ERPGs®

A significant component of community emergency response planning is the need for community emergency exposure limits, particularly guideline concentrations that can be used to anticipate adverse health effects from chemical release emergencies. When an actual chemical emergency occurs, there often is no time to measure airborne concentrations and then take action as a function of the measurement. By planning for accidental or intentional chemical releases, emergency planners and responders can use community emergency exposure limits to anticipate the scope of the impact of an accidental chemical release and can develop prevention and mitigation actions accordingly.

Emergency Response Planning Guidelines (ERPGs®) are values developed by the AIHA® Guideline Foundation's Emergency Response Planning (ERP) Committee to assist emergency response personnel in planning for accidental or intentional catastrophic chemical releases to the community. ERPGs® are developed to meet the need for community emergency exposure planning guidelines, particularly for chemicals that have high potential for uncontrolled releases and those that might pose particular hazards because of their volatility and toxicity.

The primary focus of the ERPGs® is to provide guideline levels for once-in-a-lifetime, short-term (typically 1-hour) exposures to airborne concentrations of acutely toxic, high-priority chemicals. Users may include industrial hygienists, emergency planners, and emergency responders. In order to develop ERPGs®, acute toxicity data are the primary source of information used. Other information may be used when high-quality, robust, acute inhalation toxicity data are not available. As the focus is on data from acute studies, the ERPGs® should not be used in situations where exposure could be frequent, such as in a work place, or as a consequence of frequent chemical releases.

ERPGs® are intended to be used by persons trained in emergency response planning as planning tools for assessing the adequacy of incident prevention and containment measures undertaken for chemical releases, for transportation emergency planning, and for developing facility site and community emergency response plans. The levels are not to be used to determine safe limits for routine operations, as definitive delineators between safe and unsafe exposure conditions, or as a basis for quantitative risk assessment.

ERPG® Levels

ERPG–1:The maximum airborne concentration below which nearly all individuals could be exposed for up to 1 hour without experiencing more than mild, transient adverse health effects or without perceiving a clearly defined objectionable odor.

ERPG–2:The maximum airborne concentration below which nearly all individuals could be exposed for up to 1 hour without experiencing or developing irreversible or other serious health effects or symptoms that could impair an individual's ability to take protective action.

ERPG–3:The maximum airborne concentration below which nearly all individuals could be exposed for up to 1 hour without experiencing or developing life-threatening health effects.

USE AND APPLICATION

Emergency response planning programs generally include accidental release scenarios in which air dispersion models determine concentration isopleths. Programs designed to protect the public from transportation incidents involving chemical materials also use the ERPG® values. ERPGs® also are important for compliance with the U.S. Environmental Protection Agency's (EPA) Emergency Planning and Community Right-to-know Act (EPCRA).

Those who use ERPG® values include:

- Community emergency planners
- Emergency responders
- Air dispersion modelers
- Industrial process safety engineers
- Community Action Emergency Response (CAER) participants
- Local Emergency Planning Committees (LEPCs)
- State Emergency Response Commissions (SERCs)
- Industrial hygienists

- Toxicologists
- Transportation safety engineers
- Fire protection specialists
- Government agencies
- Risk assessors and risk managers
- Resource Conservation and Recovery Act (RCRA) managers

ERPGs® can be used with dispersion models, together with other information such as inventory storage volumes and atmospheric conditions, to provide computerized estimates of the potential spread and airborne concentration in case of a release. From these estimates, action plans can be developed. The plans may vary for any given emergency depending on such things as population density, type of population (e.g., schools, elderly), terrain, weather conditions, and the nature of the release. Using estimated release rates, the physical and chemical properties of the products released, and meteorological data, the dispersion modeling methods generate estimated distances and time of arrival for ERPG® concentrations. Such information can be used when making the determination to evacuate or shelter-in-place for a potentially exposed population.

Many documents can be of assistance in conducting a risk analysis. Risk analysis in transportation settings is outlined in the U.S. Department of Transportation's (U.S. DOT) *Community Teamwork: Working Together to Promote Hazardous Materials Safety, a Guide for Local Officials* (NRT-1). In conjunction with the U.S. Federal Emergency Management Agency (FEMA) and US DOT, the U.S. Environmental Protection Agency (U.S. EPA) published a supplement to NRT-1 in December 1987. This document, entitled *Technical Guidance for Hazardous Analysis* and often referred to as the Green Book, provides technical assistance to LEPCs in assessing the lethal hazards associated with potential airborne releases of extremely hazardous substances and provides a technical applications basis for using community exposure limits.(1)

Most dispersion models, as related to accidental releases of toxic chemicals, have their roots from assumptions established in the Green Book. Consistent with the Green Book and with other emergency planning guidance, ERPGs® can be used to calculate where protective actions are needed, such as evacuation, sheltering-in-place, and isolation zones. It is important to note that during the planning process, the potential impact of an accidental or intentional release in the community can be characterized before any release takes place by calculating a modeled air dispersion value and comparing it with the ERPG®.

