

**THE REUTTER/WADE TOXICITY REPORT AND
CSEPP CIVILIAN EMERGENCY PLANNING**

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Date published—April 1999

Prepared for the
Federal Emergency Management Agency

Prepared by
OAK RIDGE NATIONAL LABORATORY
Oak Ridge, Tennessee 37831
Managed by
LOCKHEED MARTIN ENERGY RESEARCH CORPORATION
For the
U.S. DEPARTMENT OF ENERGY
under Contract No. DE-AC05-96OR22464

CONTENTS

ACRONYMS AND ABBREVIATIONS	iv
ACKNOWLEDGMENT.....	vi
1. INTRODUCTION	1
1.1 BACKGROUND ON REUTTER/WADE REPORT.....	1
1.2 PURPOSE OF THE CURRENT ANALYSIS.....	1
2. SUMMARY OF MAJOR FINDINGS IN REUTTER/WADE REPORT	1
2.1 BACKGROUND.....	1
2.2 REUTTER/WADE REVIEWS.....	2
3. FUNCTIONAL AREAS THAT COULD BE AFFECTED	5
3.1 NO DEATHS LCt.....	5
3.1.1 Emergency Planning Zones.....	6
3.1.2 Protective Actions.....	7
3.2 IMMEDIATELY DANGEROUS TO LIFE OR HEALTH CONCENTRATION	7
3.3 EIGHT-HOUR AIRBORNE EXPOSURE LIMIT.....	8
3.4 CDC ACUTE THRESHOLD EFFECTS LEVELS.....	8
3.5 LCts	8
3.6 AGENT CONTROL LIMITS.....	9
3.7 INDIRECT EFFECTS	9
3.7.1 Alert/Notification.....	9
3.7.2 Location of Facilities.....	9
4. PUBLIC INFORMATION AND EDUCATION (RISK COMMUNICATION).....	10
4.1 EXPLANATION OF UPDATED CASUALTY ESTIMATORS.....	10

4.2 IMPLICATIONS FOR PUBLIC INFORMATION10

4.3 RISK COMMUNICATION RECOMMENDATIONS10

5. HEALTH EFFECT PARAMETERS AND CSEPP11

6. PARALLEL ACTIVITIES AND CIVILIAN APPLICATIONS.....11

6.1 NATIONAL RESEARCH COUNCIL.....11

6.2 INSTITUTE FOR DEFENSE ANALYSIS.....13

6.3 U.S. ARMY CENTER FOR HEALTH PROMOTION AND PREVENTIVE MEDICINE13

6.4 U.S. ARMY ENVIRONMENTAL CENTER.....14

6.5 NEW LABORATORY STUDIES15

7. RECOMMENDATIONS16

8. REFERENCES17

ACRONYMS AND ABBREVIATIONS

AEGL	acute exposure guideline level
AEL	airborne exposure limit
ANL	Argonne National Laboratory
ATEL	Acute Threshold Effects Levels
ASB	Army Science Board
BAST	Board on Army Science and Technology (National Research Council)
BEST	Board on Environmental Studies and Toxicology
CBDCOM	Chemical and Biological Defense Command
CDC	Centers for Disease Control
CDEPAT	Chemical Defense Equipment Process Action Team
CEELS	Community Emergency Exposure Levels
COT	Committee on Toxicology (National Research Council)
CSEPP	Chemical Stockpile Emergency Preparedness Program
Ct	cumulative exposure
CWC	Chemical Weapons Convention
d	day
D2PC	Army computer dispersion model
DCSOPS	Deputy Chief of Staff for Operations and Plans
DHHS	Department of Health and Human Services
DOD	Department of Defense
ECBC	Edgewood Chemical and Biological Center
ECt	Effective concentration time integral
ED	Effective dose
EOC	Emergency Operations Center
ERCP	emergency response concept plan
ERDEC	Edgewood Research, Development and Engineering Center
FR	<i>Federal Register</i>
FUDS	formerly used defense sites
GA	Nerve agent Tabun
GB	Nerve agent Sarin
GD	Nerve agent GD
GF	Nerve agent GF
h	hour
HD	sulfur mustard
IDA	Institute for Defense Analysis
IDLH	immediately dangerous to life or health
IEM	Innovative Emergency Management, Inc.
IOM	Institute of Medicine
IPT	Integrated Product Team
IRP	Installation Restoration Program
IRZ	immediate response zone
JIC	Joint Information Center
kg	kilogram
km	kilometer
LCt	maximum dosage that can be absorbed by individuals without death occurring (source pg. 6)
LCt	lethal concentration time integral
LD ₅₀	lethal dose
m	meter
m ³	cubic meter
mg	milligram
min	minute
MIST	Man-In-Simulant Test
mph	miles per hour
NAS	National Academy of Sciences

NIOSH	National Institute for Occupational Safety and Health
NRC	National Research Council
ORNL	Oak Ridge National Laboratory
OTSG	Office of the Surgeon General (U.S. Department of the Army)
PAZ	protective action zone
PAPR	powered air-purifying respirator
PMCD	Program Manager for Chemical Demilitarization
ppm	parts per million
R&D	Research and Development
s	second
SBCCOM	Soldier Biological and Chemical Command
SCBA	self-contained breathing apparatus
USACHPPM	U.S. Army Center for Health Promotion and Preventive Medicine
USAEC	U.S. Army Environmental Center
VX	persistent nerve agent (source p. 6)

ACKNOWLEDGMENT

Background and information on U.S. Army Center for Health Promotion and Preventive Medicine activities evaluating chemical warfare agent toxicity for various Army organizations were provided to the authors by Ms. Veronique Hauschild of the Center's Hazardous and Medical Waste Program. The authors appreciate and acknowledge the contributions of Ms. Hauschild and her staff in the development of this paper.

1. INTRODUCTION

1.1 BACKGROUND ON REUTTER/WADE REPORT

The Reutter/Wade analysis (Reutter and Wade 1994) was undertaken to improve the technical basis for assessing battlefield casualties from deployment of chemical weapons containing nerve and sulfur mustard agent payloads. The analysis sought to utilize available data and modern, accepted, toxicological methods to develop agent-specific casualty estimators for U.S. military forces. The authors also estimated qualitative confidence levels for each estimator based on the quality and quantity of the data.

For percutaneous and inhalation vapor exposures, the report estimated cumulative exposures necessary to achieve lethal (LC_{50}), severe (ED_{50}), threshold (percutaneous vapor only, EC_{t50}), or mild (nasal vapor, EC_{t50}) effects. For percutaneous liquid exposures, the report estimated lethal (LD_{50}) and severe (ED_{50}) doses. The vapor exposures necessary to achieve mild ocular effects were also estimated.

1.2 PURPOSE OF THE CURRENT ANALYSIS

This report examines potential implications of the Reutter/Wade study for off-site or civilian emergency planning in the Chemical Stockpile Emergency Preparedness Program (CSEPP) and summarizes principal findings of the Reutter/Wade report, the National Academy review of Reutter/Wade, and the Institute for Defense Analysis (IDA) expert panel assessment of Reutter/Wade casualty estimators. This report also identifies how estimates of human health effects are used in CSEPP, organized by functional planning topics. Finally CSEPP casualty estimators are considered in light of the Reutter/Wade work.

2. SUMMARY OF MAJOR FINDINGS IN REUTTER/WADE REPORT

2.1 BACKGROUND

The validity and accuracy of existing human toxicity endpoint estimates for several chemical warfare nerve and vesicant agents have often been questioned. The data on which these estimates are based were generated 20–60 years ago using experimental protocols that are much different than what would be considered acceptable in a modern toxicological study. Further, when compared with current reporting practices, available documentation for current toxicity values is inadequate and incomplete. Some toxicity values in use are preliminary values that were never finalized.

