



# **Chemical Risk Assessment and Exposure Guidelines (and how AEGs fit in)**

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**Presentation to Arkansas Dept of Health - March 2003**

# AGENDA

- Background –CHPPM
- Introduction to Chemical Risk Assessment
- What are AEGLs
- What are the health effects associated with chemical warfare agent AEGLs?
- How are AEGLs used?

# Who is USACHPPM?

Pre –1994

Army Environmental Hygiene Agency  
(AEHA)



- Occupational Health
- Environmental Health

1994 – Present

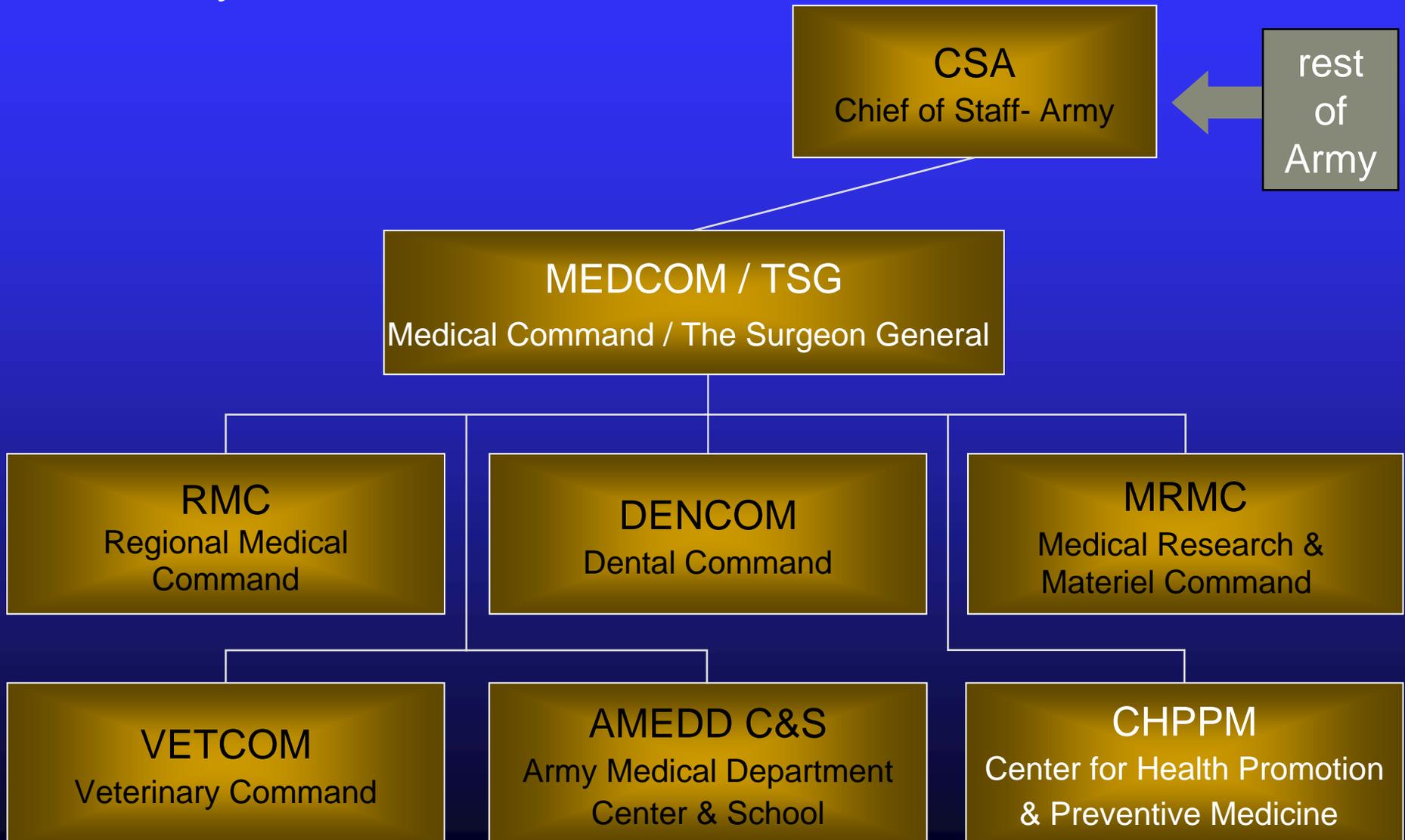
US Army Center for Health Promotion  
and Preventive Medicine (USACHPPM)



- Occupational Health
- Environmental Health
- Epidemiology and Disease Surveillance
- Toxicology
- Health Promotion and Wellness
- Laboratory Sciences
- <sup>3</sup>- Health Risk Management

# USACHPPM

U.S. Army Center for Health Promotion and Preventive Medicine



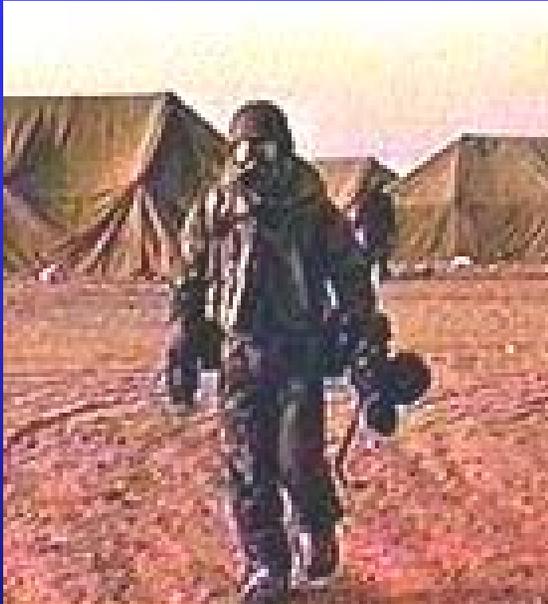
# USACHPPM MISSION

- Preventive medicine, public health, occupational health and safety, and health promotion/wellness technical services
- Advise/assist Army OTSG in policy and guidance development
- Evaluate compliance and adequacy of programs and policies (report to OTSG)
- Support world-wide technical support (Army and DoD; other Federal and State entities; international efforts)

# Example USACHPPM CWA initiatives

- **Emergency Planning and Response**
  - Army/FEMA (CSEPP) AEGL policy and supporting risk communication/ implementation guidance
  - Coordination with National Advisory Committee on AEGLs (for CWA)
  - Homeland defense planning support (Installations, States, other Federal)
  - Development of safe soil /reentry levels (1999)
  - Risk Communication support
- **Occupational and General Population and Environmental Health**
  - Re-evaluation and development of new AELs (1996-2000)
  - Soil remediation goals and waste treatment goals (1999)
  - Revision of DA Regs/Pams (40-8/173; 50-6, 385-61)
  - Coordination with CDC (supporting OEMD)
- **Military Exposures Guidelines (MEGs) for air, water soil**
  - USACHPPM TG 230 (Chemical Exposure Guidelines for Deployments)
  - TB Med 577 (Field Surveillance of Drinking Water)

# Development & evaluation of health criteria for different applications and populations



## MILITARY

- FHP
- Operations
- Army/DoD



## ENVIRONMENTAL & PUBLIC HEALTH

- US Stockpile
- Non-Stockpile
- Homeland Defense



## OCCUPATIONAL HEALTH

- Stockpile
- Homeland Defense
- Research

# Chemical Risk Assessment and Standards Development:

*What is a 'safe' or 'acceptable' level of Chemical "X"?*

## Basics of the science:

- What media (air, water, soil, surfaces?)
- Who (what population?)
- How long and/or how frequent is the exposure?
- What health effects?

