Acute Exposure Guideline Levels (AEGLs) – A New Exposure Guideline for Emergency Response Planning

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AEGL History

- Included in the SARA Title III, in response to Bhopal, India, accident – same rule established LEPCs, etc.
- In 1991, EPA and ATSDR requested the NRC to prepare guidelines for developing acute exposure guideline level.
- 1991, NRC Subcommittee on Community Emergency Exposure Levels
- 1993, the subcommittee published, *Guidelines for Developing Community Emergency Exposure Levels for Hazardous Substances.*
National Advisory Council

- Established by SARA Title III
- Membership on next slide
- Adheres to FACA (Federal Advisory Council Administration) rules – open meetings
NAC AEGL Process

- Technical Support Document (TSD) prepared by NAC subcommittee
- TSD discussed by full AEGL committee
- Proposed AEGL values adopted
- Summary published in Federal Register for public comments
- Any comments considered by NAC AEGL committee
- Final draft sent to National Academy of Sciences for peer review
The National Research Council (NRC)

- Principal operating arm of the National Academy of Sciences and the National Academy of Engineering
- Founded in 1916
- Private, non-profit institution - Not a government agency
- Provides independent science and technology advice under congressional charter issued to the National Academy of Sciences
Committee on Toxicology

- Standing Committee of the NRC since 1947
- Work performed by specifically established subcommittees
- Subcommittee Members
  - Carefully examined to:
    - Avoid unreasonable bias and ensure balance of differing viewpoints
    - Ensure absence of conflict of interest
    - Divulge bias and potential conflict of interest within the Committee
  - All committee members are volunteers, serve without compensation
NRC Reports

- Reports of NRC are written by committees composed of individuals drawn from natural or social sciences, engineering, health care, and other fields.
- Findings and recommendations in the report are not subject to approval by federal government.
- NRC report is a committee product that provides policy-makers with best thinking on scientific and technical issues of national importance.
AEGL Review Process

- Subcommittee reviews report/documents/recommendations
- Open public meeting
  - Sponsors
  - Document preparers
  - Presentations
- Closed executive session of COT committee members only
- All meetings and deliberations are tape recorded
AEGL COT Process (cont)

• Primary reviewer compiles comments and recommendations
• Becomes an interim report
• Undergoes extramural review and then goes to the NAC for incorporation
• NAC revises the TSDs the revised documents are submitted to NAC & NRC review processes
• When the NRC subcommittee concludes the revised document is scientifically valid, the AEGL document is published in an NRC report in the series Acute Exposure Guideline Levels for Selected Airborne Chemicals.
Report Review Process

• Each committee’s work reviewed by another group of COT experts to ensure findings and recommendations are well supported by evidence presented in the report
• Reviewers are anonymous to the committee until the report has been finalized
• Review coordinator reviews reviewers’ comments and ensures committee addresses all comments
• AEGL-1 is the airborne concentration (expressed as ppm or mg/m³) of a substance at or above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain subclinical, non-sensory effects. However, the effects are not disabling and are transient and reversible upon cessation or exposure.

• Exposed people will probably sense an effect at AEGL-1.
• AEGL-2 is the airborne concentration (expressed as ppm or mg/m³) of a substance at or above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting effects or impaired ability to escape.

• Exposed people need to evacuate or shelter-in-place above AEGL-2. Quickly becomes a mass casualty event
AEGL-3

• AEGL-3 is the airborne concentration (expressed as ppm or mg/m³) of a substance at or above which it is predicted that the general population, including susceptible individuals, could experience life-threatening effects or death.

• People must not be exposed to these levels. This is a mass casualty event.
Chemicals

- 1, 1, 1, 2-Tetrafluoro-ethane
- 1, 1, 1-Trichloroethane
- 1, 1-Dichloro-1-Fluoro-ethane (HCFC-141b)
- 1,2-Dichloroethene
- Acrylic Acid
- Allyl Alcohol
- Allylamine
- Aniline
- Arsine
- Boron Trifluoride
- Carbon Monoxide
- Carbon Tertachloride
- Chlorine
- Chlorine Dioxide
- Chlorine Trifluoride
- Chloroform
- Crotonaldehyde (cis/trans)
- Cyclohexylamine
- Diborane
- Dimethyldichlorosilane
- Dimethylhydrazine
- Ether
- Ethylene Oxide
- Ethylenediamine
- Ethylenimine
- Fluorine
- Furan
- G Nerve Agents (GA, GB, GD, GF)
- HFE-7100
Chemicals

- Hydrazine
- Hydrogen Chloride
- Hydrogen Cyanide
- Hydrogen Fluoride
- Hydrogen Sulfide
- Iron Pentacarbonyl
- Isobutyronitrile
- Methyl Isocyanate
- Methyl Acrylonitrile
- Methyl Nonafluorobutyl
- methylchloroform
- Methyleneisocyanate
- Methyltrichlorosilane
- Monomethylhydrazine
- Nickel Carbonyl