As a consequence, the Department of the Army established a Chemical Defense Equipment Process Action Team (CDEPAT) to examine this issue shortly after the close of the Gulf War. The CDEPAT requested that staff of the (then) Edgewood Research, Development and Engineering Center of the Chemical and Biological Defense Command (CBDCOM) (now, the Edgewood Chemical and Biological Center, or ECBC, of the Soldier Biological and Chemical Command, or SBCCOM) conduct an extensive review of the scientific basis of the existing toxicity values. This effort was documented in the 1994 draft report *Review of Existing Toxicity Data and Human Estimates for Selected Chemical Agents and Recommended Human Toxicity Estimates Appropriate for Defending the Soldier* (Reutter and Wade 1994); this document is now commonly known as “Reutter/Wade.” Because of the use and citation of some classified reports from non-U.S. sources, the entire Reutter and Wade document is

classified SECRET. In the analysis by Reutter/Wade, original data were obtained where possible and re-analyzed using contemporary methods, and the updated results were compiled. Many of the revised toxicity estimates in Reutter/Wade are lower than the current estimates in use for estimating toxic effects to the soldier on the battlefield.

According to Drs. Reutter and Wade, this difference results, in part, from the fact that the original estimates were developed for use in predicting enemy casualties during actions where maximization of toxic effect was the desired goal (for “offensive” purposes). Thus, the casualty estimators were deliberately set to kill or incapacitate the most-resistant individuals (the least sensitive) among enemy forces. If, for example, the desired endpoint was the LC_{t50} (lethal concentration time for 50% of the exposed population), such an approach would be expected to be lethal to >50% of unprotected enemy combatants because any force would be expected to include individuals more susceptible than the robust, most-resistant individuals for whom the LC_{t50} was targeted. Consequently, the original casualty estimators were never intended for use in making “force protection” decisions. Further, the Reutter/Wade analysis found that, upon recalculation, the potencies of nerve agents are higher than previously determined.

Basic assumptions in the Reutter/Wade analysis include (1) healthy, fit, trained, male, military personnel and (2) 70-kg mass/individual. These estimates were never intended, and should not be used, for estimating civilian casualties or developing civilian emergency preparedness decisions.

Results of the Reutter/Wade analysis have elicited much interest, particularly within the operational community. A number of reviews of this work have been performed by various outside bodies, notably a special Ad Hoc Study Group of the Army Science Board (ASB 1995), a Subcommittee of the Committee on Toxicology (COT) of the National Research Council (COT 1997), and a Chemical Toxicity Integrated Product Team (IPT) workshop held at the Institute for Defense Analysis (IDA 1998). The IDA activity was sponsored by the Chair of the Joint NBC Defense Board and the Deputy Under Secretary of the Army for the purpose of

- reaching a consensus on interim toxicity parameters for the chemical weapons agents of interest,
- specifying guidelines for use of these parameters, and
- identifying high priority areas for future work to improve these estimates.

Participants at the IDA workshop were made aware of the importance of these estimates for developing chemical defense equipment, estimating medical requirements, and analyzing the effects of chemical weapons against U.S. forces.

2.2 REUTTER/WADE REVIEWS

The overall conclusion of the Ad Hoc Study Group of the Army Science Board (ASB) was that the proposed Reutter/Wade toxicity values are reasonable for the purpose of protecting the soldier and are appropriate for establishing interim health-based effects criteria for safeguarding the soldier from acute toxic responses resulting from chemical agent exposures on the battlefield (ASB 1995). However, the Study Group also fully recognized that there were important considerations of risk assessment vs risk management at work in any implementation of these or similar estimates and advised that risk management and operational concerns should not govern any decision on the technical merit of the toxicological data analysis contained in Reutter/Wade. Rather, the risk manager should use those estimates, along with other economic and logistic considerations, as part of the decision-making process associated with requirements development. To improve the toxicity estimates before their final approval for use, the ASB Study Group recommended that efforts should be made to obtain any pertinent, classified, data from the intelligence community, allies, and former Eastern Bloc nations for use in performing any additional data analyses for resolving

outstanding data gaps. If this approach failed to provide the required resolution, then the Study Group further recommended performance of cost-benefit analyses to determine benefits of supporting new research (to obtain more reliable toxicity data), as compared with investing in operational developments to accommodate the Reutter/Wade revised toxicity estimates.

The COT Subcommittee on Toxicity Values for Selected Nerve and Vesicant Agents completed its analysis of Reutter/Wade and the ASB (1995) appraisal in the fall of 1997 (COT 1997); the sponsor (Office of the Army Surgeon General) released the publication in the spring of 1998. Overall, the COT Subcommittee considers that “By current standards of toxicology, the toxicity data base for the agents is inadequate, and such inadequacy is a major obstacle to the Army in developing human-toxicity estimates with statistical confidence and in developing risk-management strategies” (COT 1997, p. 3). As to specific CDEPAT agent estimates contained in Reutter/Wade, the Subcommittee grouped their appraisal into four categories:

1. some estimates were judged adequate to serve as interim estimates,
2. other estimates were judged adequate to serve as interim estimates until further research is conducted,
3. some estimates need to be lowered, and
4. a few estimates need to be raised.

These are estimates of acute exposure effects in healthy, male, military personnel. [An “acute effect” is defined by the COT (1997) as “an effect that results from a brief exposure or shortly after an acute exposure.” Further, COT (1997) defines an “acute exposure” as “a short-term exposure that lasts from minutes to hours (usually 1-24 hr)”]. In no case should these human toxicity estimates be applied to any evaluation of civilian effects. Summary tables (COT 1997, pp. 4–15) of the Reutter/Wade values and the COT Subcommittee's appraisal of them are provided for the G-agents (GA, GB, GD, GF), VX, and HD. These comparative findings are included here in Table 1. The Subcommittee further recommended that the Army convene a panel to develop research strategies for developing more scientifically sound toxicity values and consider a number of modeling and *in vitro* approaches before any serious consideration of animal and human experimentation. The COT Subcommittee recommended that the need for such experimentation should be considered on a case-by-case basis.

Participants at the IDA IPT Workshop in May 1998 were requested by the sponsors to make the following assumptions and apply them in their evaluations of studies by COT (1997), Reutter and Wade (1994), and ASB (1995):

- assume acute effects, as opposed to chronic effects or effects from low-level exposures;
- 70-kg male soldiers, as opposed to civilians or female military personnel;
- military scenarios, as opposed to use against civilians; and
- “neat” (undiluted) formulations of the agents, as opposed to other agents or modified versions of the agents

Oak Ridge National Laboratory (ORNL) received a draft version of the *Report of the Workshop on Chemical Agent Toxicity* released by the Office of Deputy Chief of Staff for Operations and Plans (DCSOPS) during the summer of 1998 (IDA 1998). Included in this draft are tables summarizing the consensus position of the workshop participants on “interim toxicity parameters” for several acute toxicity endpoints and routes of entry for the G-agents (GA, GB, GD, GF), nerve agent VX, and vesicant agent HD (IDA 1998, Tables 1–6). The IDA workshop values are compared with those of Reutter/Wade and the existing guidelines in Table 1. There was general agreement that there is considerable uncertainty regarding the