## Additional Risk Management Considerations:

- What health effects?
- What are competing risks? Are they 'voluntary'?
- What are the the possible actions to be taken?

*Bottom line – every chemical has numerous safe/acceptable "numbers"*

# Chemical Air Exposure Levels Continuum\*



Catastrophic release



Work environments



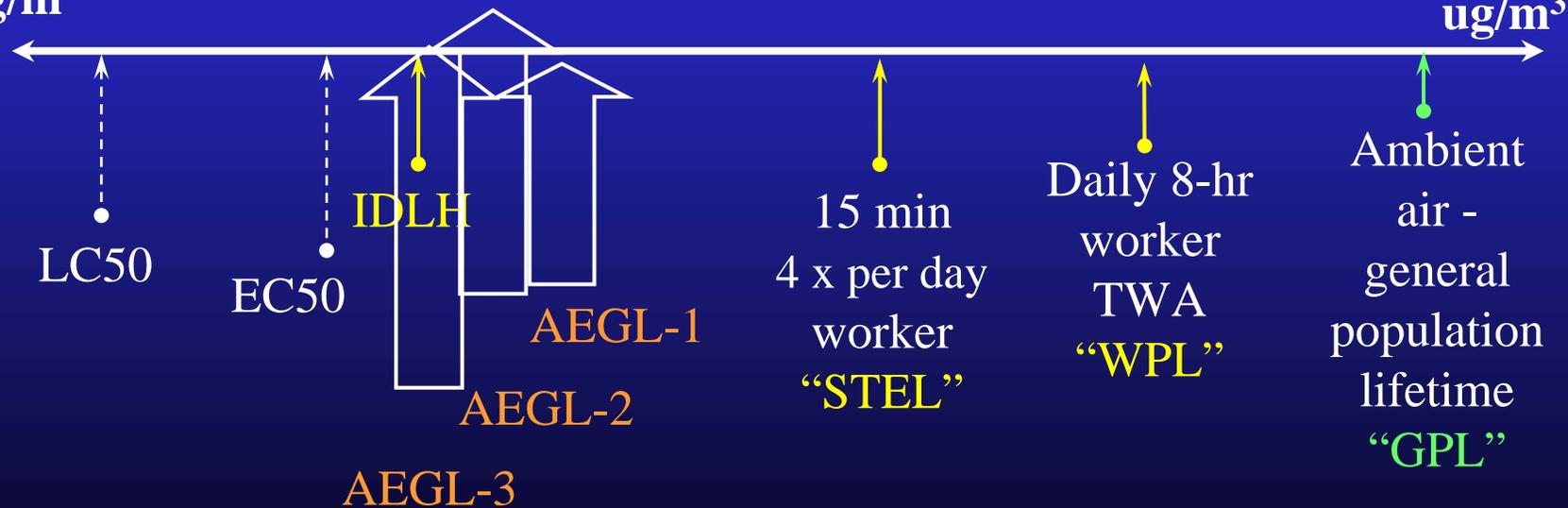
Ambient air (emissions)

*Single exposure*

*Lifetime exposure*

mg/m<sup>3</sup>

ug/m<sup>3</sup>



\*not to scale for any specific chemical— general representation

# So what are Acute Exposure Guideline Levels (AEGGLs)?

- Short-term, one-time, airborne exposure levels
- 3 levels of health severity and different exposure times
- For risk managers to appropriately balance risks and prioritize resources in
  - Emergency planning/prevention
  - Emergency response

**Concept started in the mid-80's – result of Bhopal incident**

# History of “Emergency” Exposure Limits

## Regulatory

- 1964- NRC EEGs
- 1974- NIOSH IDLHs
- 1984- EPA National Air Toxics Strategy Separates Routine from Accidental Releases
- 1986- SARA Title III
- 1990- CAA 112r

## Industry

- 1964- AIHA EELs
- 1970s- Company Specific STELs
- 1984 – Bhopal Incident
- 1985- Company Specific EELs
- 1987- ORC ERPG Task Force
- 1988- AIHA ERPG Committee

**1993 – NAS Guidance for Developing AEGLs**

**1995- Federal Advisory Committee Act (FACA)**

**1996 – National Advisory Committee on AEGLs**



## Who Establishes AEGLs?

A two-committee process (NRC 'final say' over NAC):

### National Advisory Committee (NAC) for AEGLs

*Co-chairs from EPA & Industry*

Public Sector: Federal and State agencies

Private Sector: Industry, Academia, Medical associations

International regulatory reps:  
(unofficial members at present -  
Netherlands, France, Germany)

### National Research Council (NRC) Committee on Toxicology (COT)

*Subcommittee on AEGLs*

Under National Academy of Sciences –mandate to advise Federal government

Private Sector: Industry, Academia

International technical reps:  
Canada, Netherlands, Germany

# AEGL Development Process

- ✓ Based on National Research Council (NRC) approved technical procedure (publicly available document)
- ✓ Several standardized review levels:
  - 1) DRAFT: Developed by National Advisory Committee (NAC-AEGLs);
  - 2) PROPOSED: Federal Register public comment period;
  - 3) INTERIM: NAC-AEGLs addresses public comments
  - 4) FINAL: NRC Committee on Toxicology reviews/modifies and finalizes (publishes)

# Official NAC AEGL Level Definitions:

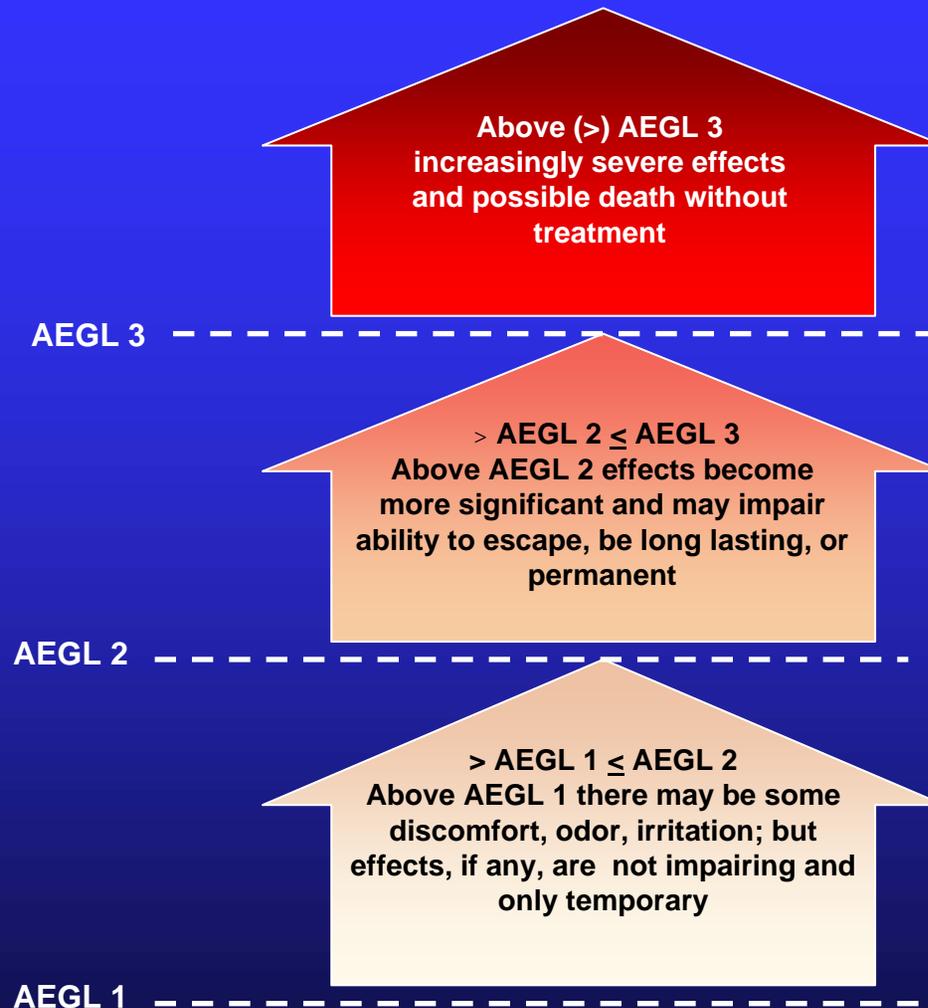
AEGL Level 1: level **above which** general population (including susceptible individuals) may have some notable discomfort ( non-disabling, transient and reversible)

