HD, and 0.0734 μg of VX can be retained in the tube. Respective concentrations would be 0.0000777 mg/m³ for G, 0.00368 mg/m³ for HD, and 0.0000734 mg/m³ for VX. These concentrations for HD and VX exceed AELs (in Army Regulation 385 61) by 20% and 700%, respectively. However, this assumes that all agents will be off-gassed into the air at once, whereas in the real world, such off-gassing is not rapid. In addition, as mentioned above, each detector is run in a clean hood for at least 24 hr prior to monitoring, thereby allowing even more off-gassing

Table 3.20 Dosage from Exposures

Agent	Challenge Concentration (mg/m^3)	Total Amount Passing Through Each Detector (mg)	AEL Value (mg/m^3)
VX	0.04 to 1.0	0.014	0.00001
GD	0.10 to 1.0	0.0149	0.00003
GB			0.0001
GA			0.0001
HD	2.0 to 50.0	0.702	0.003

AEL, airborne exposure level.

Source: U.S. Department of the Army. Safety Risk Assessment for Release of Tested, Contractor-Owned Material to Contractor, 1997.

to take place, lowering the potential amount of agent present. Finally, the SOP requires that monitoring be performed to ensure that the items are at the 3X level, and as contamination free as possible. Taking these considerations into account, the residual hazard remaining would be from VX off-gassing due to the high percentage ratio of amount sorbed to the AEL. Although the 0.0734 μg of VX does not present an appreciable liquid contact hazard, the tubing should still be considered potentially contaminated and should only be used under engineering controls. It is recommended that Tygon tubing in particular be disposed of and replaced prior to release of detector to the contractor.

For VX we can compare the maximum possible concentration given above as 0.0000734 mg/m^3 vs. a physical effects level of slightly less than 0.09 $mg\text{-}min/m^3$, where an effect like mycosis might become noticeable. Even when this level is dropped an order of magnitude, it would require 0.009 $mg\text{-}min/m^3$ divided by 0.0000734 mg/m^3, which is equivalent to 123 min of exposure for significant (e.g., noticeable effect that could be detected by the operator) exposure to occur with VX.

In the case of HD, using the maximum 2 $mg\text{-}min/m^3$ safe air concentration for the eyes, based on the MSDS, more than 2 $mg\text{-}min/m^3$ divided by 0.036 mg/m^3 (equivalent to 55 min of exposure) are necessary to pose a serious risk to the eyes.

However, the above concentrations could not be maintained for any significant length of time, since they rely on the concentration of both VX and HD to remain constant. Realistically, even in a worst case scenario, where there is no ventilation:

- Actual agent concentrations would be lower (e.g., off-gassing would proceed over time).
- There would be some movement of air about the room dispersing the agent.
- The agent would diffuse into the entire room, rather than remain confined at the concentrations mentioned above in the area where the worker is exposed.

Thus, even without the addition of engineering controls, the severity of the hazard is categorized as III, marginal.

Using similar calculations for chemical sorption of silicon tubing in the M43A1 detector in worst-case scenarios, 0.0781 μg of G, 3.66 μg of HD, and 0.0380 μg of VX could be sorbed in the tube. Again, using the same scenario as above with the MiniRae detector, if these amounts of agent are off-gassing into 1 m^3 of air, the

concentration would be 0.0000781 mg/m^3 for G, 0.00366 mg/m^3 for HD, and 0.0000380 mg/m^3 for VX. These concentration values are approximately the same as that of the MiniRae in the analysis. Therefore, severity and suggested recommendations would also be the same, and severity is also categorized as III, marginal.

If recommendations given below are implemented, particularly the 24-hr purge, monitoring to 3X levels, removal of porous parts exposed to the agent, and replacement of tubing, the probability of agent exposure for contractor personnel is categorized as D, "remote probability."

The greatest hazard risk is potential exposure of workers when they disassemble the detector and potentially release VX vapor agents. There is also a concern with respect to allowing any exposure to HD, no matter how minor, since it is a carcinogen. Since the VX value is higher than the AEL, and we want to minimize the possibility of any exposure to HD, the following recommendations should be provided to, and agreed on, by the contractors:

- Any initial disassembly operation will be done under a properly ventilated chemical fume hood.
- Workers will wear personal protective clothing and equipment (gloves, apron), and have an appropriate mask approved by the National Institute for Occupational Safety and Health (NIOSH) readily available.
- If there are signs of liquid depositions in the detector, those areas should be decontaminated with a 5% chlorine bleach solution immediately.

These actions should reduce the probability of exposing contractor personnel to any possible agent vapor even if there is an internal pathway leak to the electronic components because the hazard only consists of a single release when the unit is first opened.

In addition, the government and contractor effectively agree to accept a particular risk level before tested items are returned. ERDEC Engineering Directorate personnel agree to carry out the following activities on the contractor's detector after testing:

- Run the detector test from low to high temperatures to minimize residual agent condensing within the detector
- Ensure that any Tygon or silicone tubing, filters, or any porous materials within the air sampling path are removed and disposed of accordingly
- Decontaminate all detector surfaces
- Run each detector in a clean, agent-free chemical hood, for at least 24 hr after the last exposure
- Monitor the detector to the 3X level to ensure that there is no off-gassing of residual agents

When these activities are implemented, the risk to workers is categorized as low, at severity III and probability D.

Statement for Releasing of XXX Monitored Items to Contractor: "We, (contractor name), understand and acknowledge that while every precaution has been made to minimize the potential for any residual chemical agent material to be present internally to the detectors provided for testing, that there is a remote chance chemical

agent may be present. We, (contractor name), agree to take appropriate precautions when allowing personnel to deal with these items, to include incorporating initial disassembly conducted under engineering controls and with appropriate personnel protection to preclude any exposure. We, (contractor name), accept responsibility to ensure that personnel allowed access to these items are informed of previous testing until such a point that we have determined there is no residual hazard associated with these items. We, (contractor name), will also ensure that any entity, government or private, which we allow access to or which agree to purchase these detectors, are told of the potential risk associated with these items."