Table 1. Summary of findings

Parameter ^a	Route ^b	Existing	Reutter/Wade ^c	Committee on Toxicology/NRC Appraisal ^d	Institute for Defense Analysis ^e
Agent GB					
LCT ₅₀	PV	15,000	10,000	valid	12,000
LCT ₅₀	InhV	70	35	should be lowered	35
ECt ₅₀ threshold	PV	none	1,200	valid	1,200
ECt ₅₀ severe	PV	?	none	NA	8,000
ECt ₅₀ severe	InhV	35	25	should be lowered	25
ECt ₅₀ mild	InhV	2	0.5	should be raised	1
LD ₅₀	PL	1,700	1,700	interim value	1,700
ED ₅₀ severe	PL	none	1,000	interim value	1,000
Agent VX					
LCT ₅₀	PV	none	150	interim value	150
LCT ₅₀	InhV	30	15	should be lowered	15
ECt ₅₀ threshold	PV	none	10	interim value	10
ECt ₅₀ severe	PV	none	25	interim value	25
ECt ₅₀ severe	InhV	25	10	interim value	10
ECt ₅₀ mild	InhV	0.09	0.09	valid	0.1
LD ₅₀	PL	10	5	should be lowered	5
ED ₅₀ severe	PL	5	2.5	should be lowered	2
Agent HD					
LCT ₅₀	PV	10,000	5,000	should be lowered	10,000
LCT ₅₀	InhV	1,500	900	valid	1,000
ECt ₅₀ threshold mod	PV	none	50	interim value	50
ECt ₅₀ threshold hot	PV	none	25	interim value	25
ECt ₅₀ severe mod	PV	2,000	500	valid	500
ECt ₅₀ severe hot	PV	1000	<200	valid	200
ECt ₅₀ severe	InhV	200	100	valid	
ECt ₅₀ mild	InhV	>50	25	valid	
LD ₅₀	PL	7,000	1,400	valid	1,400
ED ₅₀ severe	PL	none	610	valid; round to 600	600

^aAll cumulative exposure (Ct) values are given in mg-min/m³; all D values are given in mg per 70-kg man.

^bAbbreviations: PV = percutaneous vapor, InhV = inhalation vapor, PL = percutaneous liquid.

^cReutter and Wade (1994).

^dCOT (1997)

^eIDA (1998)

effects of these chemical warfare agents and that these values should be used (as interim values) only if the following guidelines are met:

- Values for inhalation vapor (units of mg-min/m³) apply to 2-min exposures. The Panel recommends that 2-min values be used for G-agent exposures less than 10 min and that 10-min values (1.67 x the 2-min value) be used for exposures greater than 10 min; the Panel cautioned, however, that the “accuracy of extrapolating beyond 30–60 min is unknown.”
- Mustard agents appear to become more toxic as exposure time increases (exact relationship unknown).

- Values for percutaneous vapor (units of mg-min/m³) apply to 30-min exposures and unclothed individuals with the caution that “accuracy of extrapolation beyond 2 hours is unknown.”
- Percutaneous liquid values (mg) for G-agents and VX are expressed as total applied agent mass per 70-kg male; mustard values are for absorbed agent mass per 70-kg male.
- Presented probit slopes allow casualty estimates for around the median, between the 16th and 84th percentiles, using standard methods. Such extrapolations are considered valid only within this range of percentiles.
- Values apply only to 70-kg male soldiers; they do not apply to female soldiers or civilians.

The Panel further recommended that additional effort be given to address longer exposures and lower concentrations, the effect of clothing, and the effect of mixed populations (e.g., male and female soldiers, civilians). Methods other than probit analysis for the calculation of casualty estimators also bear further exploration; alternatives considered included “toxic load” methods.

It is our understanding that the IDA workshop findings are being finalized.

3. FUNCTIONAL AREAS THAT COULD BE AFFECTED

In this section we review how CSEPP guidance and planning practices could be affected by alteration of health effects parameters. This analysis was done by examining the contents of the CSEPP Planning Guidance document, Federal Emergency Management Agency/Department of the Army [FEMA/DA 1996]), and other CSEPP-related documents including policy papers, reports, and correspondence. The goal was to identify the use of any toxicity parameter. Special attention was given as to how the D2PC model Innovative Emergency Management, Inc. (IEM 1993) is used in the program.

This section is organized around the toxicity values identified as being used in CSEPP. A brief definition of the toxicity parameter is given, followed by a summary of how it is used. Secondary impacts of changing a toxicity parameter value are also identified.

3.1 NO DEATHS LCt

The no deaths LCt, is defined as the “maximum dosage that can be absorbed by individuals without death occurring” (IEM 1993). The values for no-deaths LCts are

HD	100 mg-min/m ³
GB	6 mg-min/m ³
VX	2.5 mg-min/m ³

Our investigation into the no deaths value did not produce good documentation on the toxicological basis for these values. We recommend that a baseline value assessment be developed for use as comparison with any developmental values.

Two functional areas are affected by the no death LC: the method for establishing the Emergency Planning Zones and the method for establishing “shelter in place” protective action policy.

3.1.1 Emergency Planning Zones

The CSEPP Planning Guidance (1996) uses the no deaths distance to define the IRZ and PAZ boundaries. The planning Guidance states:

Two factors concerning hazard are considered in the method for establishing the immediate response zone (IRZ) and protective action zone (PAZ) boundaries. The first is the time dimension—how much time would be available before a chemical agent plume arrived at a location? The second factor concerns the threat *per se*—what is (are) the geographical area(s) at greatest risk? These factors are used to determine the recommended distances for generic IRZs and PAZs at a site. (The boundaries of the precautionary zone, PZ, are not specified, although local governments may wish to set them based on catastrophic accident potential at a site.) (See Appendix A, Fig. 1).

Time

Pertinent time-distance relationships are shown in Fig. 5 of the CSEPP Planning Guidance (FEMA/DA 1996 and reproduced as Fig. 2 in Appendix A) for 3 different wind speeds (1 m/s or 2.2 mph; 2 m/s or 4.4 mph; 3 m/s or 6.7 mph). These relationships are used to help estimate the boundaries of the IRZ and PAZ. For the IRZ, the travel time of the leading edge of the agent plume roughly corresponds to wind speed. With winds at 1 m/s, it will take about 17 minutes to reach 1 km and 167 minutes to reach 10 km. At 3 m/s it will take almost an hour to reach 10 km. Unless a catastrophic accident occurred, it is unlikely that source terms would be large enough for the plume to travel a distance of 10 km. If one assumes that preplanned emergency response in the PAZ requires at least 1 hour to mobilize, then at least a 10 km immediate response zone is needed. Under this concept, a PAZ would begin at about 10 km. The outer edge of the PAZ is more flexible. Assuming that 5 hours are needed to mobilize response with little or no advance preparation, and that the agent plume travels at 1 m/s, then about 18 km would be needed for a PAZ. More conservatively, assuming a 2 m/s wind speed, the PAZ would extend to approximately 35 km. With advanced preparation, less time may be required to mobilize a response within a PAZ, but, alternatively, winds may travel faster (e.g., at 3 m/s), thus still requiring a relatively extended PAZ. Thus, time-distance relationships suggest that a PAZ should extend to approximately 35 km.

Threat distribution

Using the Army's D2PC atmospheric dispersion code, threat is represented by the distance chemical agent can travel and potentially cause fatalities. The D2PC code has been used to calculate downwind no-death distances for each accident scenario identified in each location-specific emergency response concept plan (ERCP). Releases resulting from external events (e.g., earthquakes, meteorite strikes, plane crashes) have been omitted.

The IRZ should be large enough to contain lethal plumes from credible accident scenarios under all except stable meteorological conditions. (The low wind speeds associated with stable conditions would allow sufficient time to respond.) Thus, the IRZ distance should be expanded from 10 km if necessary to contain the downwind no death distances of credible non-external event accidents under 3 m/s windspeed and D stability meteorological conditions (plus an uncertainty band of approximately 50 percent). (See Appendix A, Fig. 3).