AEGL Level 2: level **above which** general population (including susceptible individuals) may experience serious long-lasting effects or impaired ability to escape

AEGL Level 3: level **above which** general population (including susceptible individuals) could experience life threatening effects or death

***BUT: These should not be interpreted too literally....  
The final AEGL concentrations for chemicals  
(especially CWA) are designed to be VERY protective***

**Figure 1.**  
**Generic Description of AEGL Levels\***



\* Effects described are general in nature and do not reflect the specific effects associated with any particular chemical

## AMMONIA Air Criteria (mg/m<sup>3</sup>)

Exposure duration →	2-10 min	10 min	30 min	1 hr	4 hr	8 hr	8 hr/day lifetime	24 hr/day lifetime
<b>LC<sub>50</sub></b>	>5000							
<b>AEGL 3*</b>		1880	1120	770	383	272		
<b>AEGL 2*</b>		188	112	77	77	77		
<b>AEGL 1*</b>		18	18	18	18	18		
<b>AELs</b>			300 IDLH					
				27 STEL				
							18 TLV	
								0.35 (derived)

Lethality Concentration– 50 deaths – published data (animal and human) based human estimate

AEGL- Acute Exposure Guideline Levels – \*proposed levels

Occ & Public Health standards developed by OSHA, NIOSH, and EPA

## Carbon Monoxide Air Criteria (mg/m<sup>3</sup>)

Exposure duration →	2-10 min	10 min	30 min	1 hr	4 hr	8 hr	8 hr/day lifetime	24 hr/day lifetime
<b>LC<sub>50</sub></b>	>2500							
<b>AEGL 3*</b>		1700	600	330	150	130		
<b>AEGL 2*</b>		420	150	83	33	27		
<b>AEGL 1*</b>		NR	NR	NR	NR	NR		
<b>AELs</b>			1200 IDLH					
				229 ceiling				
						55 TLV		
								3 (derived)

Lethality Concentration– 50 deaths – published data (animal and human) based human estimate

AEGL- Acute Exposure Guideline Levels – \*proposed levels

Occ & Public Health standards developed by OSHA, NIOSH, and EPA

## GB (SARIN) Air Criteria (mg/m<sup>3</sup>)

Exposure duration →	2-10 min	10 min	30 min	1 hr	4 hr	8 hr	8 hr/day lifetime	24 hr/day lifetime
<b>LC<sub>50</sub></b>	3.5							
<b>AEGL 3</b>		0.38	0.19	0.13	0.07	0.051		
<b>AEGL 2</b>		0.087	0.050	0.035	0.017	0.013		
<b>AEGL 1</b>		0.0069	0.004	0.0028	0.0014	0.0010		
<b>AELs</b>			(2.0)* IDLH					
				(0.003)* STEL				
							0.003* (0.0004) WPL	
								0.0001* (0.00002) GPL

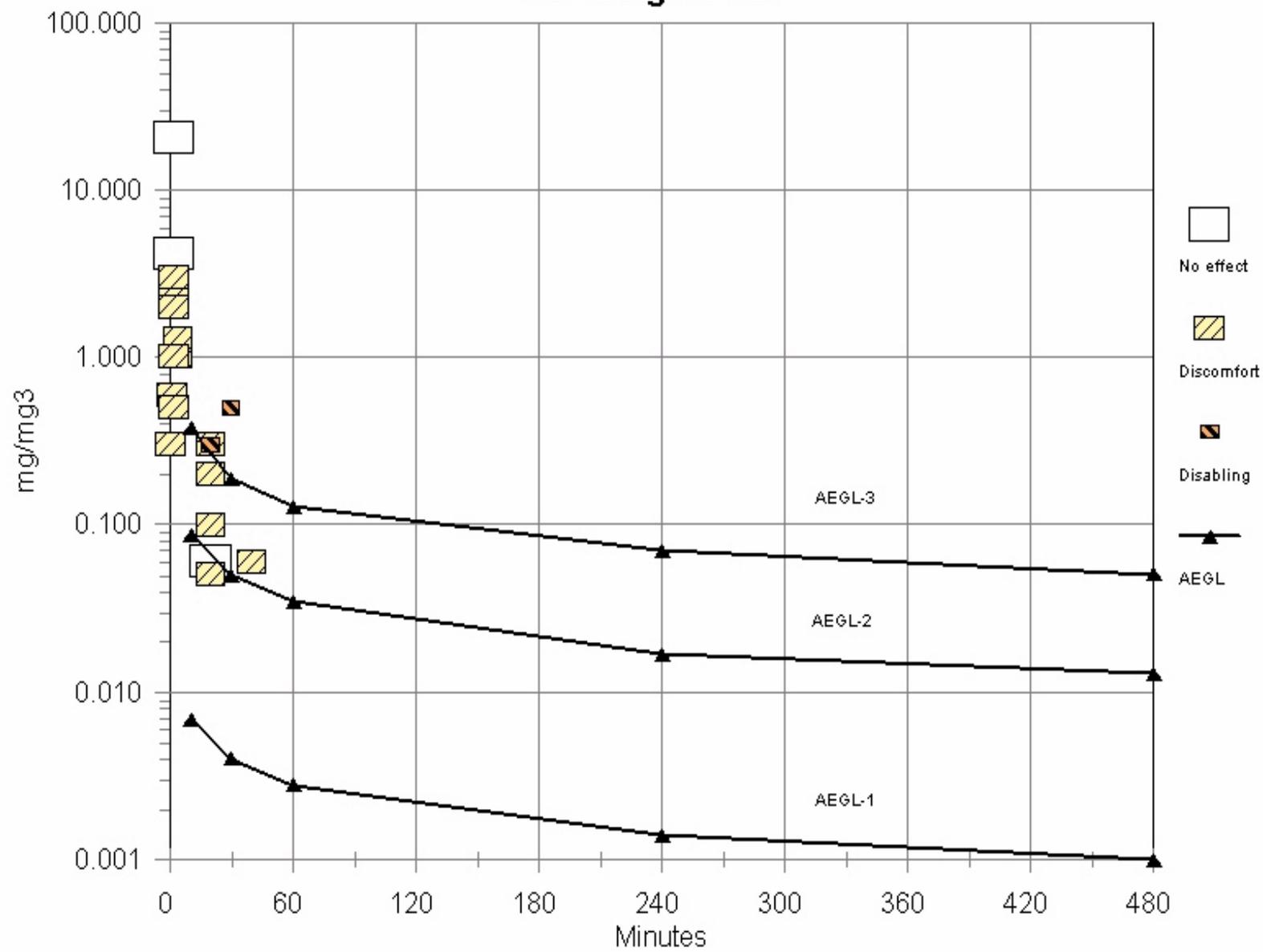
IDA - Institute for Defense Analysis ( endorsed by ASD)

AEGL- Acute Exposure Guideline Levels (developed by NRC, referenced in TG230)