Various air dispersion models, both proprietary and in the public domain, are used to model emergency response scenarios. Each model poses numerous variables that require the modeler or investigator to make custom assessments of each possible scenario. Each facility and each model is unique. The model should be carefully chosen to best meet the chemical, topographical, meteorological, and population characteristics of the facility in question. The AIHA® Guideline Foundation does not recommend any air dispersion model over another.

Under the authority of section 112(r) of the U.S. EPA's Clean Air Act, the Chemical Accident Prevention Provisions require facilities that produce, handle, process, distribute, or store certain chemicals to develop a Risk Management Program and prepare a Risk Management Plan (RMP).[2] ERPGs also can be useful in developing RMPs, site-specific ranking schemes, prioritized lists of chemicals, more detailed process hazard analyses, and process safety programs.

ERPGs® vs. OELs

Occupational exposure limits (OELs), guidelines, and standards exist to protect healthy adult workers from the effects of exposures over their working lifetime, whereas ERPGs are developed to protect the general public from rare, unanticipated, short-term chemical exposures.

RATIONALES AND INTERPRETATIONS

The documentation for each ERPG® includes a rationale that discusses the basis for the ERPG® value. The rationale is part of the comprehensive ERPG® documentation for that chemical and summarizes the data used to support the respective ERPG® value. ERPG® values are intended to provide estimates of concentration ranges above which a person could reasonably anticipate adverse health effects as a consequence of exposure to that specific chemical. ERPGs® are approximate threshold values above which there would be an unacceptable likelihood of observing the defined adverse effects.

Human responses do not occur at precise exposure levels but can extend over a wide range of concentrations. In all populations, there are sensitive individuals who will experience adverse health effects at exposure concentrations far below levels at which most individuals normally would respond. The ERPG® values should not be expected to protect everyone but should be applicable to most individuals in the general public.

ERPGs® are emergency planning and response guidelines, not occupational exposure guidelines. ERPGs® and occupational exposure guidelines differ because they are intended for

different populations, different durations of exposure, and different frequency of exposures. Users of the ERPG® values should review the documentation carefully before applying these values.

EXPOSURE PERIODS AND EXTRAPOLATION

There is a range of exposure times one might consider for acute community exposure guidelines. ERPG® values focus on a 60-minute exposure period. This decision was based on the availability of relevant toxicity information and an estimate of the exposure period that would be most useable for emergency response and planning scenarios. The ERPG® committee has and will establish ERPGs® for shorter periods upon request when there are significant reasons and data that justify a shorter exposure period.

- For exposure durations of less than 60 minutes, use of ERPG® values would be conservative and should be safe.

- For use with longer exposure periods, the ERPG® values should be extrapolated appropriately.
- For dose-dependent toxic substances, extrapolation to higher guidance levels can be considered.
- For sensory irritants with health effects that are concentration-dependent, exposure should generally be limited to a given concentration regardless of the exposure time.

NOTE: Extrapolation to higher guidance levels for shorter exposure periods should not be attempted by use of the Haber relationship (expressing the product of exposure concentration and exposure duration as a constant), or modifications thereof, without specific validating data. The Haber relationship, with or without some of the proposed modifications, does not hold true over more than small differences in exposure time.[3] The ten Berge[4] extrapolation method can also be used if there are sufficient data and expertise available to guide its implementation.

VALUE DEVELOPMENT CONSIDERATIONS

ERPGs® are determined on a case-by-case basis. Different chemicals will have different dose-response curves, can cause a wide variety of health effects, and will have different amounts and quality of toxicological data. There is no fixed formula for determining ERPG® values, and no fixed relationship or ratio between the three ERPG® values (ERPG-1, ERPG-2, ERPG-3) for any given chemical.

Development of ERPG® values is through a weight-of-evidence approach resulting from review and deliberation on the available body of data. ERPG® values are developed by comprehensive review of published and proprietary original source toxicological literature. In developing an ERPG® for a chemical, it is important to emphasize the use of acute or short-term exposure data. When evaluating adverse health effects, both immediate and delayed health effects are considered. When it is believed that adverse reproductive, developmental, or carcinogenic effects might be caused by a single exposure, the data are considered in the derivation of the ERPG®.

Human exposure data are emphasized to the extent data are available. Unfortunately, human exposure data for acute chemical exposures are often anecdotal with unknown,

estimated, or reconstructed levels of exposure. As a result, animal test data often form the basis for ERPG® values.

The most pertinent information is derived from acute inhalation toxicity studies in animals that include analytical determination of exposure concentrations, clinical observations, and histopathology. The focus is on the highest experimental levels not showing the effects described by the definitions of the ERPG® levels. In experimental data, the methods of concentration determination (i.e., nominal vs. analytical) are important considerations.

Data from repeated inhalation exposure studies, with clinical and pathologic examinations, are also considered. When inhalation toxicity data are unavailable or limited, data from studies involving other routes of exposure (such as ingestion or dermal) will be considered. More weight is given to rigorously conducted studies.

Finally, if mechanistic or dose-response data are available, these are applied as appropriate. In every data set, data considerations such as the method to determine concentration (e.g., nominal, analytical, modeling) and duration of exposure can be important.