The PAZ should be large enough to contain plumes from credible accident scenarios under more stable weather conditions. Thus, the PAZ distance should be adjusted from 35 km if necessary to contain the downwind no deaths distances of credible non-external event accidents under 1 m/s wind speed and E stability conditions (plus an uncertainty band of approximately 50 percent).

3.1.2 Protective

The CSEPP Planning Guidance (FEMA/DA 1996) states that the shelter-in-place protective actions to be included in each protective action strategy should be selected according to the following criteria:

Sheltering options are graphically depicted in Fig. 1 of Appendix D of the Planning guidance (FEMA/DA, 1996) and reproduced as Fig. 4 of Appendix A. Normal shelter-in-place should be recommended for the general population and for special populations and institutions in the IRZ and PAZ under conditions that would not allow evacuation before the arrival of a potentially life threatening level of chemical agent.

If normal shelter-in-place does not provide adequate protection for any category of accident, members of the general public, institutions, and special populations within the no death distance or within the IRZ boundary if the no death distance exceeds the IRZ, are eligible for the Enhanced Shelter Program and/or for expedient sheltering of one room in a house.

- a. Members of the general public, institutions, and special populations who cannot evacuate before the arrival of a potentially life threatening level of chemical agent and who are beyond the no death distance but are in the IRZ or within the no death distance and in the PAZ are eligible for expedient sheltering of one room in a house.
- b. Members of the general public, institutions, and special populations who cannot evacuate before the arrival of a potentially life threatening level of chemical agent and are outside the no death distance in the PAZ are only eligible for normal shelter-in-place.
- c. Pressurized/filtered shelter-in-place should be recommended for special populations and institutions within the no death distance who cannot evacuate before the arrival of a potentially life threatening level of chemical agent and for which the measures listed in item b would not provide adequate protection. Facilities/structures that are pressurized would not be eligible for access to special transportation resources to aid an evacuation.

3.2 IMMEDIATELY DANGEROUS TO LIFE OR HEALTH CONCENTRATION

The work rules for using PPE are linked to the immediately dangerous to life or health concentration (IDLH). The IDLH concept was originally developed by the National Institute for Occupational Safety and Health (NIOSH; Centers for Disease Control and Prevention, U.S. Public Health Service, U.S. Department of Health and Human Services) in the 1970's for use in selecting respiratory protection. The IDLH concept represents "the maximum concentration from which, in the event of respirator failure, one could escape within 30 minutes without a respirator" and without experiencing any irreversible health effects or escape-impairing effects (e.g., severe eye irritation) (NIOSH 1990). The IDLH values are not intended for establishing permissible exposure limits (COT 1993). For chemical warfare agents, air concentration values have been established by the Army Safety Program under the authority of the Office of the Assistant Secretary of the Army (Installation, Logistics and Environment) in AR 385-61 (DA 1997) to be operationally used as if they were NIOSH-established IDLH values. To our knowledge, the NIOSH organization has not, to date, developed or published formal IDLH values for chemical weapons agents. The "used as IDLH" values established in DA (1997) for the nerve agents are as follows:

GA/GB	0.2 mg/m ³
GD	0.06 mg/m ³
VX	0.02 mg/m ³

With regard to the vesicant agents sulfur mustard and Lewisite, Army Regulation (AR) 385-61, Sect. 2.5(g), Table 2-2, states that “Since IDLH values are used solely for the purpose of establishing the concentrations at which SCBA or supplied-air respirators are required, it is not necessary to formally establish IDLH values for H and L, since workers will already be required to wear these types of respiratory protection at concentrations much lower than what is considered IDLH for H and L, due to concerns over carcinogenicity.” The AR 385-61 guidance on this issue is intended for use by the Active Army, Army National Guard, U.S. Army Reserve, Army civilian employees, Army contractors, and other federal agencies conducting work for the Army.

CSEPP work rules state that Workers should not be sent into known, unknown, or suspected immediately dangerous to life or health (IDLH) environments (ANL, 1994).

3.3 EIGHT-HOUR AIRBORNE EXPOSURE LIMIT (AEL)

The 8-h airborne exposure limit (AEL) is designed to protect workers from unsafe concentrations of chemical agents in the work environment (DHHS 1988). Workers are allowed to be exposed to concentrations at or below these levels for 8 h/d without suffering ill effects. These values are

HD	$3 \times 10^3 \text{ mg/m}^3$
GB	$1 \times 10^4 \text{ mg/m}^3$
VX	$1 \times 10^5 \text{ mg/m}^3$

CSEPP work rules for PPE state: Workers should not be sent into areas where the airborne concentration is known, unknown, or suspected to exceed the protective capability of the powered air-purifying respirator (PAPR) [which is 50 times the 8-h AEL] unless they are equipped with a ready bag containing a CSEPP-approved PAPR and are trained in its use (Foust 1998).

3.4 CDC ACUTE THRESHOLD EFFECTS LEVELS (ATEL)

The CDC Acute Threshold Effects Levels (Thacker 1994) are Ct values that form the basis for planning protective actions such as an emergency evacuation in CSEPP. These “no effects” cumulative exposure values are protective of the general population and include vulnerable sub-groups of the population such as infants, the elderly, and previously debilitated or ill persons.

These are cumulative exposures.

HD	2.0 mg-min/m^3
L	2.0 mg-min/m^3
GB	0.5 mg-min/m^3
VX	0.4 mg-min/m^3

3.5 LCts

Lethal cumulative exposures or concentration time integrals are measured as mg-minutes per cubic meter. The subscript (i.e., LCt_{50}) refers to the percentage of the exposed population expected to die from exposure at that concentration without treatment or protection.

These values are used in CSEPP to perform resource planning for medical and decontamination functions.

3.6 AGENT CONTROL LIMITS

Appendix M (“Planning Guidelines for Recovery-Phase Activities”) of the CSEPP *Planning Guidance* (FEMA/DA 1996) states:

Responsible authorities need to decide, in advance, what their response will be if a chemical warfare agent is confirmed in soil, water, and other media at a control limit (action level concentration). Advance decisions also need to be made regarding appropriate responses if the field data are uncertain, or below the control limit. Currently, the only agent control limits promulgated for programmatic use in determining access to agent-suspect or -contaminated areas by civilian populations are those developed by the Department of Health and Human Services for atmospheric concentrations (in units of mg agent/m³ air; 53 FR 8504, 1988). Additional agent control limits for surfaces and environmental media such as drinking water, milk, meat, other food items and soil are in various stages of development and are intended for eventual use in CSEPP and other related programs.

In the time since the CSEPP *Planning Guidance* (FEMA/DA 1996) was published, initiatives supported by the U.S. Army Environmental Center (USAEC) of Aberdeen Proving Ground, Maryland, have resulted in the development of agent-specific reference dose estimates (mg/kg/d) for potential use in generating agent control limits in soil, water, and food which may be ingested or become a source of dermal contact exposure. These proposed values have been endorsed by the Office of the Army Surgeon General (OTSG 1996) for use as Army-wide interim criteria pending completion of a formal review by the Committee on Toxicology of the National Research Council (Opresko et al 1998).

3.7 INDIRECT EFFECTS

A number of emergency response activities are linked to designation of boundaries for the IRZ and PAZ. If these boundaries change, a number of secondary impacts are possible.

3.7.1 Alert/Notification

Outdoor and indoor alert/notification systems are linked to IRZ/PAZ boundary determination. Details are found in Appendix F (“Public Alert and Notification Systems: System Design Criteria and Evaluation Guide”) of the CSEPP *Planning Guidance* (FEMA/DA 1996).