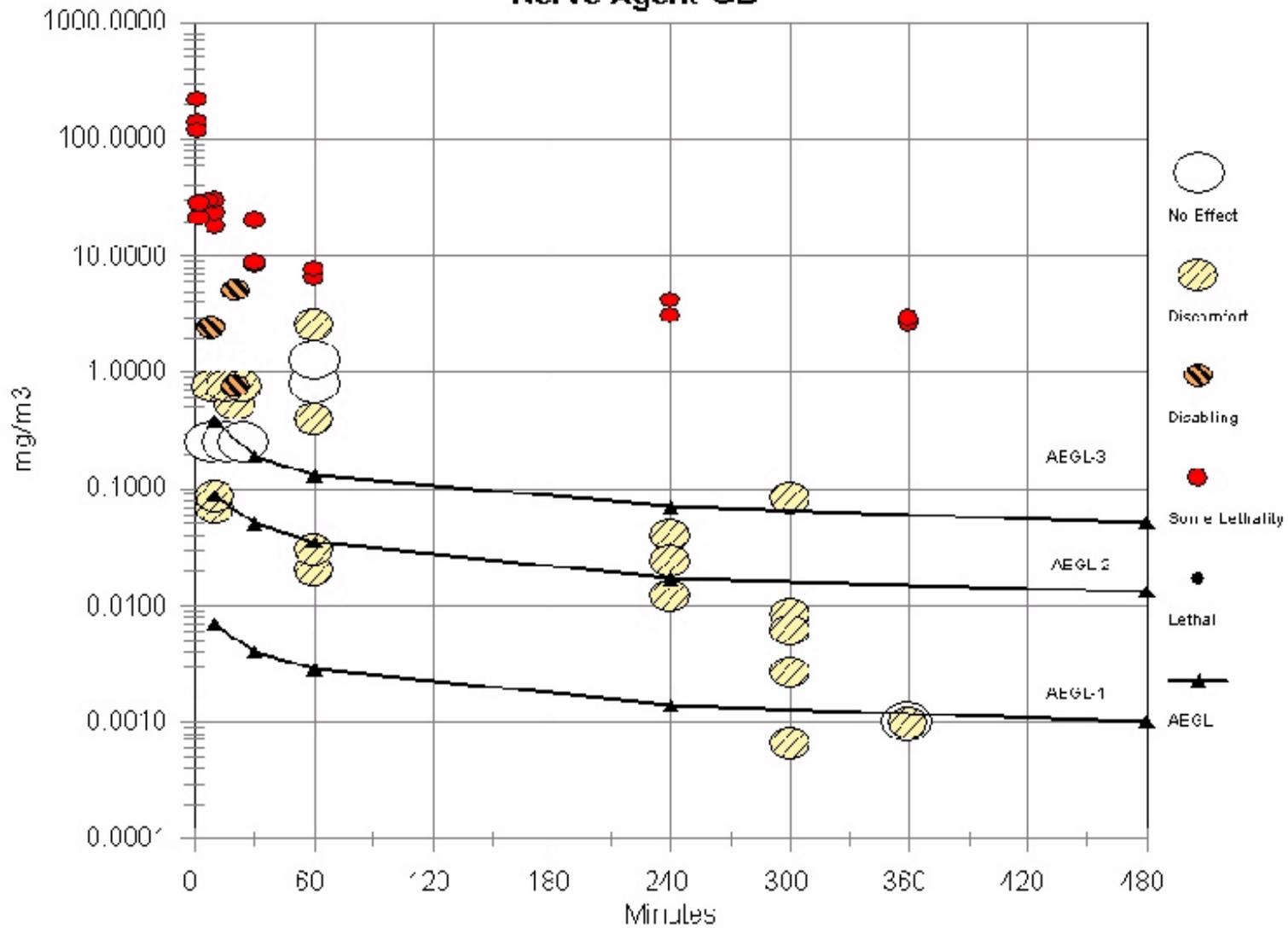
AELs- Air Exposure Limits (endorsed by CDC, occupational and general population regulatory standards)

\* under evaluation (new proposed)

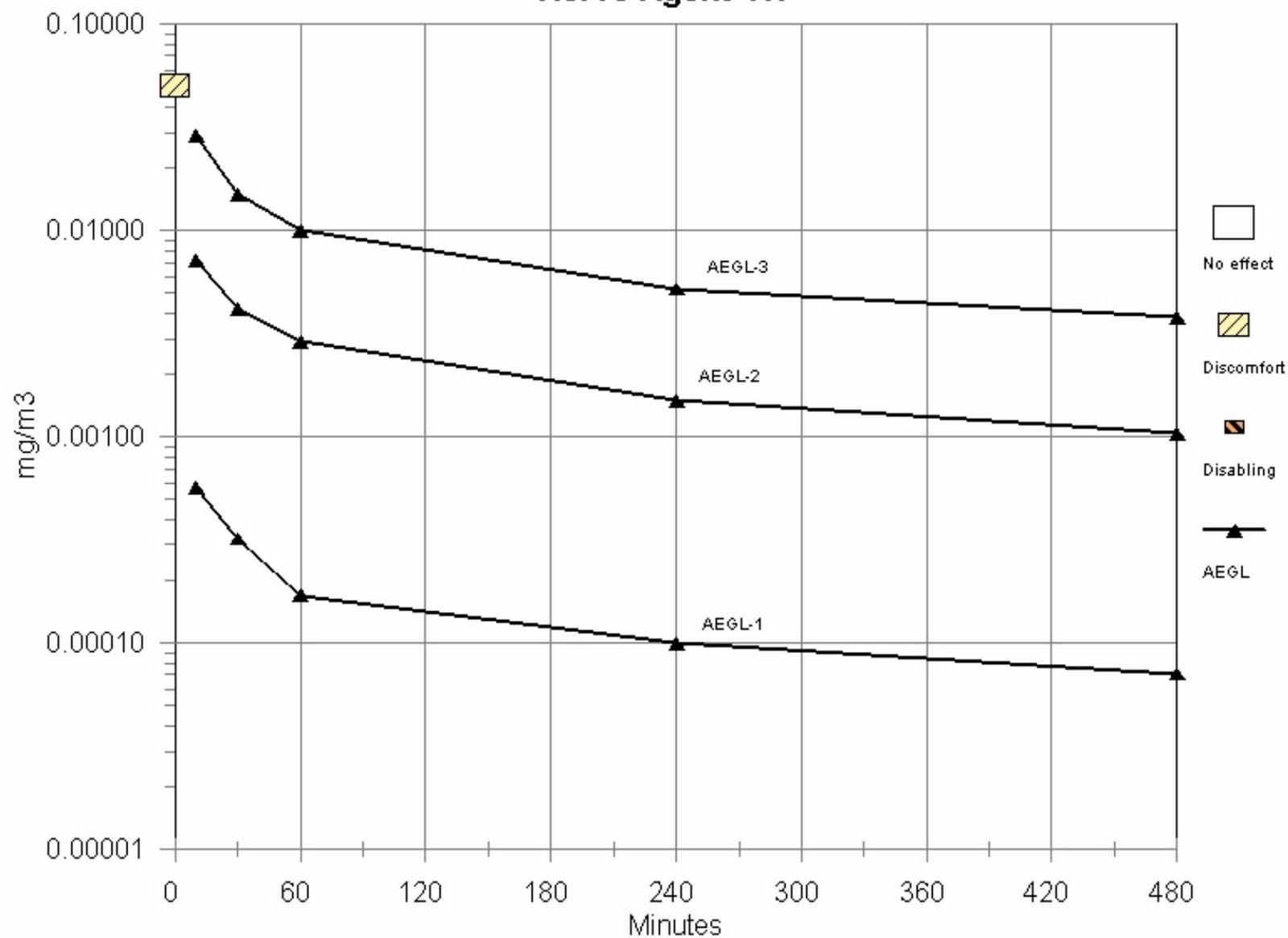
# Chemical Toxicity - TSD Human Data Nerve Agent GB