- Otto Fuel II
- Perchloromethylmercaptan
- Phenol
- Phosgene
- Phosphine
- Propionitrile
- Propylene Glycol Dinitrate
- Propylene Oxide
- Propylenimine
- Sulfur Mustard
- Tetrachloroethylene
- Toluene
- Toluene 2,4 and 2,6 Diisocyanate
- Uranium Hexafluoride
- VX
Use of AEGLS for Emergency Planning

- Notify at AEGL-1
- Ensure population can safely evacuate or shelter-in-place above AEGL-2 before the plume reaches AEGL-2 time and concentration exposures.
  - Ensure shelter-in-place will prevent AEGL-2 effects
- Avoid exposures to AEGL-3
Why AEGL-2?

- Below AEGL-2 reversible effects, no impact on ability to self-escape.
- Above AEGL-2, increasing impact on medical resources, mass casualty event
Why not AEGL-1 or AEGL-3?

- Evacuations have their own risks (don’t evacuate at AEGL-1)
  - Automobile accidents
  - Heart attacks
  - General increased stress levels (where are my other family members?, etc)
  - Every person for themselves
  - Difficult to notify direction to evacuate
- Death is not an acceptable criteria (Don’t evacuate or shelter-in-place at AEGL-3)
AEGL-1 Criteria for GB

• **Key Reference**: Mioduszewski, R.J., 2002.

• **Test Species**: Rat. 10 min (52 females), 60 min (35 females) and 240 min (55 females).

• **Exposures**: Whole body vapor exposure (0.01 to 0.48 mg/m3) for 10 min, 60 min, and 240 min.

• **Effects**: EC$_{50}$ for miosis, a reversible, local, and transient effect. No significant changes in blood RBC-ChE, BuChE, or carboxylesterase.

• **Endpoint/Rationale**: EC$_{50}$ for miosis. The miosis effects data of van Helden et al. (2001, 2002; non-human primates), Harvey (1952; human volunteers) and Johns (1952; human volunteers) are supportive.
AEGL-2 Criteria for GB

• **Key Reference**: Baker, D.J., Sedgwick, E.M. 1996.
• **Test Species**: human volunteers (8 healthy male servicemen)
• **Exposure Route**: Inhalation in exposure chamber; 0.5 mg GB/m³ for 30 min while walking and breathing normally.
• **Effects**: Miosis in 8 of 8 subjects, dyspnea and photophobia in some individuals, inhibition of RBC-ChE to approximately 60% of individual baseline and small but measurable changes in single fibre electromyography (SFEMG). Respiratory effects resolved within minutes; ocular effects resolved within 48 h. SFEMG changes considered subclinical. No permanent effects.
• **Endpoint/Rationale**: Presence of miosis in all subjects, indicates a greater level of effect than the EC₅₀. SFEMG abnormalities. The point of departure for AEGL-2 estimation is 0.5 mg/m³ for 30 min.
AEGL-3 Criteria for GB

• **Key Reference**: Mioduszewski, R.J., et al. 2000.

• **Test Species**: Rats, 50 females per time point

• **Exposure**: Whole body to one of 5 concentrations (2 to 56 mg GB vapor/m³) for one of seven exposure times (3, 10, 30, 60, 90, 240, or 360 min)

• **Effects**: lethality and sub-lethal clinical signs monitored during and after experimental exposure. Only lethality data reported at this time.

• **Endpoint/Rationale**: 14-d acute lethal toxicity of GB to female Sprague-Dawley rats. Female rats were reported to be more sensitive to GB vapor toxicity than males.
Chemical Toxicity - TSD Human Data
Nerve Agent GB

AEGL-2
AEGL-1
AEGL-3

No effect
Discomfort
Disabling

mg/mg3
Minutes

0 60 120 180 240 300 360 420 480
15 Minutes
30 Minutes
Additional Discussion

• Assume AEGL-2 c*t effect is 10 minutes
• Must be able to evacuate or shelter-in-place within 55 min
  – 45 minutes for plume
  – 10 minutes for effect
Mitigations

• Implement public risk communication program
  – Understand AEGL-1, and
  – AEGL-1 notification
  – Consider hearing impaired
• Ensure evacuation or shelter-in-place is a viable option
  – Orderly
  – Good notification process
  – Will protect public
Summary

- Risk communication is essential
- Public must be confident they will be protected
- AEGL-1, they will notice effects
- Must avoid exposures above AEGL-2 for c*t effects
  - Evacuation
  - Shelter-in-place
- Risk communication is essential