3.7.2 Location of Facilities

The location of CSEPP facilities are linked with the delineation of the IRZ/PAZ boundaries in the following manner:

- Emergency Operations Center (EOC) should be located outside the IRZ; each county in the IRZ should have an EOC.
- Joint Information Center (JIC) should be located outside the IRZ.
- Reception Centers should be located outside the IRZ and preferably outside the PAZ.
- Mass Care Centers should be located outside the IRZ and preferably outside the the PAZ.
- Traffic Staging areas should be located outside the IRZ.

4. PUBLIC INFORMATION AND EDUCATION (RISK COMMUNICATION)

Informing the public about implications of altering the cumulative exposure casualty estimators associated with individual chemical warfare agents may be challenging. However, it is critical that the Army and the Federal Emergency Management Agency (FEMA) take a proactive role in discussing any new evaluations and what they mean for civilians and CSEPP community plans. The proactive approach is important because the Army's mission success depends upon community trust. Being forthright about the updating of casualty estimators will add to the Army's credibility. The following outline provides a framework for constructing a risk communication plan.

4.1 EXPLANATION OF UPDATED CASUALTY ESTIMATORS

The revised casualty estimates must be carefully described. Factors to consider in discussions include:

- description of the validity of updated estimates,
- the continuing scientific effort to reduce uncertainty of input data,
- a reference to table with values and value changes,
- addressing the implications for Chemical Weapons Convention Treaty compliance, and
- the importance of updates to CSEPP.

4.2 IMPLICATIONS FOR PUBLIC INFORMATION

Public information about the proposed changes of the Reutter/Wade analysis should include:

- No difference in risk management approaches at this time.
- Applicable to 70-kg healthy male may mean effects occur in a larger percentage of persons who are smaller/elderly/ill/children; effects may also be more severe in these populations at the same Ct.
- Time frame of exposure may differ for civilians (than 30-min assumption).
- Depending on how the information is presented, there may be a shaking of trust in previous Army risk management model estimates—perhaps “wool over the eyes” accusations.
- Problem with public acceptance of SECRET classification of Reutter/Wade study.
- Basic understanding of changes may be lacking in communicator/media.
- Some questions from the public may be difficult for experts to answer.

4.3 RISK COMMUNICATION RECOMMENDATIONS

Recommendations to enhance the dialogue on potential risks should include:

- Contrast risk analysis with risk management.
- State where scientists think updated information may make a difference and why.
- Admit don't know when don't know.
- Discuss similar problems with other substances (DDT, asbestos).
- Promote family/community preparedness in context of evacuation/shelter-in-place.
- Discuss what steps are being taken to address toxicity values.
- Discuss when updated estimates, tailored for civilian application, will hopefully be available for CSEPP applications.

5. HEALTH EFFECT PARAMETERS AND CSEPP

A review of CSEPP documents identified the following health effect parameters as being used in the CSEPP:

- LCt—lethal concentration multiplied by time (cumulative exposure)—medical, decontamination
- no deaths cumulative exposure (LCt nd)—IRZ/PAZ boundaries, sheltering-in-place policy options
- acute threshold Cts (CDC)—Protective Action Implementation
- IDLH—PPE
- 8-h AELs—PPE
- agent control limits—Reentry

Most of the parameters used in CSEPP are not estimated in the Reutter/Wade Report. These include basic CSEPP decision parameters such as no deaths Cts, acute threshold Cts as established by the CDC, IDLH, 8-h AEL, and agent control limits. There is no quick and easy method for estimating these parameters for use in CSEPP. The only CSEPP parameter estimated in Reutter/Wade is for lethal Cts, which have been used to calculate medical and decontamination resource needs in CSEPP. We do not recommend using the Reutter/Wade lethal Ct estimates at this time in CSEPP because the authors clearly state that the estimates are not for civilian populations and because there is no approved method for scaling casualty estimators originally developed for application to military personnel to estimation of agent casualties among civilian populations.

Table 2 documents our present estimate of possible direct and secondary (or indirect) impacts of altering agent-specific toxicity parameters on CSEPP decision making.

6. PARALLEL ACTIVITIES AND CIVILIAN APPLICATIONS

6.1 NATIONAL RESEARCH COUNCIL

In addition to the Committee on Toxicology activities outlined earlier (COT 1997), other bodies of the National Research Council are examining related aspects of the same issues. Following the Tokyo subway incident of 1995 and close in time to the bombing of the Murrah Federal Building in Oklahoma City, the Office of Emergency Preparedness of the U.S. Department of Health and Human Services (DHHS) requested that the Institute of Medicine (IOM) examine and report on ways to improve civilian medical response to chemical or biological terrorist incidents. The DHHS clearly understood that “traditional military approaches to battlefield detection of chemical and biological weapons and the protection and treatment of young healthy soldiers are not necessarily suitable for use by civilian health providers dealing with a heterogeneous population of casualties in an urban environment.” The results of this multi-year effort were published as *Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response* by the National Academy Press in February 1999 (IOM 1999). One of the major R&D needs identified in the study is to develop “more complete information. . .on the toxicity and adverse health effects that could result from acute exposure to low levels of agents, especially in sensitive populations (e.g., the young, the elderly, and those in ill health).”

Table 2. Summary of impacts^a

Functional Area	Parameter						Comments
	LCT ₅₀	No-death	ATEL	IDLH	8-h AEL	Control limits	
Planning Zones		D					ND Cts used in defining EPZs
Command/Control		I	D				ND Cts affect IRZ boundary which may influence location of EOC; ATEL triggers EOC activation
Communications							No impact
Notification							No impact
Protective Action DM		D	D				ATEL determines need to take protective action; ND Cts affect eligibility for shelter-in-place
Protective Action Imp.		D	D				ATEL determines need to take protective action; ND Cts affect eligibility for shelter-in-place options
A&N		I					Warning areas determined by EPZs which are defined partly on basis of ND Cts
Traffic /Access Control		I		I		I	ND Cts affect evacuation area definition; IDLH values determine where personnel can be stationed; Control Limits determine deactivation of controls
Support Operations				I			IDLH affects identification of areas where emergency personnel can respond
PPE				D	D		IDLH level affects areas where personnel can enter or remain; 8-hr AEL defines areas where PPE must be used
Medical Services	D						LCT ₅₀ is used to estimate medical resource
Transportation							No impact
Public Affairs	I	I	I	I	I	I	The significance and reason for any parameter changes must be explained to the public
JIC		I					ND Cts affect IRZ boundary which may influence location of JIC
Evacuee Support		I					ND Cts affect EPZ boundaries which influences location of reception centers and mass care facilities
Detection/Monitoring				D	D	I	IDLH affects identification of areas where monitoring personnel can enter; Control Limits establish criteria for detection
Decon	D			I			LCT ₅₀ is used to determine resource needs; IDLH affects identification of areas where decontamination personnel can operate
Reentry				I		D	IDLH affects identification of areas where personnel can operate; Control Limits establish criteria for reentry into affected areas
Training	I	I	I	I	I	I	The significance of all pertinent parameters must be incorporated into training materials
Exercises							No impact
Automation	I						All pertinent parameters would need to be incorporated

^aD = direct impact, I = Secondary (indirect) impact.

The IOM recognizes that this information is needed to develop guidelines for “safe and effective evacuation, decontamination and other protective action.” In other work, the Department of Defense (DOD) Office of the Special Assistant for Gulf War Illnesses has asked the National Research Council to develop strategies to protect the health of future deployed U.S. forces, with focus on four developmental areas:

- analytical framework to assess risks from medical, environmental and battle-related hazards,
- improved technology/methods for detecting and tracking exposures,
- improved physical protection/decontamination, and
- improved medical protection, health consequences management, and record keeping.