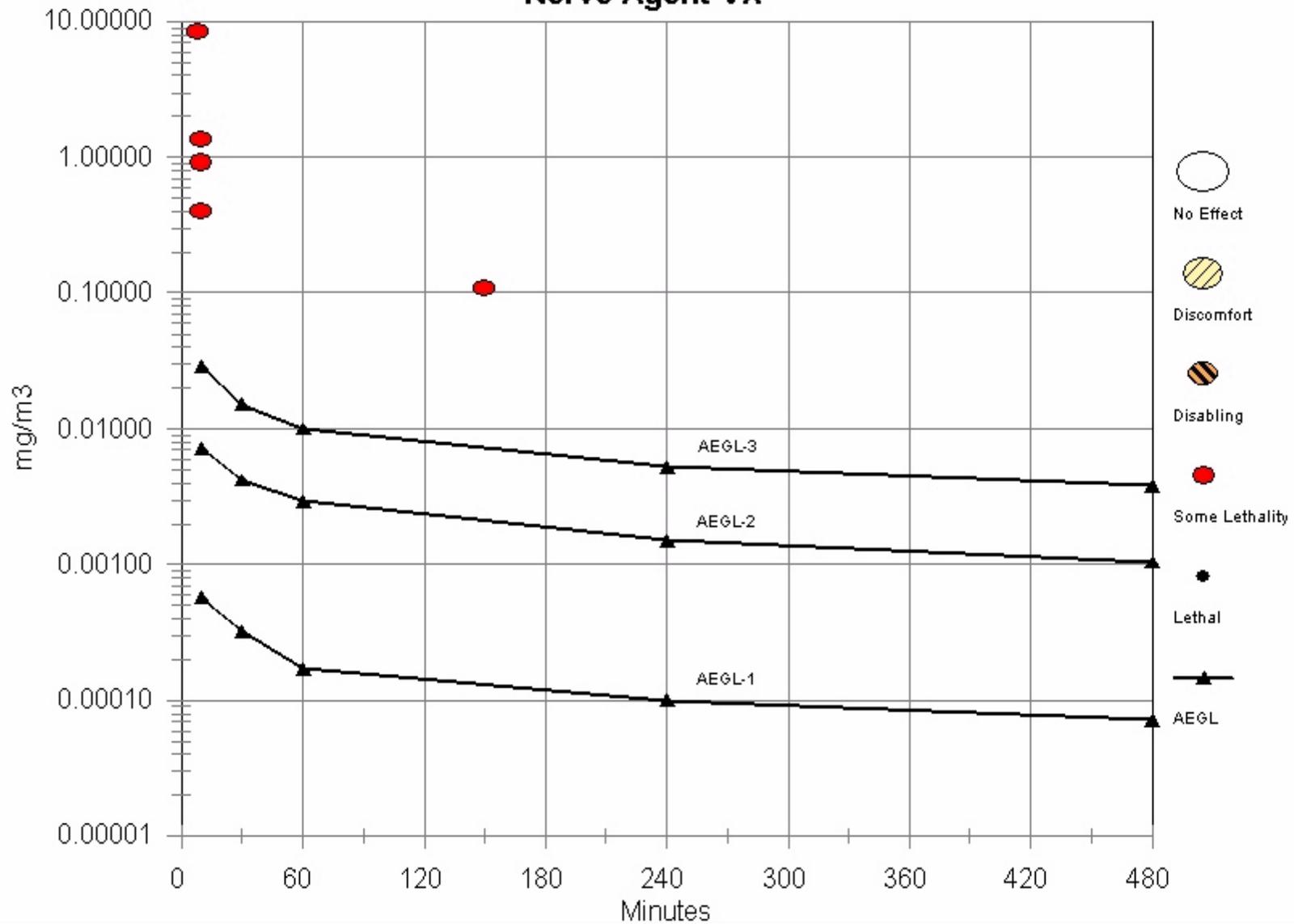
## Chemical Toxicity - TSD Animal Data Nerve Agent GB



## Chemical Toxicity - TSD Human Data Nerve Agent VX



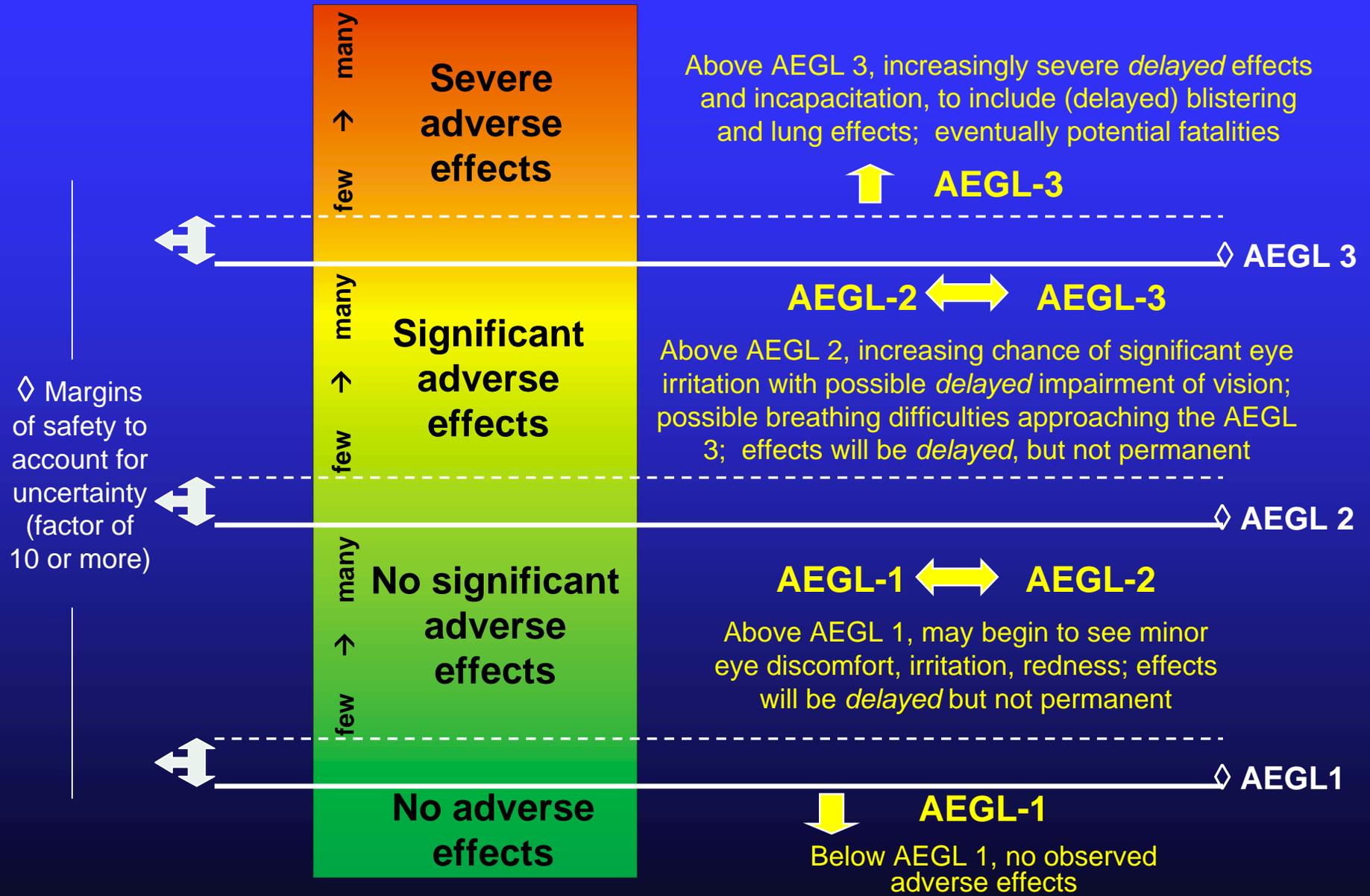
### Chemical Toxicity - TSD Animal Data Nerve Agent VX