Uncertainty Factors

When appropriate and when the data are sufficient, uncertainty factors are used when determining values for ERPG-1, ERPG-2, and ERPG-3. For all three ERPG® levels, a default uncertainty factor of 10 is applied for interspecies extrapolation when it is appropriate, based on the weight of evidence found in data. Lesser factors may be applied if justified by sufficient data. Conversely, additional factors may be applied when the data are insufficient or when there are unusually sensitive members of the general population (e.g., a specific metabolic defect that makes some individuals unusually susceptible to the toxicity of the substance under consideration).

Carcinogenicity Considerations

To evaluate possible carcinogenic effects resulting from a single exposure to a carcinogen, the procedure described by the National Research Council (NRC), is used.

If the data show the potential for carcinogenicity from long-term exposures to a chemical, the q1* calculation is performed. The q1* calculation consolidates risk estimates derived from low-dose extrapolation of animal bioassay or epidemiologic data into a single 1-hour exposure time frame and assumes a 1 in 10,000 risk of cancer.

Where appropriate, physiologically-based pharmacokinetic approaches may be used to derive the risk estimates.

Sensitization Considerations

Users of this document are cautioned that there is no known or accepted threshold level at which persons sensitized to a chemical can be exposed without potentially experiencing an adverse skin- or respiratory-related effect. Therefore, the ERPGs may not offer protection for those who are sensitized to these kinds of chemicals.

Lethality Considerations

Uncertainty factors that may be used in the derivation of ERPGs® are described below. These uncertainty factors are not absolute, but rather help to develop initial discussion points from which ERPGs may be derived.

The starting point for lethality considerations almost always begins with acute mammalian toxicity data. In examining such data, uncertainty factors must always be based on quality of the data, and therefore will be highly specific for the chemical under evaluation. Adequate

evaluation of animal lethality data as they apply to humans includes a weight-of-evidence approach that requires considerable experience with such data and professional judgment. This evaluation is also dependent on the depth and quality of the data set.

Over the years of setting ERPGs®, an empirical relationship was noted that the predicted threshold of human lethality (ERPG-3) consistently ranged near the value of 1/30 of the 1-hr LC_{50} [5], particularly for irritants. As more data were generated, it has been noted that the highest non-lethal level in animal studies ranged near the value of 1/3 of the 1-hr LC_{50}. The application of a 10-fold interspecies uncertainty factor results in a total factor of 30 applied to the 1-hour LC_{50}.

For less irritating chemicals, an uncertainty factor less than 30 might be applied to the 1-hr LC_{50}. In other cases, the uncertainty factor might be greater than 30 because of a paucity of data or the poor quality of the data available for review.

Uncertainty factors of the type used for ERPG-3 have not been developed for ERPG-2 or ERPG-1 values. ERPG-3 values are based solely on lethality and ERPG-2 and ERPG-1 values can be based on several endpoints that may not be linked mechanistically.

ERPG-1 Odor Detection Indicator and Objectionable Odor

An odor detection indicator✪ is shown with ERPG-1 values in the ERPG Table to indicate those chemicals that are likely to be detected by odor near their ERPG-1 value. See the footnotes at the end of the ERPG Table for this special indicator. This information is primarily intended for those emergency response agencies that incorporate into their planning the possibility that members of the public may call them when they detect an unusual chemical odor. This symbol indicates only that a chemical will likely be detected by odor near its ERPG-1 value.

While a detectable odor may be indicated in the table for a specific ERPG-1 value ✪, it should be understood that an ERPG-1 value can also be based on an airborne chemical concentration for a one-hour period below which only mild, transient adverse health effects are anticipated and that such health effects may or may not be associated with an objectionable or detectable odor. Furthermore, detection of an odor does not imply that a material is toxic at that level. Toxicity and odor detection have independent criteria. A substance may be toxic well below its odor threshold or exposures well above the odor threshold may be required to induce a toxic response.

Although the ERPG-1 definition incorporates the perception of a clearly defined objectionable odor, the property of an odor being objectionable is subjective, varies from one

individual to another, and therefore is not often published. Data on odor threshold or detection levels are more commonly published. In the absence of information on an objectionable odor level, the Committee may use more conservative odor threshold or detection levels instead, or may use these more conservative odor detection levels as a point of departure for estimating an objectionable level.

Lower Explosive Limit (LEL) Warnings

Lower Explosive Limit (LEL) warnings are also shown in the ERPG® Table. These warnings serve to alert emergency managers and responders that an additional physical hazard may be present in addition to the toxicity hazards. The LEL warnings are in the form of special font formatting for the ERPG® values that exceed 10%, 50%, or 100% of the LEL. In addition, an LEL column shows the LEL value in parts per million (ppm) when any of the ERPG® values (also in ppm) exceeds any of the three LEL warning levels. See the footnotes at the end of the ERPG® table for additional details. The lack of an entry in the LEL column for any particular chemical should not be interpreted that the chemical is not flammable, but only that the ERPG® values for that chemical do not exceed 10% of the LEL.

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