Workshops on all four tasks were held in January 1999, and draft working papers are currently under review. Analyses are being performed by study panels within the IOM, the Board on Army Science and Technology (see BAST 1999) and the Board on Environmental Studies and Toxicology (see BEST 1999). Draft reports are scheduled to enter NRC review in the Fall of 1999. The “risk assessment” panel is spending considerable time evaluating Haber's Rule of Inhalation Toxicity (concentration \times time = constant) and cautions that, for nerve agents, it is important to understand that each toxic endpoint (bronchoconstriction, acetylcholinesterase depression in the brain respiratory center, etc.) possesses its own Ct. The panel further points out that recovery may be occurring simultaneously with exposure at a rate different from that of the developing toxic effect. For a multiple-effects compound such as a nerve agent, estimation of an acceptable exposure is highly dependent upon the recovery half-life of the rate-determining step, the steepness of the dose response, and the susceptibility of the exposed population. It is also recognized that actual exposure conditions (“in the field”) often represent a significant departure from the ideal, and that predictive estimations of risk cannot be rigid or formulaic. These issues are directly pertinent to CSEPP needs, and are under active consideration by the “risk assessment” study panel.

In a recently published evaluation of the Army's Man-In-Simulant Test (MIST) program, a committee of the National Research Council Board on Army Science and Technology (BAST) found that “the Army has not adopted a clear approach to establishing physiologic endpoints from protective ensemble testing” and recommended that the criteria for suit performance be established (BAST 1997). This need is applicable to consideration of emergency response decision making whenever use of military protective ensembles is considered.

6.2 INSTITUTE FOR DEFENSE ANALYSIS

Workshop discussion in May, 1998, included mention of applying a factor of 10 to convert military casualty estimators for use in making estimates for the general population (IDA 1998). It was reported that there was no consensus on this approach.

6.3 U.S. ARMY CENTER FOR HEALTH PROMOTION AND PREVENTIVE MEDICINE

The U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) of Aberdeen Proving Ground, Maryland, is providing leadership in the development and application of health-based decision criteria for major chemical weapons agents. A multi-year effort to develop “health criteria documents” for chemical weapons agents is resulting in the development of updated estimates of agent AELs for occupational and general populations. These estimated AELs (in mg/m³) include estimates of worker population limits (time-weighted average for 8 h/d, 5 d/week), worker short-term exposure limits, worker IDLH levels, general population levels (time-weighted average, 24 h/d, 7 d/week), and acute exposure guideline levels (AEGl-1 values) for various exposure time periods. At present, values for each of these parameters have been prepared and documented by staff of ECBC for the G-agents (see Mioduszewski et al 1998) at the request of USACHPPM. These documented

estimates have not yet gone through a formal process of civilian agency concurrence. Similar evaluations for nerve agent VX and the vesicant agent HD are in progress and are scheduled for completion during calendar year 1999.

The AEGL concept, promulgated by the USEPA in 60 FR 55377 (USEPA 1995), addresses several time periods of concern (30 min, 1 h, 4 h, and 8 h) and is intended for use by federal, state and local agencies and organizations in the private sector concerned with emergency planning prevention and response. There are three categories of AEGL: AEGL-1, -2, and -3.

They are defined as follows :

AEGL-1 is the airborne concentration (expressed as ppm and mg/m³) of a substance at or above which it is predicted that the general population, including "susceptible" but excluding "hypersusceptible" individuals, could experience notable discomfort. Airborne concentrations below AEGL-1 represent exposure levels that could produce mild odor, taste, or other sensory irritation.

AEGL-2 is the airborne concentration (expressed as ppm and mg/m³) of a substance at or above which it is predicted that the general population, including "susceptible" but excluding "hypersusceptible" individuals, could experience irreversible or other serious, long-lasting effects or impaired ability to escape. Airborne concentrations below AEGL-2 but at or above AEGL-1 represent exposure levels which may cause notable discomfort.

AEGL-3 is the airborne concentration (expressed as ppm and mg/m³) of a substance at or above which it is predicted that the general population, including "susceptible" but excluding "hypersusceptible" individuals, could experience life-threatening effects or death. Airborne concentrations below AEGL-3 but above AEGL-2 represent exposure levels which may cause irreversible or other serious, long-lasting effects or impaired ability to escape.

In a closely related area, the USACHPPM was recently (Sept. 1998) requested by the Program Manager for Chemical Demilitarization (PMCD) to provide a version of the IDA (1998) estimates that could be used for developing general population risk assessments. The PMCD requested that these estimates include slopes as well as other non-vapor toxicity estimates not already addressed in the Health Criteria Documents (note from the above text that USACHPPM has overseen completion of a recent health criteria document for the G-agents [Mioduszewski et al. 1998]; criteria documents for sulfur mustard and nerve agent VX are in progress). A formal request to USACHPPM is expected from the PMCD through the OTSG. Initial estimates indicate that interim values may parallel the IDA (1998) values, but will need to be reduced by approximately an order of magnitude to accommodate sensitive sub-populations.

6.4 U.S. ARMY ENVIRONMENTAL CENTER

The U.S. Army Environmental Center (USAEC) of Aberdeen Proving Ground, Maryland, has responsibilities for supporting installation restoration activities at Army installations and property nationwide. USAEC functions as the program manager for the Army's Installation Restoration Program (IRP). In recent years, the need for decision criteria to determine the scale and level of installation restoration required at sites that may include chemical warfare agent contamination, at both active installations and formerly used defense sites (FUDS), has become increasingly evident. However, key data pertaining to the chronic toxicity of these agents, necessary for performing the risk analyses that are normally part of the cleanup decision process, have not been readily available. The USAEC supported development of chronic reference doses for the chemical agents GA, GB, VX, sulfur mustard, nitrogen mustard, Lewisite, and cyanogen chloride. The chronic reference dose is a concept originally developed for remediation of Superfund sites that estimates "the daily exposure [in mg/kg/d] to the human population, including sensitive subgroups, that is likely to be without

appreciable risk of deleterious effect during a lifetime” (see Opresko et al 1998). This work was performed in coordination with USACHPPM. The availability of agent-specific reference doses is key to the development of agent control limits in soil, water and food, which may be ingested or become a source of dermal contact exposure. This approach is also needed for application to planning CSEPP site recovery in the event of potential agent release.

These reference dose estimates for chemical weapons agents were developed by staff of the Life Sciences Division at ORNL and submitted by USACHPPM to the Office of the Army Surgeon General for consideration as interim criteria for conducting risk assessments at Army sites. In a memorandum dated Aug. 19, 1996, the OTSG endorsed the proposed reference doses as interim criteria pending a formal review by the COT of the National Research Council (OTSG 1996). A Subcommittee of the COT is currently reviewing these values, and their report is currently scheduled for outbrief to the OTSG in the first 6 months of 1999. These interim values are documented in Opresko et al (1998).

6.5 NEW LABORATORY STUDIES

As follow-up to recommendations of the COT Subcommittee on Toxicity Values for Selected Nerve and Vesicant Agents (COT 1997), laboratory experiments with nerve agent GB (sarin) have been initiated at ECBC, Aberdeen Proving Ground, Maryland. A number of laboratory animal species are being tested against various routes of exposure and concentrations of GB (Reutter, SR, personal communication, 29 Jan 1999). Results are preliminary and not yet published.