# Summary of CWA AEGL Status/Issues

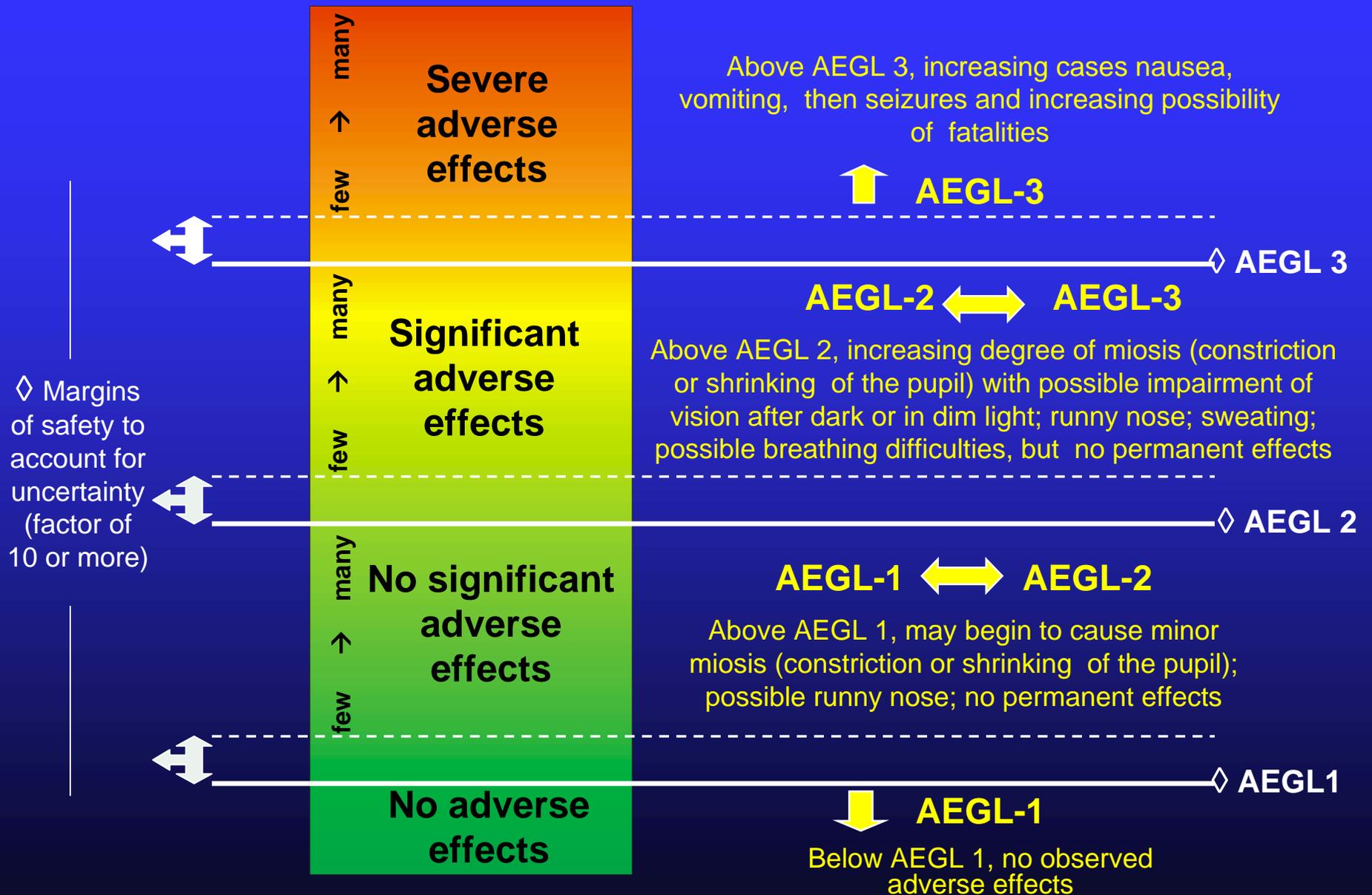
- HD and Nerve Agent AEGLs are 'FINAL':
  - NRC pre-publication (March, 2003)
  - 'Street version' publicly purchasable book by May (\$58 from the National Academies Press at 800-624-6242)
  - Or – will be viewable online: [www.nap.edu](http://www.nap.edu)
- "Final" values currently cited in USACHPPM Fact Sheets
- Overall data considered good quality (exception VX);
- Data- based values are down-adjusted with "uncertainty factors" (providing a margin of safety) to account for unknowns:
  - Animal- to human extrapolation
  - Human variability
  - Data quality

# Sulfur Mustard Health Effects and AEGLs



◆ Margin of safety addresses uncertainties that may not be completely explained by available data

# Nerve Agent Health Effects and AEGLs



◇ Margin of safety addresses uncertainties that may not be completely explained by available data

# AEGL APPLICATIONS:

## EPA Guidance for Toxic Industrial Chemicals

- US EPA Chemical Emergency Preparedness Office (CEPP) to replace use of “ERPGs” with AEGLs (*Federal Register 1996*)
- Current CEPP guidance requires use of ERPG Level 2 in Risk Management Plans (RMPs) to model potential for reaching civilian population
  - ABOVE LEVEL 2 requires facilities to develop preventive measures
- Initially Level 3 was considered, as well as IDLH, but determined not enough safety margin

# AEGL APPLICATIONS: Toxic Industrial Chemicals, cont'd

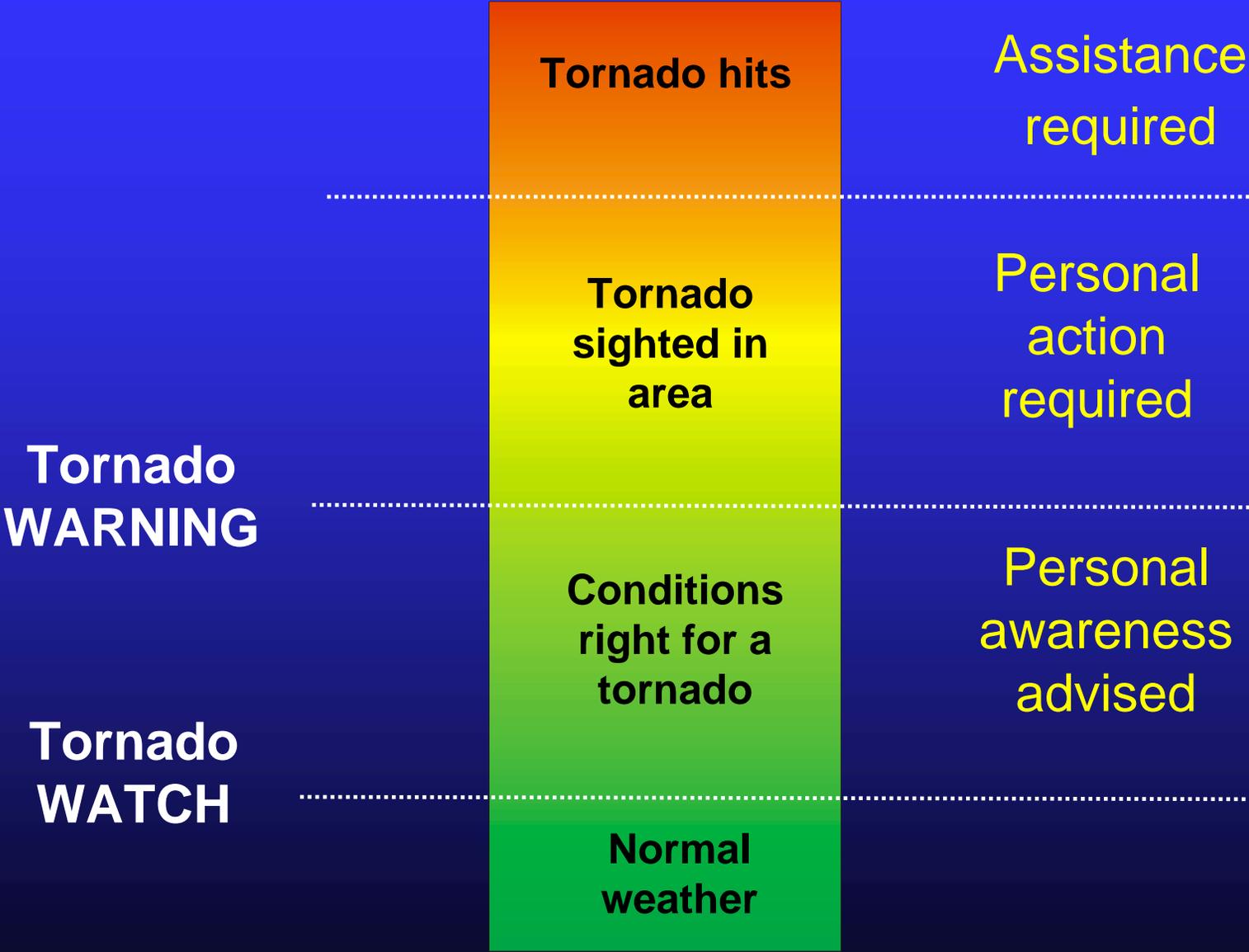
*Per representative of USEPA CEPP office:*

- **Level 1 not used in prevention aspects (planning) because**
  - ‘represents level of exposure that doesn’t cause significant, much less permanent effects, and which citizens are potentially exposed to in daily lives (pumping gas, cleaning, hobbies)’
  - ‘there are more important things to worry about during an incident’
- **No known use of Level 1 (ERPGs or AEGLs) in response implementation**
- HAZMAT teams typically use the distances identified in the Emergency Response Guidebook which presents Isolation Zones and Protective Action Distances
  - **The toxicological exposure values used to determine these boundaries included ERPG 2-3, IDLH, and LC50’s based on animal studies**

## Why Are AEGL Level 1 Values Derived?

- Demonstrates that full spectrum of health effects have been considered
  - » Level 1 and Level 3 bracket potential low end and high end effects around this action level with
  - » \* It COULD be used as a ‘notification level’ to acknowledge that exposed person may NOTICE something (but not at a critical action level)
  - » There is not a Level 1 AEGL for all chemicals if the first effect is more appropriate as a Level 2
- **BUT –the NAC-AEGL does not provide any specific implementation guidance or recommendations as to applications (they develop AEGL values only)**

# Think of a Tornado Emergency .....



# CHPPM Suggested Applications of CWA AEGLs

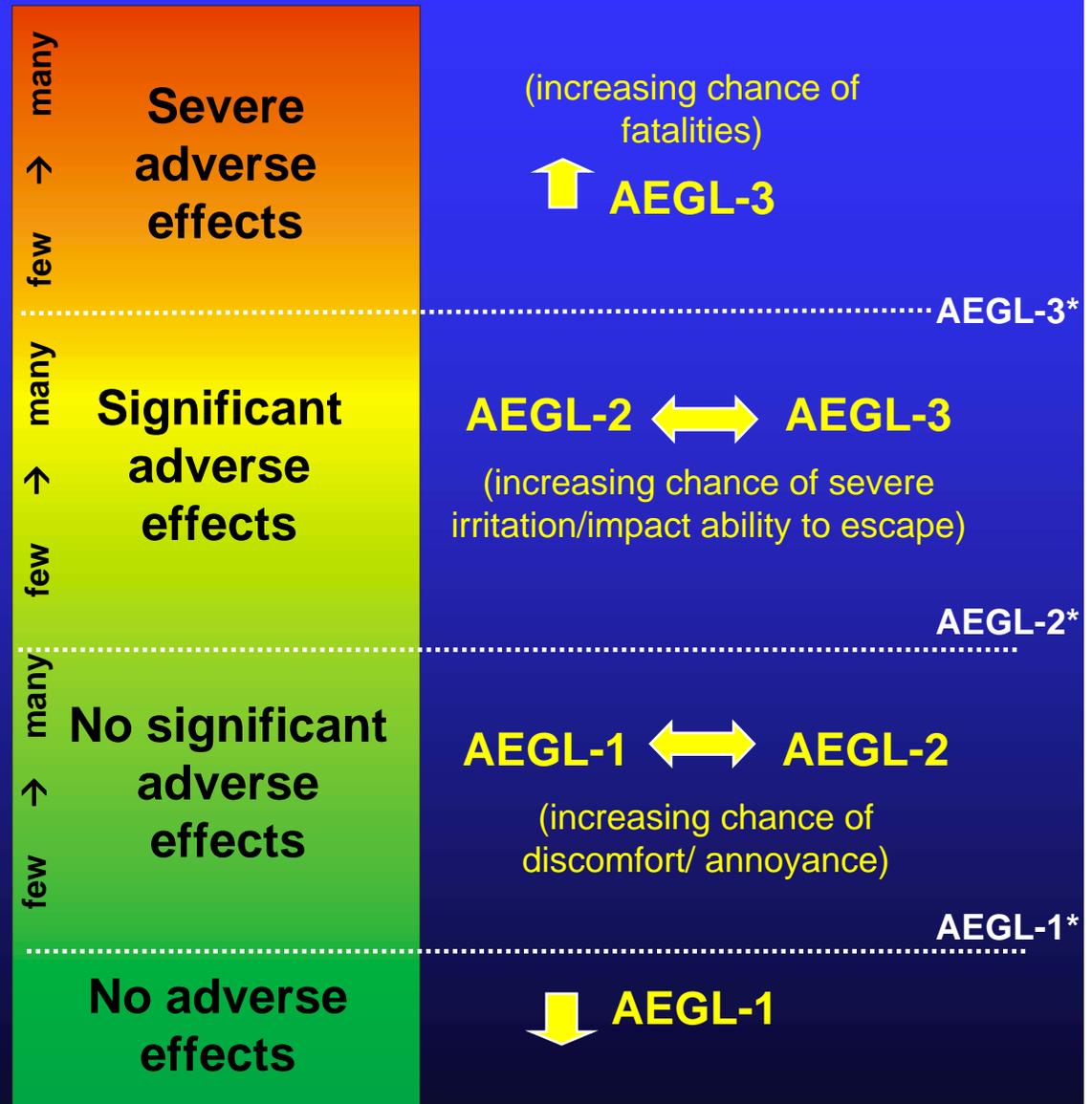
- Primary concern > AEGL-3 – be prepared to TREAT and ASSIST (rescue)