7. RECOMMENDATIONS

1. Continue the policy of not using any casualty estimators documented in the Reutter/Wade analysis in CSEPP, in agreement with Fisher and Salter (1998), until
 - the Reutter/Wade parameters are further refined for application to protective decision-making for civilian populations; and
 - appropriate agent-specific adjustments are made for no deaths Cts, acute threshold Cts (CDC), IDLH, 8 hour AEL, and agent control limits.
2. Develop a procedure and perform analyses to implement recommendation Number 1.
3. Establish joint Army and FEMA tasking of appropriate bodies to consider and publish approved estimators resulting from their evaluation of assessments to be performed as a result of implementing recommendation Number 1.
4. Issue a joint Army and FEMA policy paper containing a more detailed explanation of relevant policy and what will be done to develop updated health effect parameters for CSEPP.
5. Assess the implications for public information and risk communication programs and develop a strategy to communicate the findings.
6. Consider the development of agent-specific AEGL numbers for CSEPP and prepare guidelines for their use as an adjunct to recommendation Number 1. This would provide toxicity values designed for use in an emergency response program and would be consistent with other haz-mat programmatic directions.

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APPENDIX A

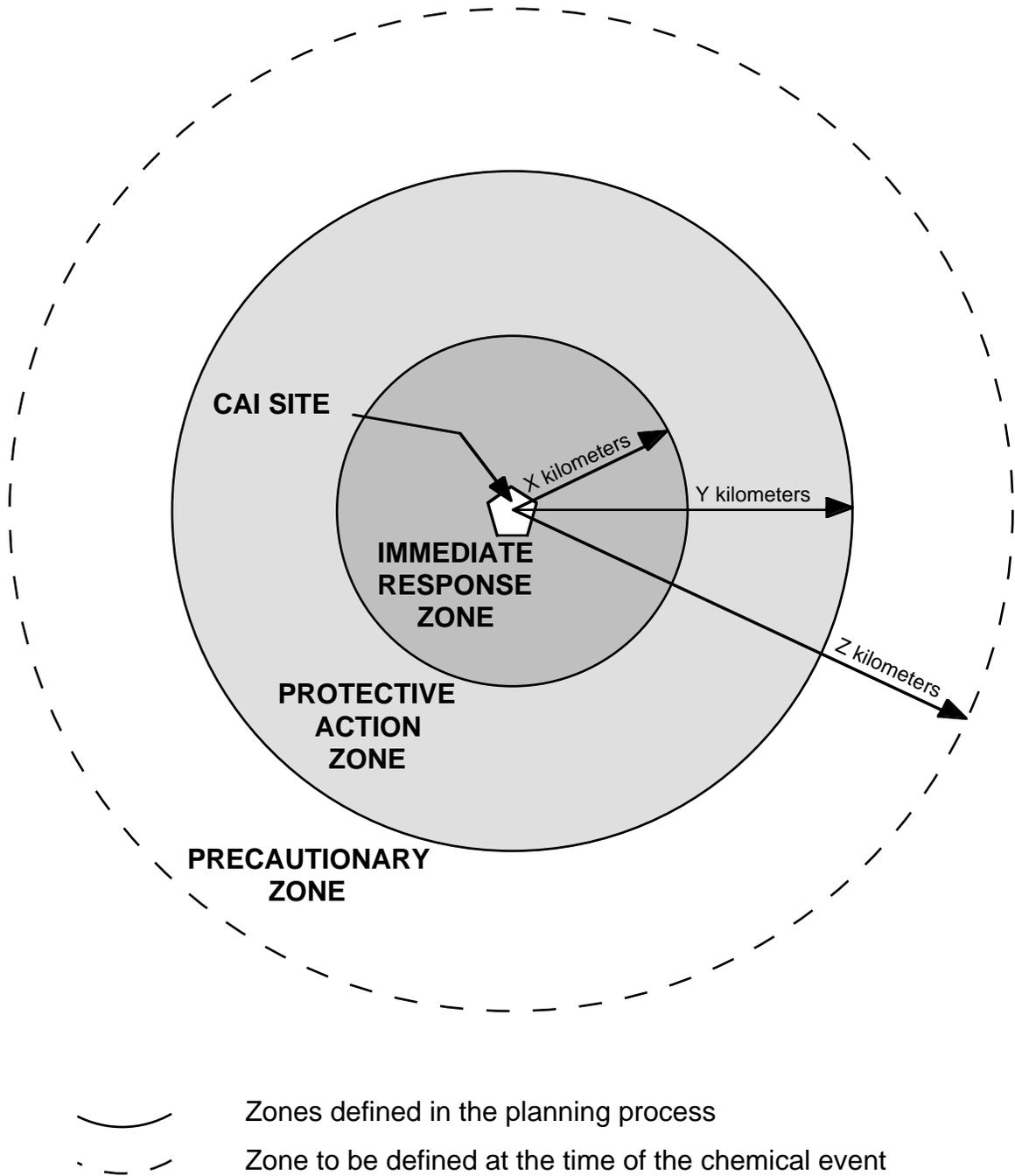


Fig. 1. Emergency planning zone concept.

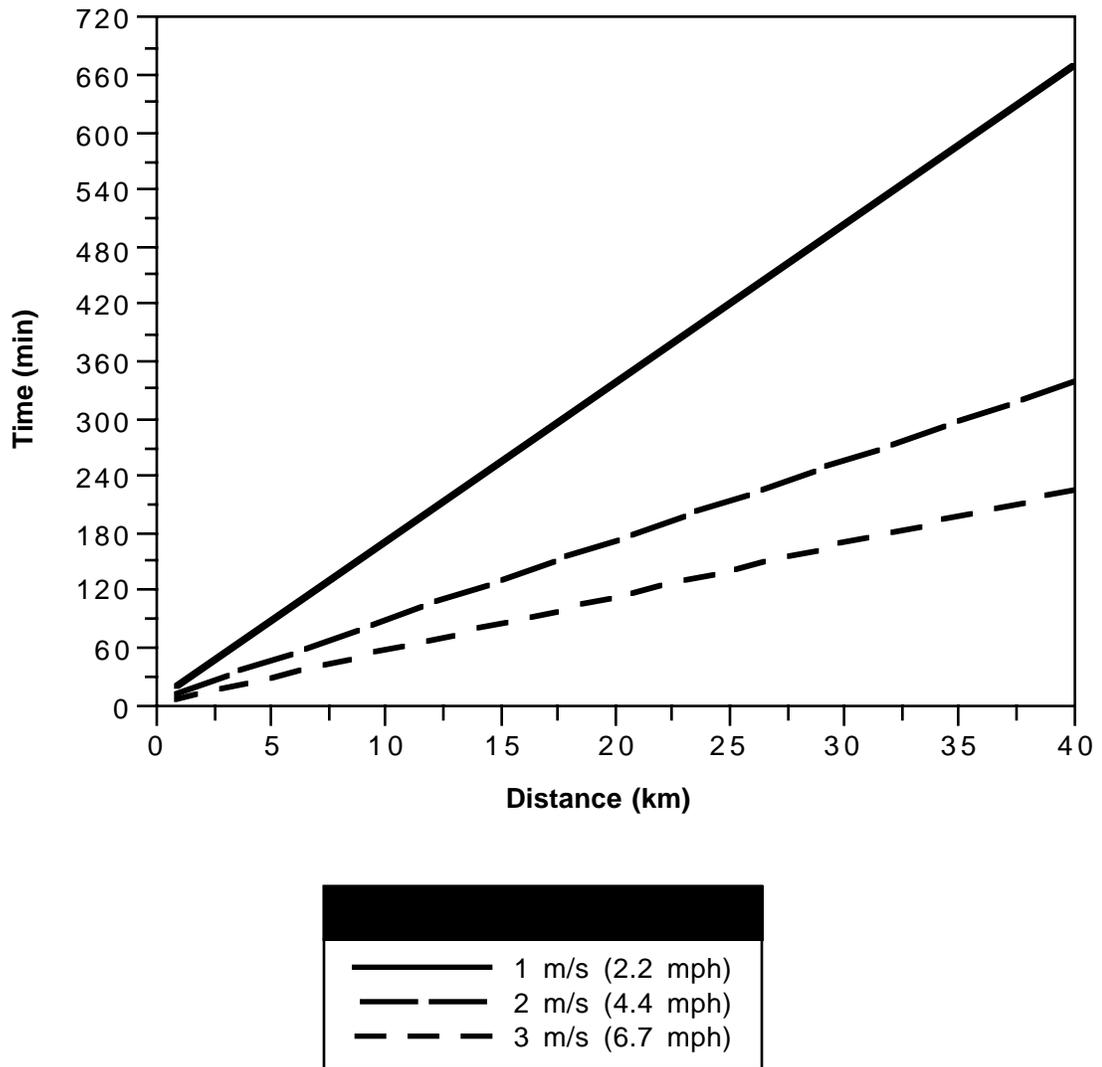


Fig. 2. Relationship between distance traveled and time of plume travel.

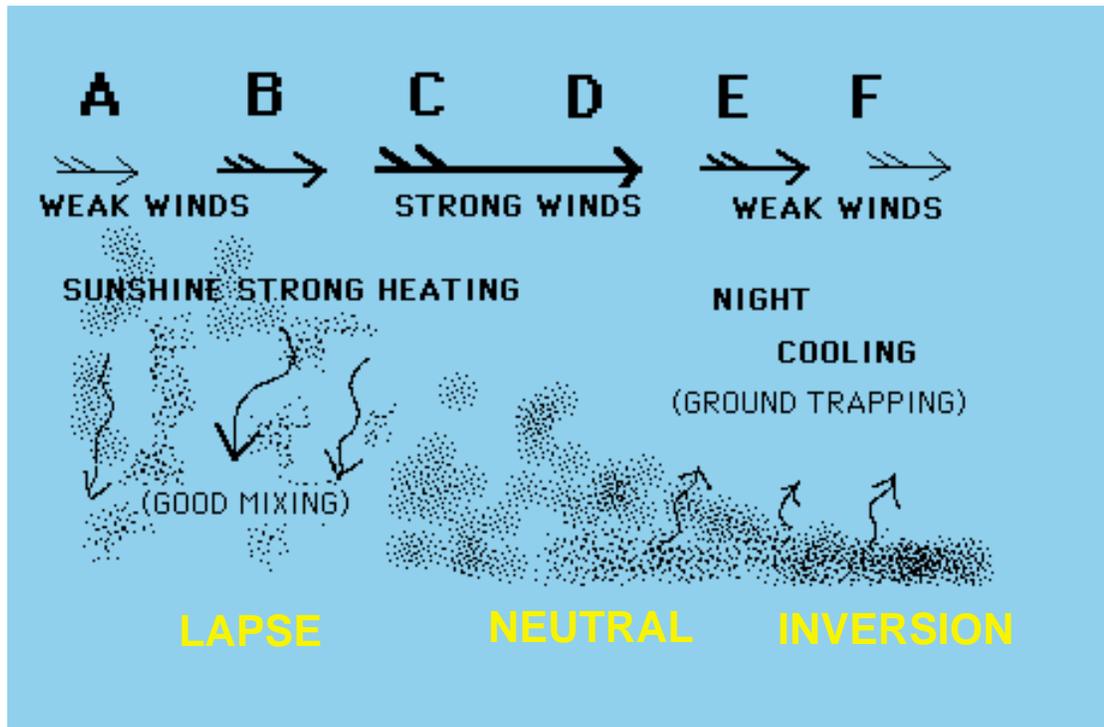


Fig. 3. Relationship among stability class, time of day, and mixing.

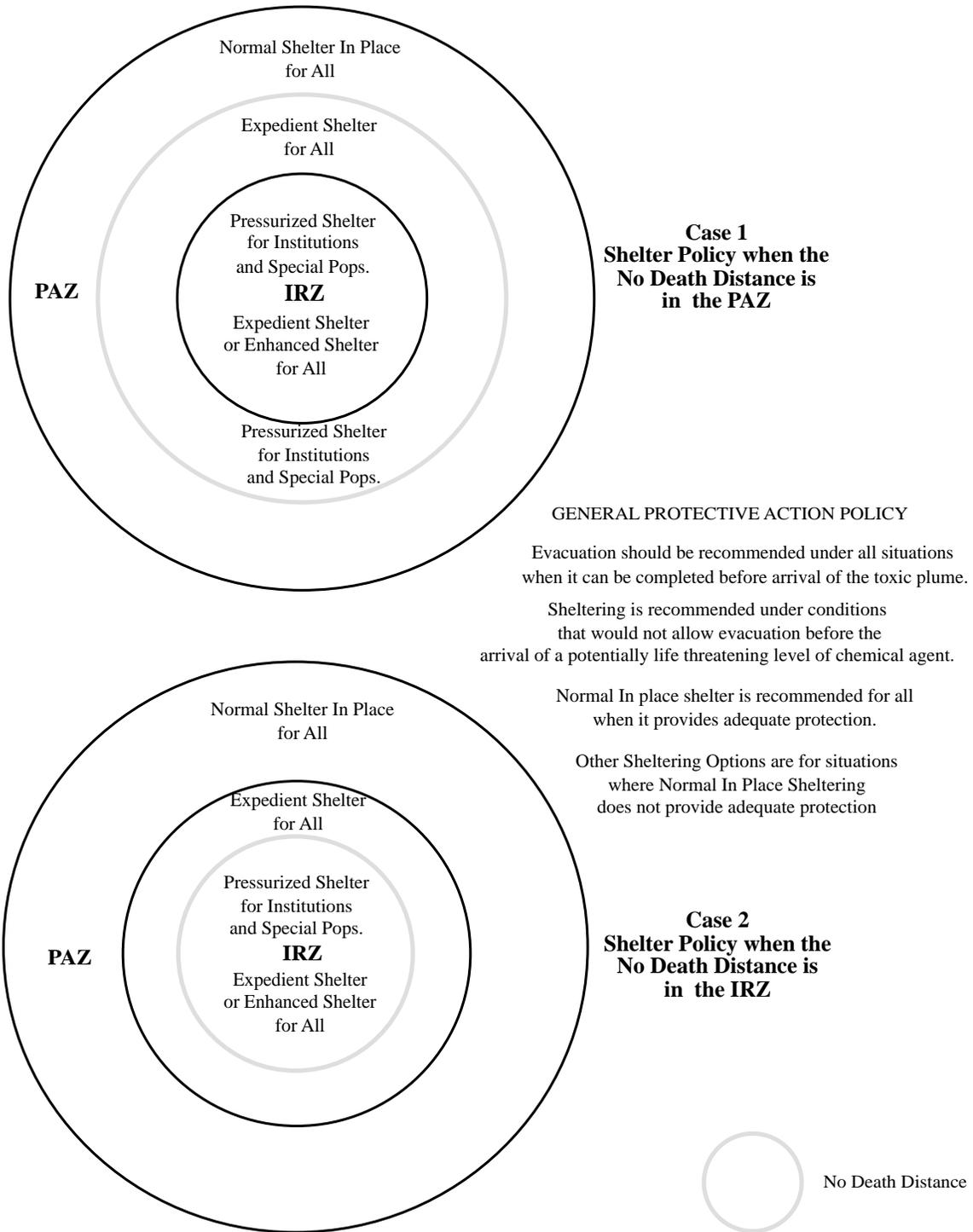


Fig. 4. Guidelines for in-place sheltering.
 Source: (FEMA/DA 1996)