- Minimize exposures between AEGL 2-3

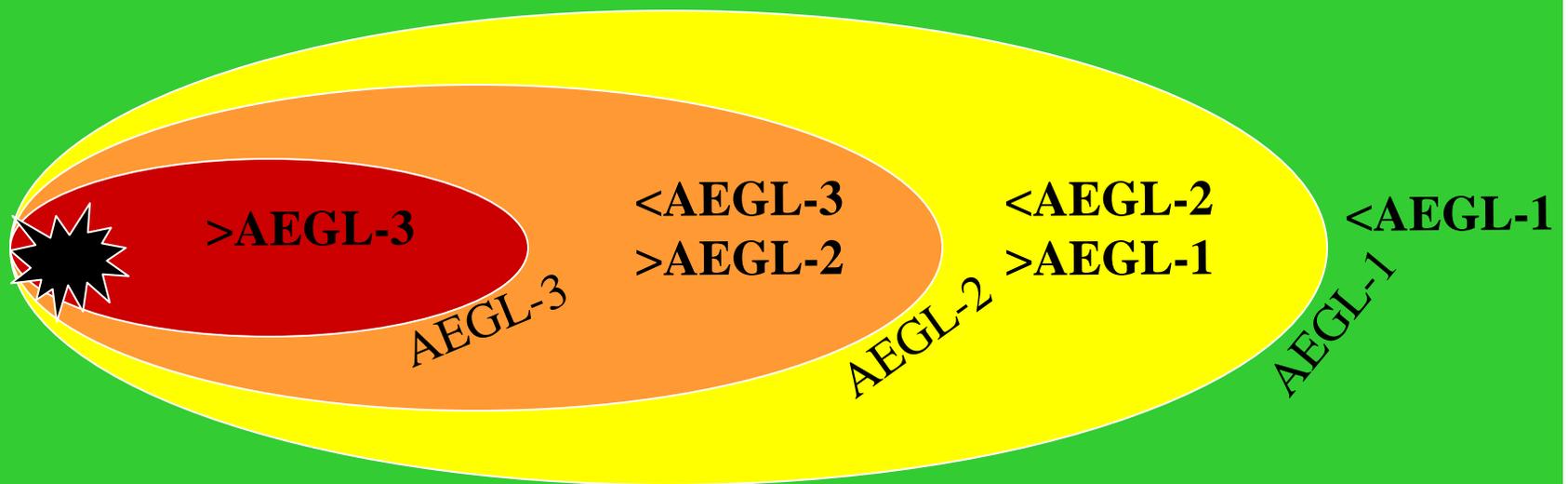
- EX: Recommend shelter-in-place (SIP) >AEGL 2

- Prevent unnecessary response related hazards:

- ‘alert’ when > AEGL1 <2
  - Prevent additional entry at > AEGL 1
  - Allow unrestricted reentry if < AEGL 1



# Example AEGL Application – CEPP and Homeland Defense



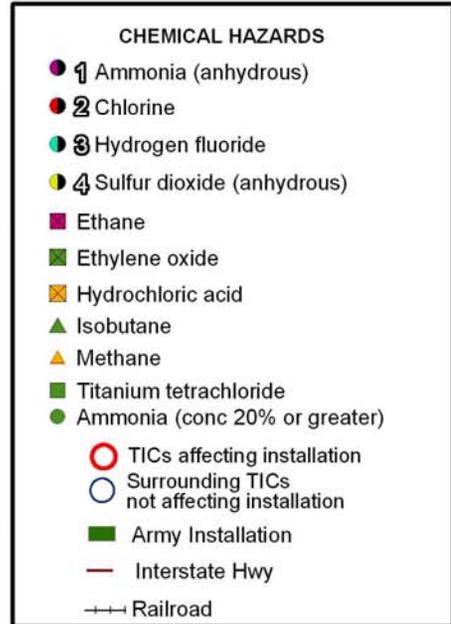
-  Possible fatalities; severe effects ; medical attention
-  Moderate effects; possible medical attention -**\*prevent these exposures\***
-  Non-permanent, mild effects– **warning range (take action at AEGL-2)**
-  No adverse health impact (possible odor, annoyance *starting at* AEGL-1)

# EXAMPLE: Installation Threat Assessment

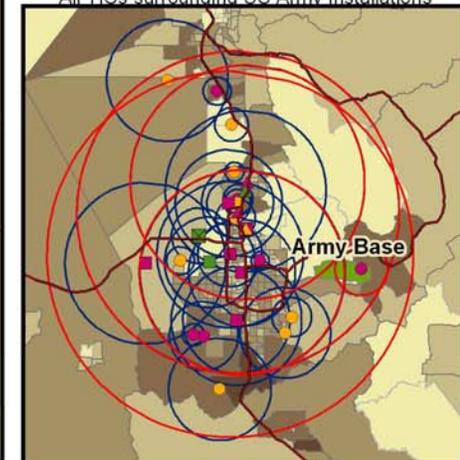


## Toxic Industrial Chemicals Affecting Sample US Army Installation

“plume” based boundaries based on AEGL-2



Sample Overview Map  
All TICs surrounding US Army Installations



# Update CSEPP AEGL Policy Paper 20 (AEGLs) and Enclosure (Risk Communication Package)

## Update to CSEPP Policy Paper Number 20

### ADOPTION OF ACUTE EXPOSURE GUIDELINE LEVELS (AEGLs)

In November 2001, CSEPP Policy Paper 20 officially adopted Acute Exposure Guidelines Levels (AEGLs) as the toxicity criteria to be used by the CSEPP community. This policy update provides an extension of the implementation goal to March 2003 and provides clarification as how this is to be accomplished.

The U.S. Environmental Protection Agency-sponsored committee that develops AEGLs has finalized the values for sulfur mustard and nerve agents. AEGL concentration levels are provided in the supporting information enclosed with this policy. Information as to the development, rationale, and specific health effects associated with AEGLs is also provided in the enclosed fact sheets.

AEGLs are to be used for CSEPP depot and off-post emergency planning and response. AEGLs are to be used in air dispersion models to establish potential areas at risk from chemical warfare accidents. The three different AEGL health effect levels allow emergency planners and responders to prioritize resources and activities associated with a chemical release. While specific decisions to take action such as evacuation or shelter-in-place may vary by location and event, this policy stipulates the following minimum decision criteria. These criteria are consistent with existing emergency planning response procedures used by industry and hazardous material (HAZMAT) response personnel:

- Consistent with CSEPP Policy Paper 1, priority should be to prevent exposures above AEGL-3, which could result in severe, incapacitating, and possibly lethal outcomes.
- To accomplish this, protective actions should be directed toward preventing or minimizing exposures above AEGL-2, above which some temporary but potentially escape-impairing effects could occur. AEGL-2 therefore defines the "minimum critical action level".
- Application of AEGL-1 may be incorporated into planning and response as a notification level, but no protective action would be required except to limit activities and request continued contact with the emergency alert system.

These criteria reflect Army/FEMA recommendations; however, final site-specific decisions for off-post responses using AEGLs are a local CSEPP community decision. States and local emergency managers selecting alternative decision-criteria should document the criteria and rationale and coordinate associated planning with Army and FEMA by the implementation date of this policy. Implementation of this policy infers that the Army has provided the modeling and software capability and output based on the described decision criteria and the States and local emergency managers have accommodated this information in their planning and response activities.

# USACHPPM Health Risk Communication Workshops



- April -- Las Vegas, NV
- June -- Providence, RI
- August -- Seattle, WA

For more information or to register on line, go to:

<http://chppm-www.apgea.army.mil/risk>

or call Ms. Suaquita Perry at 410-436-3515

# **USACHPPM POCs:**

***USACHPPM Chemical Agent Health Standards WEBSITE***

***<http://chppm-www.apgea.army.mil/HRA/Caw/index.html>***

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